Record Nr. UNINA9910822830003321 Scientific standards for studies on modified risk tobacco products // **Titolo** Institute of Medicine of the National Academies Pubbl/distr/stampa Washington, D.C., : National Academies Press, 2012 **ISBN** 1-280-38022-5 9786613558138 0-309-22399-7 Edizione [1st ed.] Descrizione fisica 1 online resource (370 p.) Disciplina 616.86506 Tobacco - Risk assessment - Research - United States Soggetti Tobacco use - Health aspects - Research - United States Products liability - Tobacco - United States Nicotine addiction - Research - United States Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia "Committee on Scientific Standards for Studies on Modified Risk Note generali Tobacco Products, Board on Population Health and Public Health Practice." Nota di bibliografia Includes bibliographical references. ""Front Matter""; ""Reviewers""; ""Preface""; ""Contents""; ""Acronyms and Nota di contenuto Abbreviations"; ""Summary""; ""1 Introduction""; ""2 Governance and Conduct of Studies""; ""3 Evidence Base and Methods for Studying Health Effects""; ""4 Methods for Investigating Addictive Potential""; ""5 Methods for Studying Risk Perception and Risk Communication""; ""6 Decision Making and Oversight of MRTP Studies: Findings and Recommendations""; ""Appendix A: Section 911 of the Family Smoking Prevention and Tobacco Control Act of 2009"" ""Appendix B: Chapters 1 and 2 from \*Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease\*"""[Appendix B] 1 Introduction""; ""[Appendix B] 2 Review: Evaluating and Regulating Biomarker Use""; ""Appendix C: Committee Biographies""; ""Appendix D: Meeting Agendas"" "Smoking-related diseases kill more Americans than alcohol, illegal Sommario/riassunto drugs, murder and suicide combined. The passage of the Family Smoking Prevention and Tobacco Control Act of 2009 gave the FDA

authority to regulate "modified risk tobacco products" (MRTPs), tobacco products that are either designed or advertised to reduce harm or the risk of tobacco-related disease. MRTPs must submit to the FDA scientific evidence to demonstrate the product has the potential to reduce tobacco related harms as compared to conventional tobacco products. The IOM identifies minimum standards for scientific studies that an applicant would need to complete to obtain an order to market the product from the FDA."--Publisher's description.