Title: Methods for Systematic Benefit-Risk Analysis in Drug-Development

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Proposal

An effective benefit-risk assessment (BRA) is critical for sponsors, regulatory and payers, from early phase development of medical products to HTA/payer’s decision making. BRA is a systematic and holistic process that requires both qualitative and quantitative assessment. The ICH M4E (R1), US FDA and EMA regulatory have already delineated the necessity of structured BRA and outlined some recommendations on methodologies of BRA. However, the appropriate quantitative methodologies and their real applications are sparse, and there are no general agreement on what analytical methods should be used. The difficulties to develop a comprehensive and theoretically sound quantitative method can reside in several dimensions, for example, the choices of proper metrics for benefit risk assessment, the choices of weighting(synthesizing) scheme when dealing with multiple criterions and the method to evaluate the uncertainties in BRA. In recent years, researchers have been proposing some quantitative methods such as Multi-Criteria Decision Analysis (MCDA)/ Stochastic Multi-attribute Acceptability Analysis (SMAA) which could be applied to some extent. In this special issue, we expect to see more innovative methodologies for BRA.