



Cardiac Safety of Noncardiac Drugs

Joel Morganroth, Ihor Gussak

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It is generally easy to define the efficacy of a new therapeutic agent. However, what is even more difficult and more challenging yet more important is to define its safety when administered to millions of patients with multi-faceted diseases, co-morbidities, sensitivities and concomitant medications. The commonest cause of new drug discontinuations, cause for disapproval from marketing and removal from the market after approval is a drug's effect on cardiac repolarization which is essentially identified by increasing the duration of the QTc interval duration on the standard 12-lead electrocardiogram (ECG). **Cardiac Safety of Noncardiac Drugs: Practical Guide-** Joel Morganroth, MD lines for Clinical Research and Drug Development is designed to present the current preclinical, clinical, and regulatory principles to assess the cardiac safety of new drugs based primarily on their effects on the ECG. Practical guidance to define cardiac safety at all stages of clinical research and drug development are featured and discussed by internationally recognized experts with academic, industrial, and regulatory experience. Each chapter contains the best available evidence, the author's personal opinions, areas of controversy, and future trends. Although some of the areas are highly specialized, this book has been designed for a broad audience ranging from medical and graduate students to clinical nurses, clinical trial coordinators, safety officers, data managers, statisticians, regulatory authorities, clinicians, and Ihor Gussak, MD, PhD scientists.

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