

DIA 2013 49th Annual Meeting "Advancing Therapeutic Innovation and Regulatory Science" June 23 – 27, 2013 Boston Convention and Exhibition Center Boston, MA

Session 119 - Hot Topics in Statistics: Working Together Effectively to Transform Our Science

On February 24, 2010, the FDA introduced the Advancing Regulatory Science Initiative, a plan that aims to apply the best science to its regulatory processes to keep pace with scientific advances. The essential role of statistics in this initiative was the basis for *Hot Topics in Statistics: Working Together Effectively to Transform Our Science* (Session 119). This session was moderated by Stephen Wilson, DrPH, (FDA), who stressed the importance of understanding how each discipline can add to decisions made at the FDA.

Robert O'Neill, PhD, (FDA), explained that there remains an absence of formal university training in regulatory science and suggested topics of curriculum to remedy this unmet need. "There is a strong need for the regulatory environment to become responsive to innovation", he implored "and advancing public health and translational science depends on this basic idea."

Marcia Testa, MPH (Harvard), provided an overview of competency-based curriculum pulling from her experiences as an educator. She described academic education models used for workforce training. Ms. Testa then proposed a model that can be employed for the development of a competency-based curriculum in regulatory sciences. "By defining the core competencies", Ms. Desta noted, 'we can design a unified national framework on what is important to teach in regulatory science".

Finally, Ralph D'Agostino, SR, PhD, MA (Boston University) reviewed and reflected on his experiences as a statistician on advisory committees to highlight the importance of statisticians in advancing regulatory science processes. He urged statisticians to be both aggressive and seek a major role on committees to bring an important level of rigor to these panels.

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