GUIDE TO CLINICAL INTERPRETATION OF DATA pdf

1: Whole Genome Sequencing and Analysis

Epidemiological studies reporting positive associations between smoking and oral contraceptives (OC) and Crohn's disease first appeared in the mids.

Part II covers features of clinical trials and interpretation of study results. Clinical trials provide the foundation for evidence-based medicine, or medical decision-making guided by data from formal research. Medical professionals keep up with the latest information by reading peer-reviewed medical journals and attending conferences. Likewise, HIV positive people can keep abreast of the state of the art by following the medical literature and community publications like BETA. Healthcare providers, therefore, must still rely heavily on clinical experience, intuition, and a careful evaluation of the various factors unique to each individual case -- the practice of medicine remains an art as well as a science. Advertisement Characteristics of Medical Research In the hierarchy of medical research, some types of studies are regarded as more credible than others. Research is considered most valid when it focuses on events in progress rather than those that have already occurred, includes enough participants observed over a long enough period so that the results are statistically significant not likely to be due to chance alone , and takes steps to reduce the influence of confounding factors and minimize bias on the part of investigators and subjects. Prospective Studies Retrospective studies look back at events that happened in the past, often using medical records. In prospective studies, a group of subjects is selected and followed forward in time. Retrospective studies are considered less reliable because it is more difficult to control or even recognize potential confounding factors when looking at past events. For example, it would not be very useful to compare the results from a recent study of atazanavir Reyataz with data from an earlys trial of a first-generation protease inhibitor such as indinavir Crixivan , because both the nature of HIV disease and the standard of care have changed so much in the intervening decade. In addition, important pieces of information may be unavailable when looking back over time. For instance, medical records dating back to the early years of the epidemic would not include HIV viral load measurements, since this test was not widely used until the mids. Study Size and Length Other factors being equal, longer trials with larger sample sizes -- that is, more participants -- are considered more reliable than shorter studies with fewer subjects. Longer and larger trials produce more data, making it less likely that the observed outcome is simply due to chance. The ability of a study to produce statistically significant results is known as its power. A report of the natural history of a disease and its treatment in a specific individual or a small group of patients is called a case report or a case series, respectively. Case reports often describe exceptional or unusual events and have the benefit of speed; as such, they may uncover uncommon side effects such as heart problems associated with protease inhibitors before they are revealed in clinical trials. This type of anecdotal evidence may be interesting, but is not considered conclusive because it is impossible to know how individual factors may have influenced the observed events. Case-control studies provide an additional level of reliability. In these studies, each person with the variable under study a case is matched with one or more individuals with otherwise similar characteristics a control. This matching makes it easier to discern the effect of a particular variable by ensuring that cases and controls are alike in other respects. In a cohort study, a group of individuals with shared characteristics is selected and followed forward in time, typically for many years. In this type of study, researchers do not perform a specific intervention such as administering a particular drug , but rather observe the effect of various factors e. Clinical trials are carefully planned studies looking at particular therapeutic interventions. The process proceeds in phases, with each successive stage lasting longer and including more subjects this is covered in "Part I: This is done to achieve a trade-off of safety and credibility. Only small numbers of participants are exposed to potentially risky new agents during Phase I trials. After a drug is shown to be generally safe, large numbers of subjects are included in Phase III trials to obtain more reliable data on efficacy how well it works. Once several studies have been done looking at a particular therapy, researchers may conduct a systematic review comprehensive overview of related studies or a meta-analysis mathematical analysis that incorporates data from multiple studies. These secondary studies provide a "big picture" summary of information amassed so far. If several well-designed trials produce similar

