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534 - TRISTIN EDWARDS

This indispensable guide focuses on validating programs written to support the clinical trial process from after the data collection stage to generating reports and submitting data and output to the Food and Drug Administration.

SAS users in the Health and Life Sciences industry need to create complex graphs to analyze biostatistics data and clinical data, and they need to submit drugs for approval to the FDA. Graphs used in the HLS industry are complex in nature and require innovative usage of the graphics features. Clinical Graphs Using SAS® provides the knowledge, the code, and real-world examples that enable you to create common clinical graphs using SAS graphics tools, such as the Statistical Graphics procedures and the Graph Template Language. This book describes detailed processes to create many commonly used graphs in the Health and Life Sciences industry. For SAS® 9.3 and SAS® 9.4 it covers many improvements in the graphics features that are supported by the Statistical Graphics procedures and the Graph Template Language, many of which are a direct result of the needs of the Health and Life Sciences community. With the addition of new features in SAS® 9.4, these graphs become positively easy to create. Topics covered include the usage of SGPLOT procedure, the SGPANEL procedure and the Graph Template Language for the creation of graphs like forest plots, swimmer plots, and survival plots.

An indispensable guide for statistical programmers in the pharmaceutical industry. Statistical programmers in the pharmaceutical industry need to create standardized clinical data using rules created and governed by the Clinical Data Interchange Standards Consortium (CDISC). This book introduces the basic concepts, pharmaceutical industry knowledge, and SAS programming practices that every programmer needs to know to comply with regulatory requirements. Step-by-step, you will learn how data should be structured at each stage of the process from annotating elec-

tronic Case Report Forms (eCRFs) and defining the relationship between SDTM and ADaM, to understanding how to generate a Define-XML file to transmit metadata. Filled with clear explanations and example code, this book focuses only on the essential information that entry-level programmers need to succeed.

Ineffective discharge management can jeopardize the successful completion of hospital treatment; but a well managed transition from hospital care to care at home depends on the efficient exchange of information with out-patient healthcare providers and professionals. This is just one way in which ICT can support healthcare and provide tools which help health professions to identify and communicate relevant data. Such tools will be increasingly important in future healthcare systems, and indeed a Europe-wide ICT infrastructure for information and data exchange may do much to revolutionize the quality of healthcare. It is therefore essential that infrastructures build on well-established standards such as Integrating the Healthcare Enterprise (IHE), even if this initially takes longer to implement. This book presents the proceedings of the annual Health Informatics meets eHealth conference, held in Vienna, Austria, in May 2017. The special topic chosen for eHealth2017 is Digital Insight – Information-Driven Health & Care, and the conference addressed the increasingly international focus of eHealth and the importance of cross-border health ICT. The papers presented here cover many eHealth topics, from maternity records to rehabilitation and from staff training to information exchange. Future ICT systems will inevitably involve machine learning and predictive analytics in order to provide actionable information to health professionals and support preventive healthcare concepts, and this book provides an insight into current research in health informatics and eHealth, addressing many issues central to the future of health and care. The book will be of interest to all healthcare researchers and practitioners.

This book constitutes the proceedings of the 14th International Conference on Applied Reconfigurable Computing, ARC 2018, held in Santorini, Greece, in May 2018. The 29 full papers and 22 short presented in this volume were carefully reviewed and selected from 78 submissions. In addition, the volume contains 9 contributions from research projects. The papers were organized in topical sections named: machine learning and neural networks; FPGA-based design and CGRA optimizations; applications and surveys; fault-tolerance, security and communication architectures; reconfigurable and adaptive architectures; design methods and fast prototyping; FPGA-based design and applications; and special session: research projects.

