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Publication Practices Among Pivotal Clinical Trials of High-Risk Medical Devices

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Abstract

High-risk medical devices must go through a special approval process before entering the market, whereby they demonstrate sufficient safety and clinical effectiveness by submitting relevant evidence. This evidence is usually obtained by conducting one or more clinical trials. There have been occasional inaccuracies in the reporting of the results of these trials, e.g., not publishing the entire study or misrepresenting unfavorable results. Our study deals with the issue of publishing clinical trials of new, high-risk, cardiovascular medical devices. The main objective of the study was to analyze the clinical studies in SSED documents that are submitted to the FDA in the premarket approval process and compare it with the information in related peer-reviewed publications. A total of 59 medical devices that met the inclusion criteria were identified in the time period 2014–2018. Of the 64 pivotal clinical studies, 81% were published, with a median time to publication of 2 months. There were no substantial differences in randomization and blinding between SSED pivotal trials and publications. Small differences were noticed in the number of patients (8%), the mean patient age and sex (15%). No differences were observed between SSED documents and published studies in terms of primary outcomes selection and definition. Only three (3.8%) outcomes were not found in publications. Our results shown a substantial improvement both in the publication rate of the pivotal trials and in the correctness of the published information for high-risk cardiovascular medical devices.

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Keywords: medical devices, regulatory process, premarket approval,·clinical studies, publication practice

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