

Automated decision support for evidence-based benefit-risk decision making

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Drug regulators assess the benefit-risk balance of new treatments based on pivotal evidence provided by clinical trials. Despite a long-standing interest in formal decision modeling, benefit-risk assessment has remained a primarily informal process. Reliance on informal assessment hides the reasoning supporting the decision and causes the regulatory process to be insufficiently transparent and traceable. The trade-offs between benefits and risks are seldom made explicit, least quantified. Two factors underly this lack of formal assessment: (1) basing a decision model on evidence from clinical trials requires sophisticated statistical modeling for which no supporting tools exist and (2) attaching weights to the criteria under consideration in benefit-risk assessment is a potential source of controversy.

We present ADDIS (Aggregate Data Drug Information System), a decision support system for evidence based regulatory decision making. ADDIS incorporates statistical methods and decision modeling in an automated framework, so that benefit-risk decision models can be easily constructed. This enables the formal, explicit and transparent assessment of benefits and risks, while taking uncertainty into account. Moreover, the implemented decision modeling techniques can be applied even with imprecise or (wholly or partially) missing preference information. In many cases, this enables a decision to be made without the need to give exact weights to the criteria. Preference elicitation can thus be less time consuming, group consensus regarding preferences is more easily reached, and potentially controversial trade-off judgments can be avoided if they are not pivotal to the decision.