WORKSHOP PROPOSAL EXAMPLE

Title (capital letters)	**STATED PREFERENCES IN DRUG EVALUATION: A COMPARATIVE ASSESSMENT OF THE USE OF STATED PREFERENCE IN THE US, CANADA, AND THE EUROPEAN UNION**
Discussion Leaders (minimum of 2 and maximum of 4 leaders from at least 2 organizations; only 2 discussion leaders per organization is permitted; please include name(s), degree(s), institution(s), city, state, & country)	**Axel C. Mühlbacher, PhD, MBA**, Professor, Health Economics and Health Care Management, Institute Health Economics and Health Care Management, IGM, Hochschule Neubrandenburg, Neubrandenburg, Germany; **Kevin Marsh, PhD**, Executive Director, Evidera Ltd, London, UK; **F. Reed Johnson, PhD**, Professor, Duke School of Medicine, Preference Evaluation Research Group, Duke Clinical Research Institute, Durham, NC, USA; **Deborah Marshall, PhD**, Professor, O'Brien Institute for Public Health, University of Calgary, Calgary, AB, Canada
Workshop purpose (Provide a clear definition of the workshop's objective. (Ensure that the purpose(s) is achievable in 60 minutes.)	To compare decision makers' use of stated preference research in the medical technology approval and reimbursement in the US, EU and Canadian regulatory environment drawing good practice lessons from the best elements of each.
Workshop description (Provide background information and details on the material to be presented, including which stakeholders will benefit from attending. It is useful to include speaker presentation length, e.g., 10 minutes, especially if there is concern that objective cannot be met in 60 minutes.)	Decision makers responsible for approving, reimbursing, and pricing drugs, are piloting and using stated preference methods, as well as encouraging manufacturers to generate patient preference data for their submissions. Prominent examples include: the FDA's Center for Devices and Radiological Health using patient preference data to inform approval decisions, IQWiG's requirement that economic evaluations be informed by patient preference data, and IMI PREFER's consideration of how and when it is best to include patient preferences in decision making. The diversity of decision makers' requirements means that the effective generation of preference evidence requires a good understanding of: 1) how these data might be used; 2) the stakeholders from whom preferences should be elicited (e.g., citizens versus patients); 3) the elicitation method that should be used; and 4) when this data should be generated– when in the drug evaluation process and at what stage of disease should preferences be elicited. An overview of the respective regulatory processes will be presented with case examples for illustration. Discussion on the use of stated preference research in the US will include: FDA use of patient-preference information in approvals for the Maestro weight-loss

	device and Exondys 51 for treating Duchenne muscular dystrophy. EU-based examples will include EMA's and IQWiG's pilot programs. Examples from Canada will include Health Canada and CADTH's use of patient preference data.
Audience interactive element (Clearly explain the workshop's audience participation element. This is an important criterion to fulfill)	Each speaker will present a schematic of how patient preference data are included in their respective regulatory process. The audience will participate in the evaluation exercise drawing on the pros and cons of each arrangement to develop an 'ideal' process for using this data in healthcare decision making.