Farida Dabouz, J Pharma Care Health Sys 2016, 3:4(Suppl)
http://dx.doi.org/10.4172/2376-0419.C1.017

The clinical data odyssey through the innovative approaches towards data quality and integrity

Farida Dabouz
FB2D Clinical Research Consulting Inc., Canada

Clinical research is a cornerstone of evidence-based medicine as well as a branch of healthcare sciences that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. Clinical research is of great value to medical practitioners/institutions but most importantly to patients and the society as a whole. 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 expand more globally to take advantage of the large treatment naive population in emerging and developing countries. However, there are key factors that need to be taken into considerations to ensure the clinical trials are successful. Concerns such as qualified data and limited number of trained operational team, have deterred pharmaceuticals to conduct their research. Increasing regulation, rising costs, and the number and complexity of clinical trials being conducted are forcing sponsors to be smart and creative in how they conduct clinical research. The advanced technology (EDC, ePRO) as well as the FDA risk-based guidance and the EMA reflection paper have opened a door to the Risk-Based Monitoring (RBM) paradigm that will help in ensuring trial integrity and validity. Good clinical research must be built upon sound ethical and scientific practice as well as a "data quality culture" within the organization.

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.

fb2clinicalresearch@sympatico.ca

Notes: