The Food and Drug Administration's (FDA's)
2015 ORSI Science Symposium
April 27, 2015
SPEAKER ABSTRACTS AND BIOGRAPHIES

Session 1: Centers for Excellence in Regulatory Science and Innovation (CERSIs) Presentations – 8:35-11:30 AM

Johns Hopkins University CERSI

CERSI	**Johns Hopkins University**
Speaker	**John Bridges, PhD**
Title and Location	**Associate Professor of Health Policy and Management, Health, Behavior and Society, International Health, Johns Hopkins Bloomberg School of Public Health; Baltimore, MD**
Biography	**John F P Bridges PhD is an international leader in the application of stated-preference methods. He is the founding editor of The Patient – Patient Centered Outcomes Research and has worked with numerous patient groups, health technology assessment agencies, regulators and international aid agencies to advance and apply these methods to document the preferences of patients and other stakeholders. Within the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) he founded the Conjoint Analysis Working Group (2006-2011), the Conjoint Analysis Task Force (2008-2010) and was the first author on the ISPOR checklist conjoint analysis. In 2006 he received ISPOR's Bernie O'Brien New Investigator Award and in 2011 received an ISPOR Distinguished Service Award for his leadership of conjoint analysis methods. He is the author of over 100 publications and a frequent speaker on patient engagement, patient preferences and benefit-risk analysis. John is an associate professor in the Department of Health Policy & Management, where he serves as the Director of the Masters of Health Science (MHS) in Health Economics, and has joint appointments in the Department of International Health and Department of Health Behavior and Society. He is core faculty within the Center for Health Services and Outcomes Research (CHSOR), the Center for Drug Safety & Effectiveness (CDSE), and the Center for Excellence in Regulatory Science and Innovation (CERSI). He is also a Faculty Research Fellow at the National Bureau of Economic Research (NBER) and a Senior Fellow at the Center for Medicine in the Public Interest (CMPI).**
Presentation Title	**Partnership to advance stated-preferences methods in regulatory science**
Presentation Abstract	**This project builds off a PCORI funded project at Johns Hopkins that advances and applies stated-preferences among people with type 2 diabetes. As a PCORI methods project, we aimed to address several research gaps pertaining to patient and community engagement and to the application of stated-preference methods to measure the priorities and preferences of patients and other stakeholders. This work parallels FDA efforts to identify and apply approaches and methods to better engage patients and caregivers in the regulatory process and to identity methods to inform regulatory benefit-risk decisions. This CERSI project aims will offer an important mechanism for communication and collaboration between the FDA and Johns Hopkins collaborators to share, review, and implement knowledge about stated-preference methods.** **This collaboration presents a significant opportunity to build synergies between existing FDA and Johns Hopkins projects. It builds off a sizable methods project funded by PCORI that will fund the development, implementation and dissemination of two important experiments. The first experiment compares traditional rating/ranking approaches to measuring priorities of people with type 2 diabetes (focused on barriers and facilitators to self-management) with innovative best-worst scaling methods. The second experiment compares traditional conjoint analysis/discrete-choice experiments approaches to innovative best-worst scaling methods to measure the treatment preferences of people with type 2 diabetes. These two experiments-of-experiments will provide important information about the comparability of various stated-**

	preference methods and will provide a vehicle for disseminating these methods. **In addition to simple comparisons of these two methods, this PCORI study also aims to compare two approaches for studying preference heterogeneity. The first approach is traditional stratification, where the preferences of different groups (including groups defined on clinical and demographic characteristics) are compared and tested. To facilitate this stratification, we plan to oversample base on race and ethnicity. The second approach, segmentation, uses techniques such as latent class analysis to identify groups with similar preferences. Differences in clinical and demographic characteristics of these groups can then be compared using traditional epidemiological methods. The study of preference heterogeneity is relevant to the FDA as a means to study difference in risk tolerance in difference subgroups of patients.**