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The importance of a detailed statistical analysis plan in clinical study report writing

Clinical trials are conducted on all new medicines and devices. Regulators will only approve a new medicine or device if these trials, together with other research data, demonstrate it has a favorable risk: benefit profile. Historically, the majority of patients recruited into clinical trials for medicine development have been from Western Europe and the US. However, clinical trials are increasingly recruiting patients from other countries, including developing countries. Also, the landscape for clinical trials has continued to evolve and change over the last twenty years. Clinical trials have become more complicated but not more efficient. The increased complexity of today's clinical trials is associated with reduced patient enrollment and retention, higher risk for protocol amendments, and longer and more costly clinical trials. Clinical trials are used to assess the benefits and harms of interventions in health care, and if conducted properly, the risk of bias is minimized, particularly bias in selection of patient populations, endpoints and analysis. There is, however, considerable evidence that clinical trials are not always well reported. The usefulness of a Clinical Study Report (CSR) depends on the clarity with which it details the relevance of its, participants, outcomes and design to the real world practice. ICH E3 is guidance on how to present the results in order to provide a level of details that will enable a secondary evaluation i.e. an assessment by regulatory authorities of the conducted analysis and conclusions drawn. ICH E9 is guidance on the content of the Statistical Analysis Plan (SAP) and presents recommendations for information to be included in key sections of CSR. A well written and complete research protocol is essential for a high quality study and avoids problems during the study. Clear and unambiguous SAP minimizes the risk of bias in the analysis and provides detailed statistical methodology used as well as the definition of Tables, Figures and Listings (TFLs) to be included in the CSR. Clear, complete and concise CSR streamlines regulatory review, publishing and facilitate the use of study results in real word.

Biography

Farida Dabouz holds a PhD in Statistics with a broad industry experience as well as academic international oncology group in Europe and Canada. In addition to her many accomplishments in Biostatistics/Data Management at Sanofi and BCIRG, she also leverages her experience in "data quality" on applying innovative approaches in the field of biostatistics, data management and medical writing to improve data processing. She has a strong experience in training site investigators and operational teams, covering all data aspects, mainly demystifying statistics in clinical trials. She is certified/active member of SOCRA and SCDM education committee, providing webinars and online courses.

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