results, confidence in the outcome is enhanced. The "gold standard" for research on medical interventions is the prospective, double-blind, randomized, controlled trial. Briefly, double-blind means that neither the investigators nor the subjects know who is receiving the experimental agent. Randomization refers to the process of assigning subjects by chance to the various treatment arms. This is done to help ensure that at the outset of the trial the subjects in the various arms are comparable, or as similar as possible in every respect except for the type of intervention they are receiving. A controlled trial is one in which the experimental agent is compared against something else, either a placebo inactive or mock therapy or an existing effective treatment these characteristics are described in more detail in Part I. Statistics Investigators are not always able to design and implement randomized controlled trials to test every hypothesis. For instance, it would be unethical to randomly assign HIV positive pregnant women either to give birth vaginally or undergo a cesarean section c-section to see which method results in a lower rate of mother-to-child HIV transmission. The best researchers can do is compare the HIV status of infants who happened to be born vaginally or through c-section, but these groups might differ in other ways e. Fortunately, researchers can use various statistical methods to make adjustments for systematic consistent and predictable differences between groups of subjects. For example, it is a common finding that individuals coinfected with HIV and hepatitis C virus HCV are more likely to be injection drug users and tend to be younger than people with HIV alone. It is also known that HCV-related liver damage increases with age and that older individuals tend to respond less well to interferon-based therapy. Investigators can also stratify their data to look separately at subgroups with different confounding characteristics. Another statistical concern related to clinical studies -- especially those that include representative "real world" populations -- is that raw data are rarely "clean," or free of potentially confounding influences. Investigators often must take multiple coexisting factors into account. Looking again at hepatitis C, it is known that, along with older individuals, men tend to respond less well to interferon than women, and African-Americans respond less well than whites. Thus, researchers looking at the relative benefits of two different interferon-based regimens would need to use mathematical models that account for how all these variables interact to influence the observed outcome. It is not uncommon that a factor that initially seems important in a univariate analysis that looks at a single variable alone will no longer appear relevant when a multivariate analysis is performed to account for multiple interacting variables. Statistical Significance As noted above, study results are considered statistically significant if there is little likelihood that the observed outcome was due to chance alone. When looking at data from different arms of an interventional clinical trial, researchers attempt to determine whether the null hypothesis -- the assumption that the various interventions are equally effective -- is true or false. Researchers use the P value to indicate the probability that an observed result is true and not just due to happenstance for example, that an experimental agent really works, not just that more of the subjects who took it had the good luck to improve. While studies may use different cut-off values, a P value below 0. Smaller P values indicate even greater certainty. A P value below 0. While the P value provides a single cut-off for statistical significance, the confidence interval CI provides a range within which the true result is likely to fall. Studies with higher power e. The actual values included in a CI also convey useful information. In an interventional trial, if the null hypothesis were true, the difference between two treatments under study or treatment and placebo would be zero. Thus, if a CI includes zero, researchers cannot rule out the possibility that the interventions were equally effective. Interpreting Significance All studies yield a certain level of false positive and false negative data. For instance, an experimental drug may seem to work for a particular subject even though it is, in fact, ineffective overall; conversely, an agent may not help a specific subject even though it is effective overall. The goal in a well-designed study is for these types of subject-specific variability to cancel each other out, so that any actual benefit of an intervention will become apparent. Failure to detect a true difference between interventions is known as a type II error, while erroneously finding a difference between two interventions that are in fact equally effective is called a type I error. In real world terms, if the observed difference in HIV viral load suppression between two study arms receiving two different drug regimens is statistically significant, this suggests that one regimen really does work better. If the observed difference is not statistically significant, it could be that the two regimens have about the same efficacy or lack thereof. But it could also mean that the

