



## **Dr. George Rochester**

(awarded in Boston, 2008)

Within the Office of Translational Sciences in CDER at FDA, George leads a multidisciplinary group, which provides quantitative support for drug safety evaluation throughout the drug life-cycle. George and a few of his colleagues (Dr. Chuck Cooper, Dr. Jake Kelsey, Dr. Jeff Summers, Dr. Chris Holland, and others) formed the MedDRA Coordination Working Group within CDER with the goal of improving the FDA drug review process.

George and his colleagues from the MedDRA Coordination Working

Group began with a series of initiatives to improve the knowledge and skills in using MedDRA terminology among clinical, statistical, and safety reviewers. These initiatives included a weekly seminar on MedDRA related discussions and making the MSSO desktop browser and MedDRA terminology (from Version 2.1 to the most recent version) available to everyone who needs these tools. Most importantly, George was instrumental in the establishment of the formal FDA MedDRA training program to clinical and statistical reviewers in CDER and CBER. George worked with the MSSO and arranged for routine training to be conducted by the MSSO staff. These training courses provide not only the basic knowledge of MedDRA structure and how to code patient information using MedDRA, but also in-depth knowledge on how to analyze MedDRA-coded data and how to apply SMQs.

In conjunction with the training, George's group is developing an SAS tool to allow reviewers to use SMQs to analyze their data. Currently, his group is working on a more robust online tool to enable reviewers to perform further case analyses after the cases are retrieved by either SMQs or ad-hoc queries.