Uncertainty in Benefit-Risk Assessment

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On behalf of the EFSP/PSI Benefit-Risk Special Interest Group
Problem Statement

To enhance transparency and clarity, a structured and evidence-based approach to benefit-risk assessment that characterizes uncertainties is desirable.
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Advancing Structured Benefit-Risk Assessment in FDA Review
The Duke-Margolis Center for Health Policy, October 2017
Question

Could **Bayesian approaches** support discussions and decisions around **benefit-risk assessments** in the presence of **uncertainty**?
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Move from Frameworks to Decisions

Representativeness: RCTS vs post-marketing

Communicate value of generated evidence to various stakeholders

Bayesian toolbox: decision theory, predictive distributions, probability, ...