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Chapter 1 : List of Guidances for Statistics in Regulatory Affairs - Wikipedia

This book covers the gamut of issues in drug development concentrating on important and sometimes subtle issues in clinical trials including design and analysis, intention to treat principle, multiple testing, Bayesian and frequentist approaches and interpretations, meta analysis, regulatory issues and ethics.

Find articles by Sandeep K. This article has been cited by other articles in PMC. Abstract Randomized controlled trials often suffer from two major complications, i. One potential solution to this problem is a statistical concept called intention-to-treat ITT analysis. ITT analysis includes every subject who is randomized according to randomized treatment assignment. It ignores noncompliance, protocol deviations, withdrawal, and anything that happens after randomization. ITT analysis maintains prognostic balance generated from the original random treatment allocation. In ITT analysis, estimate of treatment effect is generally conservative. A better application of the ITT approach is possible if complete outcome data are available for all randomized subjects. Per-protocol population is defined as a subset of the ITT population who completed the study without any major protocol violations. One potential solution to this problem is a statistical concept called intention-to-treat ITT concept. The objective of this article is to give a basic understanding of the ITT concept to the beginners in the field of clinical research. With this objective in mind, this article will review the ITT principle, with special emphasis on need and application of this concept and its pros and cons. In an RCT, the study subjects is randomly allocated to receive one of the treatments under study after assessment of eligibility but before the intervention is administered. Randomization in clinical trials reduces bias. The purpose of the RCT is to ensure that the groups differ only with respect to the interventions being compared. Moreover, in some studies, drop out of the subjects is a problem. Hence, RCTs often suffer from two major complications, i. One potential solution to this problem is a statistical concept called ITT analysis. It gives an unbiased estimate of treatment effect. Moreover, subjects may be noncompliant or may drop out from the study due to their response of treatment. Also, it minimizes type I error due to cautious approach and allows for the greatest generalizability. To begin with, if a subject who actually did not receive any treatment is included as a subject who received treatment, then it indicates very little about the efficacy of the treatment. In ITT analysis, estimate of treatment effect is generally conservative because of dilution due to noncompliance. Also, heterogeneity might be introduced if noncompliants, dropouts and compliant subjects are mixed together in the final analysis. Moreover, end-point data will differ markedly among noncompliant, dropouts and compliant subjects, and interpretation might become difficult if a large proportion of participants cross over to opposite treatment arms. Care must always be taken to minimize missing responses and to continue to follow up those who withdraw from treatment. The FDA guideline further explains that the results of a clinical trial should be assessed not only for the subset of patients who completed the study, but also for the entire patient population randomized the ITT analysis. When the ITT and per-protocol PP analyses come to essentially the same conclusions, confidence in the study results is increased. It is defined as a subset of the ITT population who completed the study without any major protocol violations. Hence, ITT analysis alone is not preferred for noninferiority trial. A possible alternative is to conduct the PP analysis where only subjects meeting the inclusion criteria are considered. But the conservative effect of the PP analysis on noninferiority and equivalence trials has not been thoroughly explored. Therefore, it has been suggested that noninferiority should be concluded only if both ITT and PP analyses permit that. However, the definition given to the modified ITT mITT in randomized controlled trial has been found to be irregular and arbitrary because there is a lack of consistent guidelines for its application. The mITT analysis allows a subjective approach in entry criteria, which may lead to confusion, inaccurate results and bias. Hence, RCT often suffers from two major complications, i. But in ITT analysis, estimate of treatment effect is generally conservative because of dilution due to noncompliance. Acknowledgments I gratefully acknowledge the help of anonymous reviewers for helpful comments and suggestions. Footnotes Conflict of Interest:

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Chapter 2 : DIA/FDA Statistics Forum

His books, Cross-over Trials in Clinical Research (, 2 nd edition) and Statistical Issues in Drug Development () are published by Wiley and his latest book, Dicing with Death () by Cambridge University Press. In , he was the first recipient of the George C Challis award for biostatistics of the University of Florida.

