Decision Analysis in Drug Regulation

project escher

Risk perception, information systems and decision support for benefit-risk assessment

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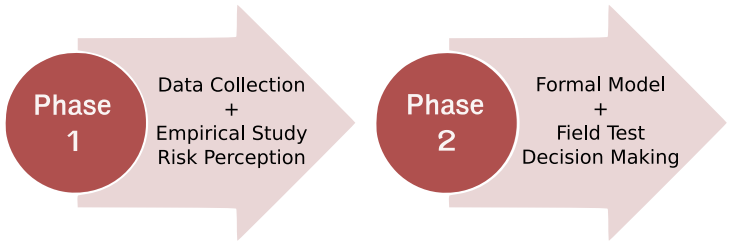
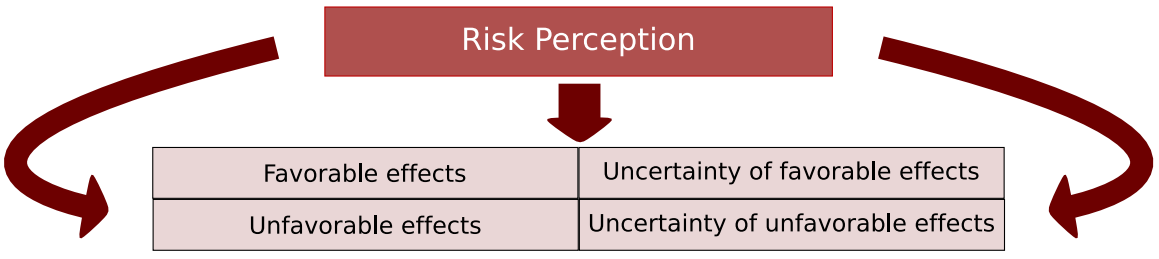
Risk Perception and Clinical Benefit Risk Assessment

Cognitive Influences in Decision Making

This study aims to aid risk analysis and decision making by exploring attitudes towards risk and uncertainty among experts in the European pharmaceutical regulatory environment.

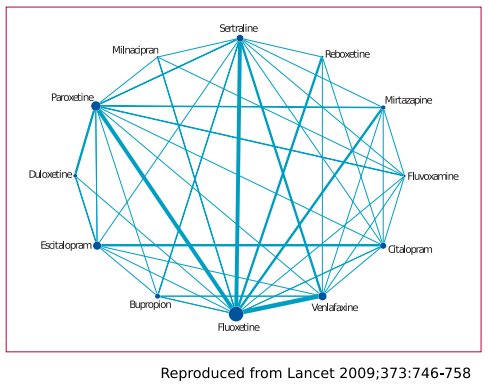




Aggregate Data Drug Information System (ADDIS)

Software for clinical trial analysis

Try it yourself!
drugis.org



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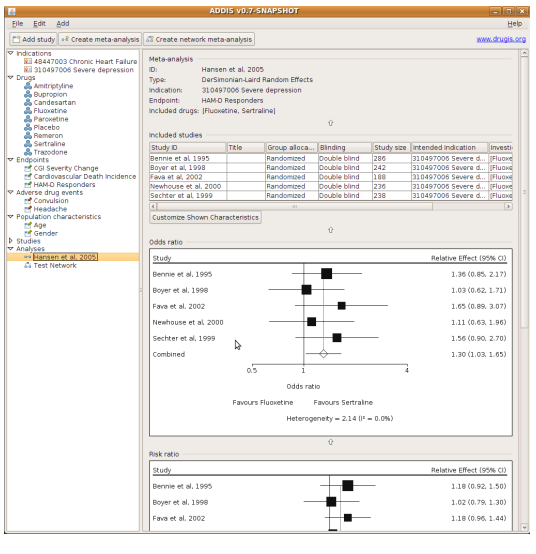
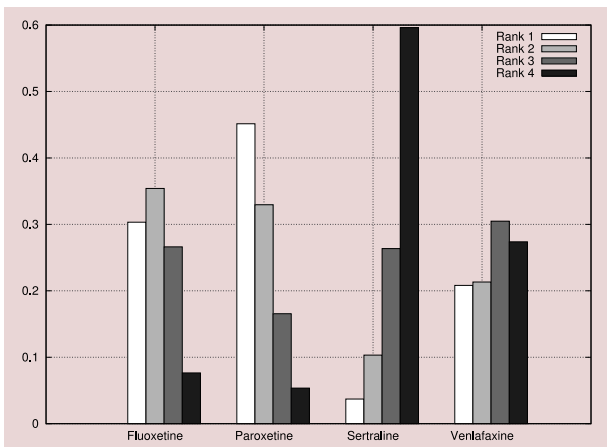


Constructing a meta-analysis includes manually collecting appropriate studies from abstract databases, and creating an ad-hoc data set for the purpose of the analysis. ADDIS implements both pair-wise and mixed-treatment meta-analyses (i.e., random effects and network meta-analyses). To help automate the labor-intensive data collection process, ADDIS allows to import study designs from ClinicalTrials.gov or to create them from scratch, to complete them with study results, and to construct (network) meta-analyses that include all relevant studies in the local database.

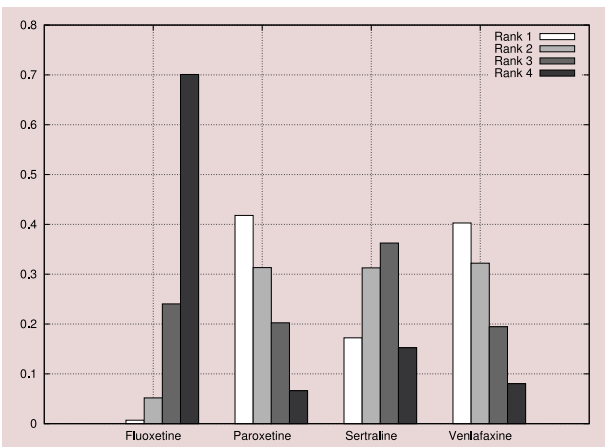
Multi-criteria Method for Drug Benefit-Risk Decision Support

Quantifying tradeoffs between drugs of the same therapeutic class

Pharmaceutical decision making is based on assessing benefits and risks of alternative drugs, ideally by considering all clinical evidence. In practice this is not achieved as the assessments are based on meta-analytical methods that allow only single criterion pair-wise comparisons. The recently proposed Mixed Treatment Comparison (MTC) models enable indirect comparisons within a set of alternative treatments. We will use MTC to construct stochastic multi-criteria models that allow to compare multiple treatments in terms of multiple criteria.



Suitability of anti-depressants for mild depression, results of multi-criteria model (Tervonen et al. 2010)



Suitability of anti-depressants for severe depression, results of multi-criteria model (Tervonen et al. 2010)

T. Tervonen, H.L. Hillege, E. Buskens and D. Postmus (2010). A state-of-the-art multi-criteria model for drug benefit-risk analysis. SOM Research School Report No. 10001. University of Groningen.

This study was performed in the context of the Escher project (T6-202), a project of the Dutch Top Institute Pharma