This is not a traditional book. The book has a lot of code. If you don't like the code first approach do not buy this book. Making code available on Github is not an option. This book is for people who have some theoretical knowledge of machine learning and deep learning and want to dive into applied machine learning. The book doesn't explain the algorithms but is more oriented towards how and what should you use to solve machine learning and deep learning problems. The book is not for you if you are looking for pure basics. The book is for you if you are looking for guidance on approaching machine learning problems. The book is best enjoyed with a cup of coffee and a laptop/workstation where you can code along. Table of contents: - Setting up your working

environment - Supervised vs unsupervised learning - Cross-validation - Evaluation metrics - Arranging machine learning projects - Approaching categorical variables - Feature engineering - Feature selection - Hyperparameter optimization - Approaching image classification & segmentation - Approaching text classification/regression - Approaching ensembling and stacking - Approaching reproducible code & model serving There are no sub-headings. Important terms are written in bold. I will be answering all your queries related to the book and will be making YouTube tutorials to cover what has not been discussed in the book. To ask questions/doubts, visit this link: https://bit.ly/aamlquestions And Subscribe to my youtube channel: https://bit.ly/abhitubesub

This book provides an introduction to health interoperability and the main standards used. Health interoperability delivers health information where and when it is needed. Everybody stands to gain from safer more soundly based decisions and less duplication, delays, waste and errors. The third edition of Principles of Health Interoperability includes a new part on FHIR (Fast Health Interoperability Resources), the most important new health interoperability standard for a generation. FHIR combines the best features of HL7's v2, v3 and CDA while leveraging the latest web standards and a tight focus on implementability. FHIR can be implemented at a fraction of the price of existing alternatives and is well suited for use in mobile phone apps, cloud communications and EHRs. The book is organised into four parts. The first part covers the principles of health interoperability, why it matters, why it is hard and why models are an important part of the solution. The second part covers clinical terminology and SNOMED CT. The third part covers the main HL7 standards: v2, v3, CDA and IHE XDS. The new fourth part covers FHIR and has been contributed by Grahame Grieve, the original FHIR chief.

Drug Discovery and Evaluation has become a more and more difficult, expensive and time-consuming process. The effect of a new compound has to be detected by in vitro and in vivo methods of pharmacology. The activity spectrum and the potency compared to existing drugs have to be determined. As these processes can be divided up stepwise we have designed a book series "Drug Discovery and Evaluation" in the form of a recommendation document. The methods to detect drug targets are described in the first volume of this series "Pharmacological Assays" comprising classical methods as well as new technologies. Before going to man, the most suitable compound has to be selected by pharmacokinetic studies and experiments in toxicology. These preclinical methods are described in the second volume „Safety and Pharmacokinetic Assays". Only then are first studies in human beings allowed. Special rules are established for Phase I studies. Clinical pharmacokinetics are performed in parallel with human studies on tolerability and therapeutic effects. Special studies according to various populations and different therapeutic indications are necessary. These items are covered in the third volume: „Methods in Clinical Pharmacology".

This book constitutes the refereed proceedings of the 11th International Symposium on Applied Reconfigurable Computing, ARC 2015, held in Bochum, Germany, in April 2015. The 23 full papers and 20 short papers presented in this volume were carefully reviewed and selected from 85 submissions. They are organized in topical headings named: architecture and modeling; tools and

compilers; systems and applications; network-on-a-chip; cryptography applications; extended abstracts of posters. In addition, the book contains invited papers on funded R&D - running and completed projects and Horizon 2020 funded projects.

As the Web grows and expands into ever more remote parts of the world, the availability of resources over the Internet increases exponentially. Making use of this widely prevalent tool, organizations and individuals can share and store knowledge like never before. Cloud Technology: Concepts, Methodologies, Tools, and Applications investigates the latest research in the ubiquitous Web, exploring the use of applications and software that make use of the Internet□s anytime, anywhere availability. By bringing together research and ideas from across the globe, this publication will be of use to computer engineers, software developers, and end users in business, education, medicine, and more.

Like many other industries, health care is increasingly turning to digital information and the use of electronic resources. The Institute of Medicine's Roundtable on Value & Science-Driven Health Care hosted three workshops to explore current efforts and opportunities to accelerate progress in improving health and health care with information technology systems.

A classic that just keeps getting better, The Little SAS Book is essential for anyone learning SAS programming. Lora Delwiche and Susan Slaughter offer a user-friendly approach so that readers can quickly and easily learn the most commonly used features of the SAS language. Each topic is presented in a self-contained, two-page layout complete with examples and graphics. Nearly every section has been revised to ensure that the sixth edition is fully up-to-date. This edition is also interface-independent, written for all SAS programmers whether they use SAS Studio, SAS Enterprise Guide, or the SAS windowing environment. New sections have been added covering PROC SQL, iterative DO loops, DO WHILE and DO UNTIL statements, %DO statements, using variable names with special characters, the ODS EXCEL destination, and the XLSX LIBNAME engine. This title belongs on every SAS programmer's bookshelf. It's a resource not just to get you started, but one you will return to as you continue to improve your programming skills. Learn more about the updates to The Little SAS Book, Sixth Edition here. Reviews for The Little SAS Book, Sixth Edition can be read here.

