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Rebecca (Becky) Noel is the Global Benefit-Risk Leader at Eli Lilly and Company, where she and her team are responsible for providing benefit-risk assessment support across the Lilly portfolio. Since 2005, Becky has been extensively involved in developing and promoting systematic methods for benefit-risk assessment, both internally at Lilly and externally via the PhRMA Benefit-Risk Action Team (BRAT), the PhRMA Benefit-Risk Global Convergence issues team, the Center for Innovation in Regulatory Science (CIRS) Benefit-Risk Task Force, and the Innovative Medicines Initiative projects (PROTECT and PREFER) devoted to benefit-risk assessment and the development and use of patient preference information in benefit-risk decision making. Becky recently served as the PhRMA Deputy for the ICH Expert Working Group responsible for the update of benefit-risk guidance in the Clinical Overview as well as a lead and discussant on multiple panels, workshops, and professional societies including IOM, DIA, ISPOR, and ISPE. Along with other Lilly colleagues, Becky also recently edited and contributed to the book, *Benefit-Risk Assessment in Pharmaceutical Research and Development.*

Becky graduated from the University of Kentucky School of Public Health with a Master’s of Science in Public Health (MSPH) and from the University of Alabama at Birmingham School of Public Health, with a Doctorate of Public Health (DrPH), where she had a dual focus on international health and epidemiology. She joined Eli Lilly and Company in 2002.

**Abstract: 2017 Il-6: Quantitative benefit-risk assessment of DILI**

Assessing the benefit–risk profile of treatment options is a prominent challenge facing all sectors of health care, from industry and regulators to prescribers to patients seeking to make more informed treatment decisions. Much progress has been made by both industry and regulators toward a more structured approach to assessing and communicating the benefits and risks of medicines, with a similar focus on considerations of benefit-risk tradeoffs,
measurement of tradeoffs, and the strength of evidence required to make decisions. In the
U.S., this progress has been realized through the reauthorization of the Prescription Drug User
Fee Act (PDUFA V), which called for FDA to develop and implement a structured approach to
benefit-risk during review, updated guidance on the development and presentation of benefit-
risk information in the Clinical Overview for new drug submissions, and via Periodic Benefit-Risk
Evaluation Reports submitted on a routine basis for marketed products. In addition, the FDA
recently published a premarket benefit–risk guidance for medical devices. From an industry
perspective, for marketing authorization applications and other activities such as advisory
committee hearings, it is believed that there is value for all stakeholders in being able to better
articulate the benefit-risk profile of a product and to having a more systematic discussion of
relevant benefits, risks, and their associated uncertainties. However, while these advances
have laid out principles which should guide a benefit-risk assessment, none specify
methodologies or even tools for conducting a benefit-risk assessment. This presentation will
focus on some of the more promising tools to structuring and presenting benefit-risk
assessments.