Einladung zum Biometrischen Kolloquium

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'E-SYNTHESIS: A SYSTEM FOR EVIDENCE AMALGAMATION IN PHARMACOVIGILANCE'

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ABSTRACT:

Adverse drug reactions pose a significant problem to drug manufacturers, are a serious risk to patients, and constitute a major ethical problem in licensing decisions of pharmaceutical products. Current standards for drug evaluation are mainly based on a methodology developed for the assessment of benefits, which focuses on internal validity and on the exclusion of biases.

However, evidence for harm often emerges unsystematically and unpredictably in form of anecdotal reports, case series and survey data. Hence the received methodology faces overwhelming challenges in integrating such diverse evidence.

The ERC project PhilPharm "Philosophy of Pharmacology: Safety, Statistical Standards, and Evidence Amalgamation" GA (639276) develops a theoretical framework for the justification of probabilistic confirmation of causal hypothesis on the basis of all the available evidence on safety. This consists of a Bayesian epistemic network incorporating Bradford Hill guidelines, as indicators of causality, and other indicators of evidence quality. The system is grounded on philosophical theories of causality and is neutral with respect to standards statistical schools ("frequentist", "neymanite", Bayesians of various sorts).

We present here a case study which illustrates how such system may be implemented, and explore the potentials for implementing such theoretical framework into a dedicated software.

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