Unlock the essentials of SAS programming! Fundamentals of Programming in SAS: A Case Studies Approach gives a complete introduction to SAS programming. Perfect for students, novice SAS users, and programmers studying for their Base SAS certification, this book covers all the basics, including: working with data creating visualizations data validation good programming practices Experienced programmers know that real-world scenarios require practical solutions. Designed for use in the classroom and for self-guided learners, this book takes a novel approach to learning SAS programming by following a single case study throughout the text and circling back to previous concepts to reinforce material. Readers will benefit from the variety of exercises, including both multiple choice questions and in-depth case studies. Additional case studies are also provided online for extra practice. This approach mirrors the way good SAS programmers develop their skills—through hands-on work with an eye toward developing the knowledge necessary to tackle more difficult tasks. After reading

this book, you will gain the skills and confidence to take on larger challenges with the power of SAS.

Clinical trials are the engine of progress in the development of new drugs and devices for the detection, monitoring, prevention and treatment of cancer. A well conceived, carefully designed and efficiently conducted clinical trial can produce results that change clinical practice overnight, deliver new oncology drugs and diagnostics to the marketplace, and expand the horizon of contemporary thinking about cancer biology. A poorly done trial does little to advance the field or guide clinical practice, consumes precious clinical and financial resources and challenges the validity of the ethical contract between investigators and the volunteers who willingly give their time and effort to benefit future patients. With chapters written by oncologists, researchers, biostatisticians, clinical research administrators, and industry and FDA representatives, Oncology Clinical Trials, provides a comprehensive guide for both early-career and senior oncology investigators into the successful design, conduct and analysis of an oncology clinical trial. Oncology Clinical Trials covers how to formulate a study question, selecting a study population, study design of Phase I, II, and III trials, toxicity monitoring, data analysis and reporting, use of genomics, cost-effectiveness analysis, systemic review and meta-analysis, and many other issues. Many examples of real-life flaws in clinical trials that have been reported in the literature are included throughout. The book discusses clinical trials from start to finish focusing on real-life examples in the development, design and analysis of clinical trials. Oncology Clinical Trials features: A systematic guide to all aspects of the design, conduct, analysis, and reporting of clinical trials in oncology Contributions from oncologists, researchers, biostatisticians, clinical research administrators, and industry and FDA representatives Hot topics in oncology trials including multi-arm trials, meta-analysis and adaptive design, use of genomics, and cost-effectiveness analysis Real-life examples from reported clinical trials included throughout

Quality of life studies form an essential part of the evaluation of any treatment. Written by two authors who are well respected within this field, Quality of Life: The Assessment, Analysis and Interpretation of Patient-reported Outcomes, Second Edition lays down guidelines on assessing, analysing and interpreting quality of life data. The new edition of this standard book has been completely revised, updated and expanded to reflect many methodological developments emerged since the publication of the first edition. Covers the design of instruments, the practical aspects of implementing assessment, the analyses of the data, and the interpretation of the results Presents all essential information on Quality of Life Research in one comprehensive volume Explains the use of qualitative and quantitative methods, including the application of basic statistical methods Includes copious practical examples Fills a need in a rapidly growing area of interest New edition accommodates significant methodological developments, and includes chapters on computer adaptive testing and item banking, choosing an instrument, systematic reviews and meta analysis This book is of interest for everyone involved in quality of life research, and it is applicable to medical and non-medical, statistical and non-statistical readers. It is of particular relevance for clinical and biomedical researchers within both the pharmaceutical industry and practitioners in the fields of cancer and other chronic dis-

eases. Reviews of the First Edition – Winner of the first prize in the Basis of Medicine Category of the BMA Medical Book Competition 2001: “This book is highly recommended to clinicians who are actively involved in the planning, analysis and publication of QoL research.” CLINICAL ONCOLOGY “This book is highly recommended reading.” QUALITY OF LIFE RESEARCH

Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators. At the same time, sharing clinical trial data presents risks, burdens, and challenges. These include the need to protect the privacy and honor the consent of clinical trial participants; safeguard the legitimate economic interests of sponsors; and guard against invalid secondary analyses, which could undermine trust in clinical trials or otherwise harm public health. Sharing Clinical Trial Data presents activities and strategies for the responsible sharing of clinical trial data. With the goal of increasing scientific knowledge to lead to better therapies for patients, this book identifies guiding principles and makes recommendations to maximize the benefits and minimize risks. This report offers guidance on the types of clinical trial data available at different points in the process, the points in the process at which each type of data should be shared, methods for sharing data, what groups should have access to data, and future knowledge and infrastructure needs. Responsible sharing of clinical trial data will allow other investigators to replicate published findings and carry out additional analyses, strengthen the evidence base for regulatory and clinical decisions, and increase the scientific knowledge gained from investments by the funders of clinical trials. The recommendations of Sharing Clinical Trial Data will be useful both now and well into the future as improved sharing of data leads to a stronger evidence base for treatment. This book will be of interest to stakeholders across the spectrum of research--from funders, to researchers, to journals, to physicians, and ultimately, to patients.

This is a revised and very expanded version of the previous second edition of the book. "Pharmacokinetic and Pharmacodynamic Data Analysis" provides an introduction into pharmacokinetic and pharmacodynamic concepts using simple illustrations and reasoning. It describes ways in which pharmacodynamic and pharmacodynamic theory may be used to give insight into modeling questions and how these questions can in turn lead to new knowledge. This book differentiates itself from other texts in this area in that it bridges the gap between relevant theory and the actual application of the theory to real life situations. The book is divided into two parts; the first introduces fundamental principles of PK and PD concepts, and principles of mathematical modeling, while the second provides case studies obtained from drug industry and academia. Topics included in the first part include a discussion of the statistical principles of model fitting, including how to assess the adequacy of the fit of a model, as well as strategies for selection of time points to be included in the design of a study. The first part also introduces basic pharmacokinetic and pharmacodynamic concepts, including an excellent discussion of effect compartment (link) models as well as indirect response models. The second part of the text includes over 70 modeling case studies. These include a discussion of the selection of the

model, derivation of initial parameter estimates and interpretation of the corresponding output. Finally, the authors discuss a number of pharmacodynamic modeling situations including receptor binding models, synergy, and tolerance models (feedback and precursor models). This book will be of interest to researchers, to graduate students and advanced undergraduate students in the PK/PD area who wish to learn how to analyze biological data and build models and to become familiar with new areas of application. In addition, the text will be of interest to toxicologists interested in learning about determinants of exposure and performing toxicokinetic modeling. The inclusion of the numerous exercises and models makes it an excellent primary or adjutant text for traditional PK courses taught in pharmacy and medical schools. A diskette is included with the text that includes all of the exercises and solutions using WinNonlin.

The language of Ancient Egypt has been the object of careful investigation since its decipherment in the nineteenth century, but this is the first accessible account that uses the insight of modern linguistics. Antonio Loprieno discusses the hieroglyphic system and its cursive varieties, and the phonology, morphology and syntax of Ancient Egyptian, as well as looking at its genetic ties with other languages of the Near East. This book will be indispensable for both linguists and Egyptologists.

Pharmaceutical companies, academic researchers, and government agencies such as the Food and Drug Administration and the National Institutes of Health all possess large quantities of clinical research data. If these data were shared more widely within and across sectors, the resulting research advances derived from data pooling and analysis could improve public health, enhance patient safety, and spur drug development. Data sharing can also increase public trust in clinical trials and conclusions derived from them by lending transparency to the clinical research process. Much of this information, however, is never shared. Retention of clinical research data by investigators and within organizations may represent lost opportunities in biomedical research. Despite the potential benefits that could be accrued from pooling and analysis of shared data, barriers to data sharing faced by researchers in industry include concerns about data mining, erroneous secondary analyses of data, and unwarranted litigation, as well as a desire to protect confidential commercial information. Academic partners face significant cultural barriers to sharing data and participating in longer term collaborative efforts that stem from a desire to protect intellectual autonomy and a career advancement system built on priority of publication and citation requirements. Some barriers, like the need to protect patient privacy, pre- sent challenges for both sectors. Looking ahead, there are also a number of technical challenges to be faced in analyzing potentially large and heterogeneous datasets. This public workshop focused on strategies to facilitate sharing of clinical research data in order to advance scientific knowledge and public health. While the workshop focused on sharing of data from preplanned interventional studies of human subjects, models and projects involving sharing of other clinical data types were considered to the extent that they provided lessons learned and best practices. The workshop objectives were to examine the benefits of sharing of clinical research data from all sectors and among these sectors, including, for example: benefits to the research and development enterprise and benefits to the analysis of safety and