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Chapter 3 : statistical_issues_in_drug_development_statistics_in_practice

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Sandeep Kumar Gupta, House No. This article has been cited by other articles in PMC. Abstract Mainly, two statistical methodologies are applicable to the design and analysis of clinical trials: Most traditional clinical trial designs are based on frequentist statistics. In frequentist statistics prior information is utilized formally only in the design of a clinical trial but not in the analysis of the data. On the other hand, Bayesian statistics provide a formal mathematical method for combining prior information with current information at the design stage, during the conduct of the trial, and at the analysis stage. It is easier to implement adaptive trial designs using Bayesian methods than frequentist methods. The Bayesian approach can also be applied for post-marketing surveillance purposes and in meta-analysis. The basic tenets of good trial design are same for both Bayesian and frequentist trials. It has been recommended that the type of analysis to be used Bayesian or frequentist should be chosen beforehand. Switching to an analysis method that produces a more favorable outcome after observing the data is not recommended. One route of optimization is to make better use of all available information, and Bayesian statistics provides this opportunity. Mainly, two statistical methodologies are applicable to the design and analysis of clinical trials: However, Bayesian statistics provide a formal mathematical method for combining prior information with current information at the design stage, during the conduct of the trial, and at the analysis stage. This theorem of Bayes was not published during his lifetime but only after his death, when his work was found in his desk by a friend. Bayesian statistics starts with a prior belief expressed as a prior distribution , which is then updated with the new evidence to yield a posterior belief also a probability distribution. Bayesian statistics provides a mathematical method for calculating the likelihood of a future event, given the knowledge from prior events. These methods, thus, directly address the question of how new evidence should change what we currently believe. It has been recommended that appropriate prior information should be carefully selected and incorporated into the analysis correctly. It is recommended that as many sources of good prior information as possible should be identified. The first of these is the sample data, expressed formally by the likelihood function. The second is the prior distribution, which represents the additional external information that is available. The likelihood function is also an essential component of frequentist statistics, but the prior distribution is used only in the Bayesian approach. The posterior distribution is the product only of the prior and the likelihood function. This updated distribution is called the posterior distribution. The triplot is useful to show how the two types of information data and prior are combined. It gives a graphical representation of prior to posterior updating. Collectively, the probabilities for all possible values of the unobserved outcome are called the predictive distribution. Thus, exchangeability of trials is important in the development of realistic models for combining trial data with prior information. Bayesian hierarchical modeling is a specific methodology used to combine results from multiple studies to obtain estimates of safety and effectiveness parameters. The name hierarchical model derives from the hierarchical manner in which observations and parameters are structured. For Bayesian hypothesis testing the posterior distribution may be used to calculate the probability that a particular hypothesis is true, given the observed data. When good prior information exists, the Bayesian approach may enable this information to be incorporated into the statistical analysis of a trial. When the prior information is based on empirical evidence, such as data from clinical studies rather than information based mainly on personal opinion, then the Bayesian methods are usually less controversial. The doses given to subjects are determined by prior and historical data, and data obtained from previously dosed subjects are used to determine the range of doses to be explored. A probability of toxicity is assigned to each dose based on historical data or investigator input; these probabilities represent prior information and are the starting point for the search for the MTD. A model is defined that represents the doseâ€”response relationship, and subjects are treated at the starting dose, dose is

