1. Record Nr. UNINA9910960256203321 Autore Mack Alison Titolo Perspectives on biomarker and surrogate endpoint evaluation: discussion forum summary / / Alison Mack, Erin Balogh, and Christine M. Micheel: Committee on Qualification of Biomarkers and Surrogate **Endpoints in Chronic Disease** Washington, D.C., : National Academies Press, 2011 Pubbl/distr/stampa **ISBN** 9786612976056 9780309187008 0309187001 9781282976054 1282976052 9780309163255 0309163250 Edizione [1st ed.] 1 online resource (139 p.) Descrizione fisica Altri autori (Persone) BaloghErin MicheelChristine Soggetti Biochemical markers Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Bibliographic Level Mode of Issuance: Monograph Note generali Includes bibliographical references (p. 99-102). Nota di bibliografia Introduction -- Committee findings and recommendations -- FDA Nota di contenuto perspectives -- National institutes of health perspectives -- Industry perspectives -- Public health, consumer, and consulting organization perspectives -- Presentation by Thomas Fleming: biomarkers and surrogate endpoints in chronic disease -- Key themes, challenges, and opportunities -- Importance of the biomarker discussion forum. Sommario/riassunto In 2010 the Institute of Medicine (IOM) recommended a framework for the evaluation of biomarkers in the chronic disease setting. Published in the book Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease, the framework is intended to bring consistency and transparency to the previously disparate process of biomarker

evaluation. Following the book's release, the IOM convened a 2-day discussion forum in Washington, DC, in order to provide an opportunity

for stakeholders to learn about, react to, and discuss the book.

Presentations reviewed the authoring committee's work process, recommendations, and provided perspectives on the book from the point of view of participants. Thomas Fleming, professor of biostatistics and statistics at the University of Washington, gave a keynote presentation on the critical issues in the validation of surrogate endpoints, a specific use of a biomarker. The present volume recounts the discussion forum proceedings, focusing in turn on each represented sector. A summary of Dr. Fleming's presentation then sets the committee's recommendations within the context of biomarker utilization. Lastly, this summary examines the main themes raised by stakeholders, and the challenges and opportunities presented to stakeholders by the book's recommendations.--