

Methods: A US Food and Drug Administration and European Medicines Agency website search was conducted to determine current medical device regulations. A comprehensive literature search was done from Google Scholar to determine the differences in drug and medical device development.

Results: Designing well-controlled prospective clinical trials of medical devices presents unique challenges that differ from those faced in studies of pharmaceuticals. Clinical outcomes observed in medical device studies, unlike drug trials, are influenced not only by the product under evaluation and the patient but also by the skill and discretion of the health care professional. Medically appropriate alternative treatment regimens may not be available to provide randomized, concurrent controls in device trials. Because devices are often developed by small companies, financial constraints often limit the new product development and testing.

Conclusions: Medical device development is faced with unique challenges. Managing the design issues in clinical trials and complying with increasingly stringent regulatory guidelines is necessary to bring new devices faster to market with reduced cost.

Key words: clinical trials, EMA, medical devices, USFDA.

Disclosure of Interest: None declared.

References:

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DEVELOPMENT OF MEDICAL DEVICES

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Background: The medical devices sector helps save lives by providing innovative health care solutions regarding diagnosis, prevention, monitoring, treatment, and alleviation. Medical devices are classified into 1 of 3 categories in the order of increasing risk: Class I, Class II, and Class III.¹ Medical devices are distinguished from drugs for regulatory purposes based on mechanism of action. Unlike drugs, medical devices operate via physical or mechanical means and are not dependent on metabolism to accomplish their primary intended effect.^{2,3}

Objectives: This study focused on regulations and differences in medical device and pharmaceutical drug development. It also highlighted the unique challenges faced while doing medical device development.