study was underpowered or too small to demonstrate an effect. Larger and longer-lasting studies -- those with higher power -- are more likely to produce significant results. Studies with low power produce wide CIs, meaning the true result could lie within a broad range. Statistical tools are available to help investigators determine in advance how large a sample size they will need to detect a true difference between study groups. Reporting Study Results After a clinical trial is completed, investigators typically present their research results to their colleagues. The two main venues for disseminating data from medical research are scientific meetings and professional journals. Scientific Conferences Often researchers first publicly present their findings at conferences devoted to their fields of study. In addition, pharmaceutical companies commonly sponsor meetings to present the latest research on their experimental drugs. The most interesting or groundbreaking studies are usually presented orally by one of the authors, often accompanied by slides. While study abstracts are typically submitted months in advance, important last-minute results are sometimes included as "late-breakers. Abstracts from both oral and poster presentations are typically published in a catalog and may also be made available on the Web. Medical Journals The "gold standard" for the presentation of medical research is publication in a peer-reviewed professional journal. Journal editors send out submitted articles for review, usually by selected colleagues who work in the same field, to ensure that the study appears well designed, the methods sound, and the data plausible. Medical journal articles adhere to a basic standard format and usually include the following elements: This usually includes a statement summarizing the problem or issue to be investigated, a brief review of what is known to date with references to key literature , the rationale for the study why was it done? These sections which may be combined provide in-depth information about how the study was designed and carried out, including a detailed description of the study population, which treatment s were used, which tests were performed, and how data was collected and analyzed. This section gives a detailed description of the data collected by the researchers and the results of their statistical analyses, often including tables, charts, and graphs. In this section the authors interpret their results, draw their conclusions, and discuss what their findings mean -- for example, whether the initial hypothesis was confirmed, how the results might affect clinical practice, potential limitations of the study, and suggestions for further research. Finding Useful Research Results With improvements in information technology -- and a shift away from the notion that medical professionals are unquestionable authorities -- a growing number of people have taken an interest in exploring medical research for themselves. But just because a great deal of medical information is available on the Internet and elsewhere does not suggest that all of it is credible. National Library of Medicine. With so much information available, entering a broad search term like "HIV" can feel like taking a drink from a fire hose. Users will obtain more useful and relevant results using narrower search criteria, for example a specific drug name or side effect. MEDLINE provides free access to research abstracts, but users often must dig up actual medical journals to obtain the full text of articles. University and medical center libraries carry the most popular, reputable medical journals, and usually a selection of smaller, more specialized ones as well. Although intended for use by students and staff, some university libraries allow members of the public to access their collections. Most medical journals are available on the Web, but generally offer only abstracts for free. Some provide immediate free full-text access to studies deemed particularly important or groundbreaking, and others offer full access to issues that are more than six months or a year old. Other good online sources of medical information include sites sponsored by the federal government e. Pharmaceutical company Web sites can provide useful information in particular, full prescribing information for specific drugs but beware of bias. To address concerns that unfavorable study data about experimental drugs have not been widely available, the industry trade group Pharmaceutical Research and Manufacturers of America PhRMA recently launched an online repository of published and unpublished clinical trial results at www. See the table below for tips on locating credible medical information on the Internet. Tips for Researching Medical Information on the Internet Check that the information comes from a credible source e.

GUIDE TO CLINICAL INTERPRETATION OF DATA pdf

2: Practical Guide to Clinical Data Management - Susanne Prokscha - Google Books

data interpretation or evaluation of clinical interpretations of data. The text provides practical and insightful procedures to examine and draw conclusions from clinical research data.

In a clinical trial, a priori planned interim analyses, their nature and reason for performance are defined in the protocol. Data for such an analysis are then usually source-verified by the field monitor and central data review concerns only such verified data. Upon a tightly coordinated query process, where usually field monitors are involved again and provide support for the sites, the data base can be locked for the respective data analysis. Challenges for data review and interim analyses in a non-interventional study NIS However, the situation is much more complicated in the non-interventional setting. In a NIS, the following characteristics may present a challenge for data review and interim analyses: Only rarely the observational plan of a NIS defines a priori interim analyses and, if any, the description is very vaguely. Patient enrollment in a NIS cannot be guided as within a clinical trial, therefore the timing of the interim analysis may be difficult to predict far ahead. A NIS usually involves many more patients than a clinical trial and data are usually less standardized e. Thus, often automatic plausibility checks e. In some NIS, only particular items are verified by the monitors, in others, only a random sample of patient data are subject to monitoring, and again in others, there might be no on-site monitoring at all. Thus, in most NIS the central data review is usually performed on data that were not source verified and thus usually of lower quality than in a clinical trial. So what does this mean? However, this is an unrealistic scenario in the vast majority of NIS â€" in a study with thousands of patients, it is likely that dealing with data unlock-requests would be more than a full-time job. Therefore, different approaches for central data review seem more efficient in the NIS setting. In addition, the continuous and batch-wise review approaches are most effective when they go hand in hand in a coordinated manner. Assessing and closing failed edit checks on a regular basis often provides a good basis for a continuous data review. Only if you perform a regular data review, you will be able to realize if a majority of sites has troubles with a given edit check or question. Consequently, you can react before people get frustrated with the study. Batch-wise data review This approach is especially useful when data that require review are to be reviewed in a longitudinal manner i. This is often the case when the interim analysis should include patients who have reached a given relevant study milestone e. The batch then contains those patients with a defined degree of completeness of their data sets, which can be analyzed in a meaningful way. There are many circumstances, where patient data that has already been subject to review may need to be reviewed again â€" e. In such cases, it may be beneficial to program listings where only de novo entered or changed data are displayed. However, keep in mind that the plausibility of certain data entries in the last visit may only be judged when also looking at the data from the first visit. Therefore, listings and data presentations that allow for both â€" a quick overview on new entries as well as the whole picture â€" may be the most useful approach. Summary and recommendations Even though a NIS does not require a per protocol defined interim analysis, pre-defining and long-term planning of interim analyses is certainly beneficial. Precise definition of the goal of an interim analysis and focusing only on those data that are needed to achieve this goal are strongly advisable â€" this saves time and effort also for the sites and is more cost effective; it is advisable to streamline the data review activities with the statistical analysis plan development. Streamline your data review activities with the activities of your CRAs and centralized monitoring; if possible coordinate site visits in a way that can help the sites resolve queries raised during medical data review. Streamline any other data review activity with your medical data review â€" e. Make realistic time plans â€" not only for your data review teams but also, and foremost, for your sites and give them time to review queries and correct data or provide answers. More information Get the latest articles as soon as they are published:

