Abstract:
In clinical research, once a focused question is formulated we carefully choose a study design that minimizes the risk of bias within the available resources. Consequently when deciding which questionnaire to use for patient-related outcomes, we often seek those that are common, reasonably easy-to-administer and most importantly those that have been "validated". But what does this mean? In this talk, I will discuss the perspectives of the US Food and Drug Agency (FDA) and the European Medicines Agency (EMEA) on what constitutes sufficient evidence when using a PRO measure to support a labeling claim. In the discussion, some practical considerations for instrument selection will also be provided.

Biography:
Dr Bautista is a statistician based at the Center for Quantitative Medicine, Office of Clinical Sciences of the Duke-NUS Graduate Medical School. She has an interest in Latent Variable Modeling in general and currently works on its applications in health measurement.

Her other appointments are with the Singapore Clinical Research Institute where she is a trial statistician and the Singapore Branch of the Australasian Cochrane Center which provides training and support in the conduct of systematic reviews of health care interventions. Dianne also serves as a quantitative resource person at the AMRI at KKH and SGH campuses and is a member of the Clinical and Behavioral Assessment Core in the latter.

Speaker:
Dr. Dianne Bautista
Assistant Professor
Centre for Quantitative Medicine
Office of Clinical Sciences
Duke-NUS Graduate Medical School
Biostatistician
Singapore Clinical Research Institute

Host:
Dr. Benjamin Haaland
Assistant Professor
Centre for Quantitative Medicine
Office of Clinical Sciences
Duke-NUS Graduate Medical School

Date:
Thursday, 22 November 2012

Time:
12.30pm – 1.30pm

Venue:
Duke-NUS Graduate Medical School
Singapore
Amphitheatre, Level 2
8, College Road, Singapore 169857

All are welcome to attend. No RSVP is required. Lunch will be served from 12.00pm onwards, outside the amphitheatre.