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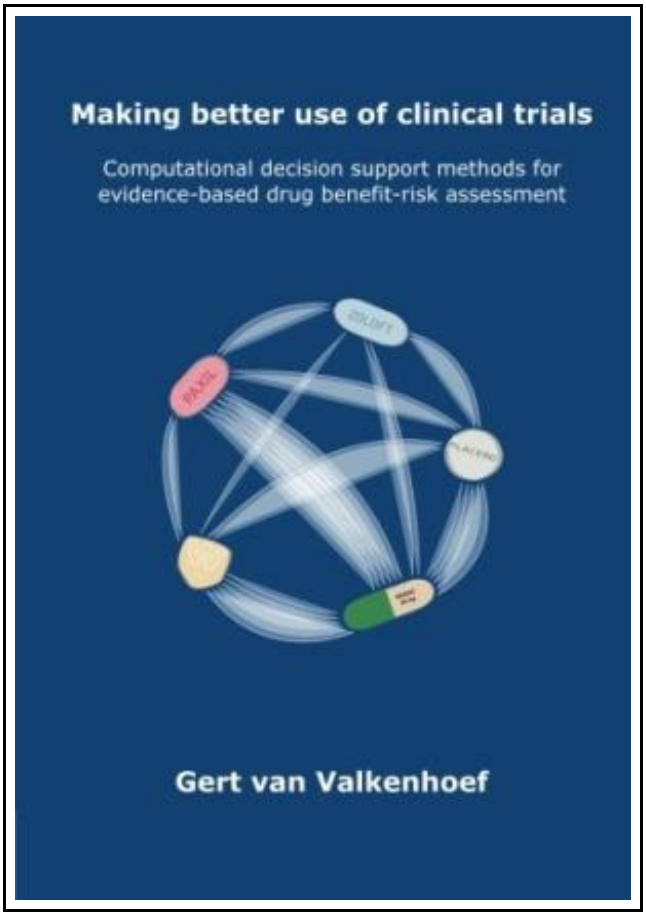

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MAKING BETTER USE OF CLINICAL TRIALS: COMPUTATIONAL DECISION SUPPORT METHODS FOR EVIDENCE-BASED DRUG BENEFIT-RISK ASSESSMENT

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Purdue University Press, United States, 2012. Paperback. Book Condition: New. 242 x 170 mm. Language: English . Brand New Book ***** Print on Demand *****.Health care policy decision makers routinely evaluate the health impact of alternative treatment options. Here benefit-risk assessment is key, consisting of weighing the favorable effects (benefits) and unfavorable effects (risks) of the alternatives. For example, before a new drug is allowed on the market, regulators evaluate its benefit-risk balance in comparison to placebo or competing drugs. Ideally, benefit-risk assessments are based on the best available evidence, typically meaning randomized controlled trials. However, finding the evidence and explicitly linking it to the assessment is complicated by several factors. First, the results of clinical trials are mainly made available in text-based documents that can not be processed automatically. Second, the data from these trials must be combined into a consistent basis for benefit-risk analysis. Third, quantitative decision models are required to directly link decisions to the underlying evidence and to make trade-off decisions explicit. This thesis addresses these topics through the development of the Aggregate Data Drug Information System (ADDIS), an integrated system for decision support based on databases of structured clinical trials data. Novel algorithms are presented to automate network meta-analysis to combine clinical trials results and multi-criteria decision models are developed to support benefit-risk assessment. ADDIS is open source software, available from /.

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