efficacy. Sharing Clinical Research Data: Workshop Summary identifies barriers and challenges to sharing clinical research data, explores strategies to address these barriers and challenges, including identifying priority actions and "low-hanging fruit" opportunities, and discusses strategies for using these potentially large datasets to facilitate scientific and public health advances.
This classic work of Reformed theology is the third of four volumes now available in English.

Carpenter's Guide to Innovative SAS Techniques offers advanced SAS programmers an all-in-one programming reference that includes advanced topics not easily found outside the depths of SAS documentation or more advanced training classes. Art Carpenter has written fifteen chapters of advanced tips and techniques, including topics on data summary, data analysis, and data reporting. Special emphasis is placed on DATA step techniques that solve complex data problems. There are numerous examples that illustrate advanced techniques that take advantage of formats, interface with the macro language, and utilize the Output Delivery System. Additional topics include operating system interfaces, table lookup techniques, and the creation of customized reports.
This real-world reference for clinical trial SAS programming is packed with solutions that can be applied day-to-day problems. Organized to reflect the statistical programmers workflow, this user-friendly text begins with an introduction to the working environment, then presents chapters on importing and massaging data into analysis data sets, producing clinical trial output, and exporting data.

This book explains how medical photography is part of the workflow in many specialties: it is needed for registries, to preserve information, for follow up, second opinion and teaching, among others. The book gathers information on this field, providing valuable practical tips for those that have never used photography for medical uses as well as those who use it regularly. Covering specialities ranging from dermatology, plastic surgery, dentistry, ophthalmology and endoscopy to forensic medicine, specimen photography and veterinary medicine, it highlights standardization for each procedure and relevance to ethical, patients' perception of medical photography, cybersecurity and legal aspects. The book also presents practical sections explaining how to organize a photographic file, coding, reimbursement, compliance, use of social media and preservation as well as in depth concepts on sharp focus on blurred vision. This volume will appeal to all clinicians and practitioners interested in acquiring a high level of technical skill in medical photography.
An indispensable guide to SAS Clinical Programming, this book is the first guide on this topic, to be written by an Indian author. Written in an instructive and conversational tone for people who want to make their career in SAS Clinical Programming and entry level programmers for their day-to-day tasks. It is equipped with practical, real world examples, detailed description of programs, work flows, issues, resolutions and key techniques. This book is a personal SAS Clinical trainer. It explains the art of SAS Clinical Programming in eighteen easy steps, covering everything from basics to ADS, TLF Creation, as well as CDISC SDTM and ADaM specifications. Many statistical concepts are explained in an easy way so that you feel confident while using Statistical Procedures.

If you are already working as a SAS Clinical Programmer, this book will aid you with sharpening your skills.

For decades researchers and programmers have used SAS to analyze, summarize, and report clinical trial data. Now Chris Holland and Jack Shostak have updated their popular Implementing CDISC Using SAS, the first comprehensive book on applying clinical research data and metadata to the Clinical Data Interchange Standards Consortium (CDISC) standards. Implementing CDISC Using SAS: An End-to-End Guide, Revised Second Edition, is an all-inclusive guide on how to implement and analyze the Study Data Tabulation Model (SDTM) and the Analysis Data Model (ADaM) data and prepare clinical trial data for regulatory submission. Updated to reflect the 2017 FDA mandate for adherence to CDISC standards, this new edition covers creating and using metadata, developing conversion specifications, implementing and validating SDTM and ADaM data, determining solutions for legacy data conversions, and preparing data for regulatory submission. The book covers products such as Base SAS, SAS Clinical Data Integration, and the SAS Clinical Standards Toolkit, as well as JMP Clinical. Topics included in this edition include an implementation of the Define-XML 2.0 standard, new SDTM domains, validation with Pinnacle 21 software, event narratives in JMP Clinical, STDM and ADAM metadata spreadsheets, and of course new versions of SAS and JMP software. The second edition was revised to add the latest C-Codes from the most recent release as well as update the make_define macro that accompanies this book in order to add the capability to handle C-Codes. The metadata spreadsheets were updated accordingly. Any manager or user of clinical trial data in this day and age is likely to benefit from knowing how to either put data into a CDISC standard or analyzing and finding data once it is in a CDISC format. If you are one such person--a data manager, clinical and/or statistical programmer, biostatistician, or even a clinician--then this book is for you.

