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| Autore | Mussen Filip |
| Titolo | Benefit-risk appraisal of medicines [[electronic resource] ] : a systematic approach to decision making / / Filip Mussen, Sam Salek, Stuart Walker |
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| ISBN | 1-282-25949-0<br>9786612259494<br>0-470-74811-7<br>0-470-74812-5 |
| Descrizione fisica | 1 online resource (306 p.) |
| Altri autori (Persone) | SalekSam<br>WalkerStuart R. <1944-> |
| Disciplina | 615.19<br>615/.1901 |
| Soggetti | Drugs - Testing<br>Pharmaceutical policy - Decision making |
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| Formato | Materiale a stampa |
| Livello bibliografico | Monografia |
| Note generali | Description based upon print version of record. |
| Nota di bibliografia | Includes bibliographical references and index. |
| Nota di contenuto | Benefit-Risk Appraisal of Medicines; Contents; Foreword; Preface; 1 Concept and Scope of Benefit-Risk Evaluation of Medicines; 1.1 Historical background; 1.2 The regulatory systems for assessing medicines; 1.3 Benefit-risk assessment: definitions; 1.4 Views and perceptions of benefits and risks of medicines; 1.5 Stages and concepts in benefit-risk assessment; 1.6 Benefit-risk assessment: the current regulatory environment; 1.7 Benefit-risk assessment in other disciplines; 1.8 Specific methods and models for benefit-risk assessment<br>1.9 Discussions with stakeholders on the concepts and models for benefit-risk evaluation2 Criteria for a Benefit-Risk Model: a Conceptual Framework; 2.1 Introduction; 2.2 Regulatory guidelines on benefit and risk criteria; 2.3 Identification, definition and rationale of relevant benefit and risk criteria; 2.4 Verification of the list of benefit and risk criteria by means of a survey; 3 Review of the Current Benefit-Risk Assessment Models; 3.1 Background; 3.2 Evaluation of the existing benefit-risk assessment models; 3.3 Review of models in single clinical |

trials and for specific medicines

3.4 Conclusion3.5 Newer models; 4 Defining a Systematic Approach to Decision Making; 4.1 Introduction; 4.2 Objectives and features of the ideal model for benefit-risk assessment; 4.3 The use of decision-analysis techniques for the development of the new model; 5 Development and Application of a Benefit-Risk Assessment Model Based on Multi-Criteria Decision Analysis; 5.1 Introduction; 5.2 Conceptualization of the new model; 5.3 Reasons for using decision analysis techniques in the new model; 5.4 The use of MCDA in the new model; 5.5 Development of the new model

5.6 Applicability of the new model5.7 Summary; 5.8 Review of the MCDA model; 6 A Future Framework for Benefit-Risk Appraisal of Medicines; 6.1 Background; 6.2 Development of a benefit-risk framework for regulatory review of new medicines; 6.3 Prerequisites of a benefit-risk framework for the registration of a new medicine; 6.4 Current status of benefit-risk assessment among companies and agencies; 6.5 Constructing a benefit-risk framework; 6.6 Conclusion; Appendices

Appendix 1 Summary Reports of the CMR International Institute for Regulatory Science March 2004 and June 2005 Workshops on Benefit-RiskAppendix 2 Office of Health Economics Briefing: Challenges and Opportunities for Improving Benefit-risk Assessment of Pharmaceuticals from an Economic Perspective - James Cross and Louis Garrison (August 2008); Appendix 3 Reflection Paper on Benefit-risk Assessment Methods in the Context of the Evaluation of Marketing Authorisation Applications of Medicinal Products for Human Use - Committee for Medicinal Products for Human Use (March 2008) Appendix 4 Commentaries on 'A Quantitative Approach to Benefit-risk Assessment of Medicines' Pharmacoepidemiology and Drug Safety, 2007, 16

Sommario/riassunto

Benefit-risk assessment is at the centre of the approval process for every new medicine. The ability to assess the risks of a new medicine accurately and to balance these against the benefits the medicine could bring is critical for every regulatory authority and pharmaceutical company. Despite this there are very few tried and tested evaluative models currently available.  The authors of this book have developed a new, pioneering tool for the assessment of benefits and risks for new medicines in development. This model utilises a multi-criteria decision analysis which involves selecting,

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| Titolo | Small unit actions in Afghanistan / / general editor, Donald P. Wright ; Afghan study team authors, Anthony E. Carlson [and five others] |
| Pubbl/distr/stampa | Fort Leavenworth, Kansas : , : Combat Studies Institute Press, US Army Combined Arms Center, , 2012 |
| Descrizione fisica | 1 online resource (xi, 151 pages) : illustrations, maps |
| Collana | Vanguard of valor ; ; volume II |
| Disciplina | 958.104/742 |
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