DIA Annual Meeting session titled – A Public-Private Partnership

June 24, 2009

A session was held at the 45th DIA Annual Meeting titled Patient-Reported Outcomes Consortium: A Public-Private Partnership. The session was chaired by Bob Assenzo, PhD, Executive Director of Education at the Critical Path Institute. As outlined in the abstract below, the overall objective of the session was to describe the impetus for the creation of the Patient-Reported Outcomes Consortium and its current status. Copies of the slides shown during the three presentations in the 90-minute DIA session are available through the links below the abstract.

Abstract

Patient-reported outcomes instruments provide information concerning the patient’s perspective of an intervention or therapy on one or more aspects of the patient’s health status. PRO instrument development is expensive and time consuming because of the extensive qualitative research and validation testing process. It is unlikely that any one entity will possess all the necessary expertise and resources to accomplish the work needed to design, evaluate, and qualify an accurate PRO instrument in an expeditious manner. Further, FDA’s advisory role in instrument development is resource intensive and must be duplicated across multiple sponsors who may be developing treatments in the same disease area. To facilitate the development of PRO instruments for use in clinical trials designed to evaluate the safety and effectiveness of medical products, the Food and Drug Administration and the Critical Path Institute developed an overarching framework for collaboration with pharmaceutical, biotechnology, device and diagnostic companies, academia, vendors, and other governmental agencies to leverage resources and expertise toward mutually beneficial goals and in the interest of public health. This session will describe the main objectives of the PRO Consortium and its research program, consortium membership, consortium management, roles and responsibilities of the consortium members, selection of PRO instruments for development, and current status of the consortium.