increased steadily and dose-limiting toxicities are observed. Then, the next best estimate of the MTD is calculated based on the prior information and the new information from the study. Based on this approach, subjects are treated up to the dose that currently available evidence indicates to be the best estimate of the MTD. The CRM is flexible and allows different numbers of subjects to be treated per dose, and accommodates specific dose-limiting toxicity rates that are expected in different therapeutic areas. Proof-of-concept studies are carried out to obtain early evidence of clinical efficacy using a small, targeted, number of subjects, the aim being to obtain evidence to justify full-fledged clinical development. Traditional designs might unnecessarily expose an excessive number subjects to an ineffective arm before concluding the utility of the drug and, moreover, conclusions can only be drawn once the study is completed. Two-stage Simon designs, three-stage designs, optimal flexible two-stage designs, or adaptive two-stage designs can address these limitations. These studies are implemented in stages, as suggested by their names. The data from subjects in the study are examined at each stage and, depending on the results, a decision is made to stop the study early or to enroll additional subjects into the next stage. Bayesian predictive power can help in these interim adaptations and can make this decision-making process more efficient. The Bayesian approach allows the use of the posterior distribution from a premarketing study as a prior distribution for surveillance purposes. Information provided by clinical trials can be updated with postmarketing data if exchangeability can be justified between pre- and postmarketing data. This meta-analysis of multiple data sets is of course more properly the domain of Bayesian statistics. In a Bayesian trial decisions have to be made at the design stage regarding the prior information, the information to be obtained from the trial, and the mathematical model to be used to combine the two. Any change in the prior information at a later stage of the trial may hamper the scientific validity of the trial results. Although Bayesian analyses are often computationally intense, recent breakthroughs in computational algorithms and computing speed have made it possible to carry out calculations for very complex and realistic Bayesian models. It has been recommended that a Bayesian adaptive trial be planned in advance. Switch from a frequentist to a Bayesian analysis or vice versa is not recommended once a trial has been initiated. For instance, if the investigator knows that one treatment is doing better at an interim analysis, he or she may assign it with a higher probability to future patients. In order to minimize operational biases, the design should be well planned in advance and the adaptive algorithm should be prespecified. The details of the adaptive design that may reveal evolving treatment differences is best referred to Institutional Review Boards IRBs. Bayesian designs provide an efficient and effective method for evaluating new molecules during the early phases of drug development. The Bayesian approach can also be applied for postmarketing surveillance purposes and in meta-analysis. The basic tenets of good trial design are the same for both Bayesian and frequentist trials. It has been recommended that the type of analysis to be used Bayesian or frequentist should be chosen beforehand; switching to an analysis method that produces a more favorable outcome after observing the data is not recommended. Footnotes Conflict of Interest: Methods in health service research. An introduction to bayesian methods in health technology assessment. 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Chapter 4 : Stephen Senn Consultancy

Statistics in Practice is an important international series of texts which provide detailed coverage of statistical concepts, methods and worked case studies in specific fields of investigation and study.

