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WORKSHOP PROPOSAL EXAMPLE

Title (in title case)	**Patient-Centered Benefit-Risk Analysis: Regulatory Developments And Prospects**
Discussion Leaders (minimum of 2 and maximum of 4 leaders from at least 2 organizations; please include name(s), degree(s), institution(s), city, state, & country)	**Discussion Leaders: F. Reed Johnson, PhD, Senior Research Scholar, Duke Clinical Research Institute, Duke University, Durham, NC, USA; John F.P. Bridges, PhD, Associate Professor, Department of Health Policy and Management and International Health, John Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; Lou Garrison, PhD, Professor, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington, Seattle, WA, USA; Bennett Levitan, MD, PhD, Senior Director, Benefit-risk Assessment, Epidemiology, Janssen Research & Development, LLC, Titusville, NJ, USA**
Workshop purpose (objective of a workshop) **Purpose and Description can have a combined maximum 300 word count**	**PURPOSE: This workshop will focus on recent efforts to engage patients in regulatory decision making and to incorporate patient preferences into regulatory benefit-risk analysis. Workshop participants will become familiar with alternative methods for eliciting and summarizing qualitative and quantitative data on patients' benefit-risk tradeoff preferences and be able to critically evaluate how novel approaches to stakeholder involvement could influence the evolution of regulatory science.**
Workshop description (provide a clear description of the topic including background information & audience participation)	**DESCRIPTION: Participants will obtain an overview of recent developments at FDA related to patient engagement and use of qualitative and quantitative preference data. The workshop will review a) how benefit-risk preferences are considered by other Federal agencies, b) how regulators have responded to mandates to become more patient-centered, c) how industry uses patient risk-preference data in drug development and regulatory submissions, and d) what role patient advocacy has in regulatory reviews. Drs. Johnson, Bridges, and Levitan will describe recent efforts by FDA's Centers for Drugs and Devices to elicit patient-preference data, including advisory-committee testimony, therapeutic-area public meetings, public-comment dockets on FDA patient engagement, and draft guidance currently in development on including patient-preference data in regulatory submissions. Dr. Garrison will assess the practicality and usefulness of preference data for drug development. Audience participation will include a survey of attendees' perspectives on patient-centered benefit-risk analysis and participants will be encouraged to share their experience and perspectives during the workshop. This interactive and informative workshop will be valuable to researchers, clinicians, and industry analysts who are interested in understanding recent developments in patient-centered regulatory benefit-risk assessment.**