Medical Device Innovation Consortium Patient Centered Benefit-Risk
Request for Proposals

Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk (PCBR) project team is seeking proposals for a contract to complete a systematic review of the literature regarding communicating risks and benefits of medical interventions to patients and to physicians as part of a project on best practices in risk-benefit communication in regulated medical devices.

Background

As part of the development of best practices on benefit-risk communication, we are seeking a structured and systematic literature review of the existing literature and practices regarding how to most effectively communicate benefits and risks of medical procedures to patients and physicians. This review and analysis of the existing literature will inform the development of a report on best practices for benefit-risk communication regarding regulated medical devices, including consideration of communication practices in product labeling and informed consent. Specifically, we are interested in the literature on applied uses of benefit-risk communication, such as research on shared decision-making, decision aids, consent practices and other applied uses of benefit-risk communication.

This report on best practices in communicate benefits and risks of regulated medical devices to patients and physicians will be drafted by a project work group overseen by the MDIC PCBR Steering Committee based on the literature review. The Steering Committee may request consultation and input from the literature review authors as a part of the development of this best practices report.

Additional Details and Requirements

Proposals should include a research plan for the conduct of the literature review, biosketches of key research personnel and subject matter experts, and a detailed cost estimate. The research plan should include plans for how this work would build on other work previously done in this area, specifically the 2011 FDA publication "Communicating Risks and Benefits: An Evidence-Based User's Guide" and 2014 IOM workshop summary "Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks of Pharmaceutical Products."

Because of the required timeline of the best practices report, we will require completion of an initial draft of the literature review to be completed four months after the initiation of the project and completion of the final draft by seven months after project initiation. Initiation of the project is contingent on MDIC receiving project funding by a government contract currently pending.

Please send proposals to MDIC PCBR Program Manager Stephanie Christopher, schristopher@mdic.org, 952-314-2730. Deadline for proposals is Friday, June 12, 5 p.m.