3: A Guide to GCP for Clinical Data Management

Full text Full text is available as a scanned copy of the original print version. Get a printable copy (PDF file) of the

complete article (K), or click on a page image below to browse page by page.

4: Guide to clinical interpretation of data - CORE

Streamline any other data review activity with your medical data review - e.g. it might be advisable to perform a reconciliation between safety and clinical data base along with the data review, in order to avoid conflicting or duplicate queries to the sites.

5: Data Review for interim analysis: issues & consideration check-list

Note: Citations are based on reference standards. However, formatting rules can vary widely between applications and fields of interest or study. The specific requirements or preferences of your reviewing publisher, classroom teacher, institution or organization should be applied.

6: Guide to Interpretation of Hemodynamic Data in

Clinical Interpretation Guide For years, doctors have asked for the operational capability to analyze data from their Humphrey Â® Field Analyzer (HFA â„¢) using a Mac or PC, right in their.

7: A Guide to Clinical Trials - www.enganchecubano.com

Covering EKG's, X-Rays, MRI's, graphs, paper recordings, blood gas results, laboratory results, patient case histories and more, Data Interpretation in Anesthesia provides an enhanced and stimulating learning format for residents in training and practitioners alike.

8: Guide to Clinical Interpretation of Data - Europe PMC Article - Europe PMC

Clinical Interpretation Guide For years, doctors have asked for the operational capability to analyze data from their Humphrey Â® Field Analyzer (HFA â„¢) using a Mac or PC.

GUIDE TO CLINICAL INTERPRETATION OF DATA pdf

Coping with college I believe i can fly piano Priests and Prelates Structure of society and state in early dynastic Sumer The 9/11 Commission Report: Denying Sanctuaries to Terrorists Why they are called chopsticks 2nd grade math addition worksheets A pocket of renegades The findings of Dr. Meade Layne Serial triggering model Jacob Rachmilewitz Graphic design price list 2017 Vocal sheet music The great Indian cookbook How big is a whale? The dark knight returns 1986 At zero joe vitale Developmental Stages: Conscious and Unconscious Chicago and the American literary imagination, 1880-1920 First Certificate Avenues Revised Edition Students book (Cambridge First Certificate) Reel 105. September 15-30, 1851 Donald says thumbs down Treasure Island (Stepping Stone Book Classics) Pathways Of The Heart Hawk Fisher 2:win (Hawk and Fisher, No 2) Corrosion and oxidation of metals Dont Get MAD Get Wise The South African building plan Recuerdos de los viejitos = In the Path of the Big Wind The First British Commonwealth Wonders and curiosities of the railway; or, Stories of the locomotive in every land. Spiders th story Stream analysis jerry porras V. 1. Dragon cemetery History of caste in india Miracles in the storm The far and the deep. Business Administration of a City School System Six Stuart Davis Cards (Small-Format Card Books) The instant, no. I-II