Therapeutic & Diagnostic Device Outcomes Research

An outcomes research primer for those in the therapeutic and diagnostics devices field with the purpose to inform:
1) Health outcomes researchers on the unique characteristics of therapeutic and diagnostic devices, and
2) Medical device developers and researchers on the basic principles of clinical, economic, and patient reported outcomes research for therapeutic and diagnostic devices

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This book, THERAPEUTIC AND DIAGNOSTIC DEVICE OUTCOMES RESEARCH, is organized into eleven sections. In Section I and II, the unique features of medical & diagnostics devices, including the development of these devices are described. In Section III, the unique regulatory requirements for therapeutic and diagnostic device approval in the United States as well as the European Union for devices are presented. In Sections IV, V, VI, and VII clinical outcomes research, in general, and clinical research issues specific to therapeutic and diagnostic devices is presented. Section IV describes therapeutic and diagnostic device outcomes research study design, measurement, and practices issues to consider; Section V, VI, and VII describe clinical outcomes research for therapeutic devices, diagnostic devices, and therapeutic devices / drug combination, respectively. In Section VIII economic issues to consider for medical and diagnostic devices as well as a tutorial on how to conduct economic outcomes evaluations with specific therapeutic or diagnostic devices examples are presented. In Section IX, a tutorial on how to conduct therapeutic and diagnostic device patient reported outcomes as well as the use of this information in health care decisions is presented. In Section X and XI, the use of therapeutic and diagnostic device outcomes research (clinical, economic, and patient reported outcomes) in developing evidence for health care decisions including reimbursement decisions are then discussed.

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