This monograph is an ideal primer for medical and computer science professionals designing and understanding data infrastructure for medical research. It is intended to technical/computer scientists and medical professionals who want to understand the challenges involved

Master the Shiny web framework—and take your R skills to a whole new level. By letting you move beyond static reports, Shiny helps you create fully interactive web apps for data analyses. Users will be able to jump between datasets, explore different subsets or facets of the data, run models with parameter values of their choosing, customize visualizations, and much more. Hadley Wickham from RStudio shows data scientists, data analysts, statisticians, and scientific researchers with no knowledge of HTML, CSS, or JavaScript how to create rich web apps from R. This in-depth guide provides a learning path that you can follow with confidence, as you go from a Shiny beginner to an expert developer who can write large, complex apps that are maintainable and performant. Get started: Discover how the major pieces of a Shiny app fit together Put Shiny in action: Explore Shiny functionality with a focus on code samples, example apps, and useful techniques Master reactivity: Go deep into the theory and practice of reactive programming and examine reactive graph components Apply best practices: Examine useful techniques for making your Shiny apps work well in production

The editors have engaged leading scientists in the field to participate in the development of this book, which is envisioned as a “one of a kind” contribution to the field. The book is a comprehensive text that puts fundamental bioanalytical science in context with current practice, its challenges and ongoing developments. It expands on existing texts on the subject by covering regulated bioanalysis of both small and large molecule therapeutics from both a scientific and regulatory viewpoint. The content will be useful to a wide spectrum of readers: from those new to bioanalysis; to those developing their experience in the laboratory, or working in one of the many critical supporting roles; to seasoned practitioners looking for a solid source of information on this exciting and important discipline.

The purpose of the book is to provide an overview of clinical research (types), activities, and areas where informatics and IT could fit into various activities and business practices. This book will introduce and apply informatics concepts only as they have particular relevance to clinical research settings.

Dear Colleagues, Cancer survival rates and successful organ transplantation in patients continues to increase due to improvements in early diagnosis and treatments. Since immuno-suppressive therapies are frequently used, the mortality rate due to secondary infections has become an ever-increasing problem. Opportunistic fungal infections are probably the deadliest threat to these patients due to their difficult early diagnosis, the limited effect of antifungal drugs and the appearance of resistances. In recent years, a considerable effort has been devoted to investigating the role of many virulence traits in the pathogenic outcome of fungal infections. New virulence factors (hypoxia adaptation, CO2 sensing, pH regulation, micronutrient acquisition, secondary metabolites, immunity regulators, etc.) have been reported and their molecular mechanisms of action are being thoroughly investigated. The recent application of gene-editing technologies such as CRISPr-Cas9, has opened a whole new window to the discovery of new fungal virulence factors. Accurate fungal genotyping, Next Generation Sequencing and RNAseq approaches will undoubtedly provide new clues to interpret the plethora of molecular interactions controlling these complex systems. Unraveling their intimate regulatory details will provide insights for a more target-focused search or a rational design of more specific antifungal agents. This Special Issue is show significant discoveries, proofs of concept of new theories or relevant observations in fungal pathogenesis and its regulation. Dr. Fernando Leal Guest Editor

Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk was selected for The First Clinical Research Bookshelf - Essential reading for clinical research professionals by the Journal of Clinical Research Best Practices. Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk provides drug safety/pharmacovogilance professionals, pharmaceutical and clinical research scientists, statisticians, programmers, medical writers, 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 pre- and post-marketing risk assessment. With decades of pharmaceutical research and drug safety expertise, au-

thors Dr. Klepper and Dr. Cobert 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 is 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 (I-AS) -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)