Record Nr. UNINA9910810514303321 Advancing regulatory science for medical countermeasure development **Titolo** : workshop summary / / Theresa Wizemann, Bruce M. Altevogt, and Anne B. Claiborne, rapporteurs Washington, D.C.,: National Academies Press. 2011 Pubbl/distr/stampa **ISBN** 0-309-21493-9 1-283-25354-2 9786613253545 0-309-21491-2 Edizione [1st ed.] Descrizione fisica 1 online resource (150 pages) Altri autori (Persone) WizemannTheresa M AltevogtBruce M ClaiborneAnne B Disciplina 616.0250973 Soggetti Emergency management - United States - Evaluation Disaster medicine - United States - Evaluation Weapons of mass destruction - Health aspects Chemical agents (Munitions) Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Note generali Description based upon print version of record. Nota di bibliografia Includes bibliographical references. Nota di contenuto ""Front Matter""; ""Reviewers""; ""Contents""; ""Tables, Figures, and Boxes""; ""Acronyms""; ""1 Introduction""; ""2 MCM Enterprise and Stakeholder Perspectives""; ""3 Cutting-Edge Efforts to Advance MCM Regulatory Science""; ""4 MCM Regulatory Science Needs for At-Risk Populations""; ""5 Crosscutting Themes and Future Directions""; ""6 Closing Remarks""; ""References""; ""Appendix A: Workshop Agenda""; ""Appendix B: Participant Biographies"" Sommario/riassunto Whether or not the United States has safe and effective medical countermeasures--such as vaccines, drugs, and diagnostic tools-available for use during a disaster can mean the difference between life and death for many Americans. The Food and Drug Administration

(FDA) and the scientific community at large could benefit from improved scientific tools and analytic techniques to undertake the

complex scientific evaluation and decision making needed to make essential medical countermeasures available. At the request of FDA, the Institute of Medicine (IOM) held a workshop to examine methods to improve the development, evaluation, approval, and regulation of medical countermeasures. During public health emergencies such as influenza or chemical, biological, radiological/nuclear (CBRN) attacks, safe and effective vaccines, treatments, and other medical countermeasures are essential to protecting national security and the well being of the public. Advancing regulatory science for medical countermeasure development examines current medical countermeasures, and investigates the future of research and development in this area. Convened on March 29-30, 2011, this workshop identified regulatory science tools and methods that are available or under development, as well as major gaps in currently available regulatory science tools. Advancing regulatory science for medical countermeasure development is a valuable resource for federal agencies including the Food and Drug Administration (FDA), the Department of Health and Human Services (HHS), the Department of Defense (DoD), as well as health professionals, and public and private health organizations"--Publisher's description.