Notes from the Field: Implementation of CDISC Standards at AstraZeneca

“There is an increasing demand for standardized clinical information, as well as an increasing need to scale our CDISC standards capabilities,” noted Alex Hromcenco and Sam Hume of AstraZeneca (AZ) at the beginning of their presentation at the 2011 CDISC International Interchange in Baltimore, Maryland. Mr. Hromcenco and Mr. Hume went on to discuss these issues as well as how AZ had successfully implemented CDISC standards and become a major contributor to CDISC.

Before the implementation of CDISC standards, AZ started by standardizing the way data was collected in house. This activity began on a per project basis and eventually developed into corporate standards. These corporate standards were created using best practices from both Astra and Zeneca, two separate companies until their merger in 1999. Yet this very project-focused approach did not support end-to-end standards outside of a project; there were significant variations in standards between projects and not enough supporting technology. Compliance and support were weak due to these factors.

People at AZ began to notice and become increasingly interested in CDISC and created an AZ CDISC Network to foster grass roots support and provide a forum for information sharing on CDISC topics. AZ became a member and sponsor of CDISC, participating in several CDISC teams. Ultimately, AstraZeneca created the Clinical Information Standards Governance Organization (CISGO) to centralize support for global standards development and governance. The Clinical Information Standards Strategy developed by CISGO identified alignment with the CDISC standards as a key component. This Strategy sought to improve information exploitation by aligning existing standards and clinical information systems with standards like the CDISC Study Data Tabulation Model (SDTM).

In 2011, AZ began to move forward on a roadmap, developed by the AZ CDISC Network, which would lead toward standards-based drug development. CISGO has developed an end-to-end standards model, and future plans include increased use of Protocol, CDASH, ADaM, SEND and ODM.

Mr. Hromcenco and Mr. Hume stressed the influences supporting adoption of CDISC standards, stating that 1) the steady rate of progress in CDISC standards development, 2) FDA support/submission guidance, 3) peer organization participation, 4) increasing externalization, 5) CDISC communication and 6) increasing demand for information exploitation all were favorable factors toward implementing CDISC standards.