Project Name: Education Subteam	**Date Initiated: July 2011**

Team Members:
Beat Neuenschwander, David Ohlssen, Fanni Natanegara, Frederic Bois, Jeff Wetherington, John Seaman, Karen Price, Nelson Kinnersley, George Rochester

Co-Chairs: Fanni Natanegara, Beat Neuenschwander

Approximate frequency of meetings: monthly

Problem Statement

Despite substantial improvements in Bayesian methodology and an increasing number of Bayesian applications in many fields, there are education and practice gaps related to the use of Bayesian approaches in the drug regulatory process. These gaps hamper Bayesian activities of statisticians and non-statisticians working in different roles (industry, health-authorities, and academia). Feedback during the April 2011 FDA/DIA Statistics Forum suggested that although there have been a number of efforts to increase education and awareness of Bayesian methods, there are still many hurdles to overcome when trying to implement Bayesian approaches in clinical trials.

What are barriers which prevent statisticians and non-statisticians in drug development to use Bayesian methods in their daily work? Why are the different parties in drug development hesitant to adopt Bayesian methods on a more routine basis? How can education, communication, and implementation of Bayesian methods be incorporated in good statistical practices in the regulation of pharmaceuticals?

A coordinated effort is needed to target the education and implementation issues related to Bayesian activities in drug development. In order to facilitate and increase Bayesian implementations, educational gaps for statisticians and non-statisticians need to be identified and addressed.

Goal Statement

The goal of the education workstream is to coordinate and provide Bayesian educational support which will help the different parties to implement Bayesian approaches in drug development on a more regular basis as appropriate. We intend to provide education at a variety of levels, i.e., to meet the needs of statisticians and non-statisticians working in different organizations (industrial, regulatory, etc). The main goals are to
- Identify the main groups of people that are in need of Bayesian education,
- Identify the group specific needs,
- Describe available and potentially missing group-specific educational material, and
- Identify channels for knowledge transfer and make information available.

Potential Impact

Having direct access to targeted education materials will eventually have beneficial impact at various levels:
- enhance understanding of Bayesian methods by statisticians
- better the parties' ability to communicate the Bayesian approach to non-statisticians
- promote wider acceptance of Bayesian methods by the regulatory bodies and stakeholders.

Project Scope

Areas for sub-team to consider
- Survey (for statisticians and non-statisticians) to be sent out within various organizations to find out about gaps, difficulties and specific educational needs.
- Identification and availability of educational material and media (training courses, papers, books etc)
- White Paper(s) that will cover different aspects of education and implementation issues:
    - update on the current state of Bayesian approach in the health care industry, based on the survey and (e.g.) Winkler 2001.
    - provide links to relevant material addressing specific needs of various parties

- After results from the survey are available, depending on the specific needs
    - develop training materials , e.g.,
        - Identify ways Bayesian approaches complement and further enhance traditional approaches
        - Physician education: need to ensure physicians know how to INTERPRET Bayesian analyses and understand foundations of Bayesian approach (eg help define priors)
        - Statistician education: need to ensure statisticians know how to IMPLEMENT (and interpret) Bayesian analyses.
    - extension of the team will be considered after the scope and gaps have been determined.
- Potential venues to roll out the materials:
    - Mandatory: DIA website
    - Optional: others possibilities are EU2P, Medical CE, Wikiversity, iTunes U, Wolfram, etc

Project Plan/Key Deliverables/Timeline

- Q1-2012: Survey
- Q1-2012: White paper, table of contents
- Q1-Q3-2012: identification of relevant education materials
- Q3-2012: white paper (draft)
- Q4-2012: white paper (final) also submit as a manuscript in 2013
- 2012 and later: Presentations/sessions on future statistical/Bayesian/clinical trial meetings
- 2012: F2F meeting

Key References
- Spiegelhalter, Abrams, Myles (2003), *Bayesian Approaches to Clinical Trials and Health-Care Evaluation*
- Berry, Carlin, Lee, Mueller (2010), *Bayesian Adaptive Methods in Clinical Trials*
- Special issue *Clinical Trials* (2006) of the FDA/John Hopkins Bayesian Workshop 2004.
- CDRH guidance document
- Berry, CDRH white paper
- Special issue of *American Statistician*; Volume 62, Number 3, August 2008 Special Section: Teaching Bayes to nonstatistics graduate students.
- Winkler, RL (2001) "Why Bayesian analysis hasn't caught on in healthcare decision making". *International Journal of Technology Assessment in Health Care,* 17:1 (2001)