Good clinical practice [1] is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Data monitoring committees [3] EMA deals with independent data monitoring committees. It highlights the key issues involved when sponsors include data monitoring committees as a part of their trial management. Adjustment for baseline covariates in clinical trials [5] EMA provides advice on how to address important baseline covariates in designing, analysing and reporting clinical trials. It mainly focuses on confirmatory randomised trials. Clinical trials in small populations [6] EMA addresses problems associated with clinical trials when there are limited numbers of patients available to study. Common issues in drug development. Reflection paper on extrapolation of efficacy and safety in paediatric medicine development. Ethnic factors in the acceptability of foreign clinical data. FDA Use of real-world evidence to support regulatory decision-making for medical devices. Choice of a non-inferiority [12] EMA provides guidance on two types of non-inferiority trials: Switching between superiority and non-inferiority [13] EMA addresses the issues of superiority, non-inferiority and equivalence from the perspective of an efficacy trial with a single primary variable. Investigation of subgroups in confirmatory clinical trials [14] EMA provides guidance for assessors in European regulatory agencies on assessment of subgroup analyses in confirmatory clinical trials. Endpoints[edit] FDA: Clinical trial endpoints for the approval of cancer drugs and biologics [15] provides recommendations to applicants on endpoints for cancer clinical trials submitted to the Food and Drug Administration FDA to support effectiveness claims in new drug applications NDAs , biologics license applications BLAs , or supplemental applications. One pivotal study [16] EMA provides guidance on two topics: Extrapolation of efficacy and safety in medicine development [18] EMA discusses the need and possibility to develop a framework for extrapolation approaches that are considered scientifically valid and reliable to support medicine authorisation. Missing data in confirmatory clinical trials [19] EMA explains how the presence of missing data in confirmatory clinical trials should be addressed and reported in a dossier submitted for regulatory review. It provides an insight into the regulatory standards that will be used to assess confirmatory clinical trials with missing data. Multiplicity issues in clinical trials [20] EMA addresses the multiplicity in the clinical trials in the context of an application for marketing authorisation of a medicinal product. The randomization is discussed in: Reporting[edit] ICH E3: Structure and content of clinical study reports [21] aims to allow the compilation of a single core clinical study report acceptable to all regulatory authorities of the ICH regions. Read together with questions and answers. Development Safety Update Report. Study design[edit] ICH E4: Dose response information to support drug registration [26] provides guidance on obtaining dose-response information. It describes the study designs for assessing dose-response. Statistical principles for clinical trials [28] section III provides a general overview of common designs in clinical trials. Choice of control group in clinical trials [29] describes the general principles involved in choosing a control group for clinical trials intended to demonstrate the efficacy of a treatment and to discuss related trial design and conduct issues. Methodological issues in confirmatory clinical trials planned with an adaptive design [30] EMA focuses on the opportunities for interim trial design modifications, and the prerequisites, problems and pitfalls that must be considered as soon as any kind of flexibility is introduced into a confirmatory clinical trial intended to provide evidence of efficacy. EMA Guideline on bioanalytical method validation. References classified by special populations[edit] Gender[edit] FDA: Evaluation of Sex-Specific Data in Medical Device Clinical Studies [33] provides guidance on the study and evaluation of sex-specific data in medical device clinical studies. Geriatrics[edit] ICH E7: Studies in support of special populations: It gives special consideration to the differences in pharmacokinetic, pharmacodynamic and dose response studies in elderly patients. It also covers drug drug

interaction studies. Specifically, this guidance makes recommendations about how to demonstrate that a new antidiabetic therapy to treat type 2 diabetes is not associated with an unacceptable increase in cardiovascular risk. EUnetHTA Guidelines have been developed to help the assessors of evidence to process, analyse and interpret the data. Endpoints used for Relative Effectiveness Assessment Composite endpoints. The guideline is not intended to give a comprehensive list of validated surrogate endpoints and how well they predict final clinical endpoints. Endpoints used in Relative Effectiveness Assessment Safety. Endpoints used for Relative Effectiveness Assessment Health related quality of life and utility measures. As such, it relates mainly to the use of HRQoL measures in clinical trials. The perspective taken is that of the assessor of the relative effectiveness of an intervention in the context of a reimbursement request. It provides a set of internationally agreeable best practice recommendations for the selection of the most appropriate comparator when completing a REA. The guideline is not intended to give a detailed understanding of the meta-analytic techniques described, but rather to explain the main strengths and weaknesses of the methodologies. The guideline discusses some common issues in meta-analysis that must be considered when interpreting results. Finally, the guideline provides a set of recommendations regarding the use of direct and indirect comparisons in a relative effectiveness assessment REA. General methods version 5. It describes key principles of appraisal methodology and is a guide for all organisations considering submitting evidence to the technology appraisal programme of the Institute. References classified as country specific[edit] This section is empty. You can help by adding to it.

Chapter 5 : Use of Bayesian statistics in drug development: Advantages and challenges

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Chapter 6 : Intention-to-treat concept: A review

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Chapter 8 : FIELDS INSTITUTE - Statistical Issues in Biomarker and Drug Co-development Workshop

Statistical issues in drug development. [Stephen Senn] -- Drug development is the process of finding and producing therapeutically useful pharmaceuticals, turning them into safe and effective medicine, and producing reliable information regarding the.