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| Nota di contenuto | ""Front matter""; ""Acknowledgments""; ""Contents""; ""Summary""; ""1 Introduction""; ""2 Evaluation of Current and Future TMT-Used Animal Models""; ""3 Ethical and Regulatory Challenges in the Development of Countermeasures""; ""4 Developing New Animal Models for Biodefense Research""; ""5 Alternative Approaches to Animal Testing for Biodefense Countermeasures""; ""Appendix A: The Animal Rule""; ""Appendix B: Draft Guidance for Industry""; ""Appendix C: Developing Animal Models for Use in Animal Rule Licensure: The NIAID Approach""; ""Appendix D: Presentations to the Committee"" ""Appendix E: Statement of Task""""Appendix F: About the Authors"" |
| Sommario/riassunto | "The Transformational Medical Technologies (TMT) has been a unique component of the U.S. Department of Defense (DoD) medical biodefense efforts since 2006. Its mission is to advance countermeasure research and development in support of the broader goal of the DoD to protect warfighters from emerging infectious diseases and future genetically engineered biological weapons. The TMT, using advanced science and technology approaches, focused on |

the development of roadspectrum countermeasures that target common host and pathogen pathways or enhance the host's immune response. Many of these pathogens are lethal or cause such debilitating diseases in humans that it is ethically inappropriate to test the efficacy of these countermeasures in human volunteers. In lieu of human participants, these products may be tested in animals and approved for human use under the provisions of the Food and Drug Administration (FDA)'s 2002 Animal Rule. The reliance on animal models for the development and licensure of medical countermeasures against biothreats is challenging for a number of reasons. The ad hoc Committee on Animal Models for Assessing Countermeasures to Bioterrorism Agents prepared a consensus report that would address the challenges stemming from developing and testing medical countermeasures against biothreat agents in animal models. Animal Models for Assessing Countermeasures to Bioterrorism Agents evaluates how well the existing TMT-employed or candidate animal models reflect the pathophysiology, clinical picture, and treatment of human disease as related to the agents of interest. The report addresses the process and/or feasibility of developing new animal models for critical biodefense research, placing emphasis on the need for a robust and expeditious validation process in terms of the FDA's Animal Rule. The report also evaluates alternatives to the use of animal models based on the premise of the Three Rs"--Publisher's description.
