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HL7, CDISC, and the FDA—Moving on Down the Path to Data Standards

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ABSTRACT

Globalization, law (The Food and Drug Administration Amendments Act of 2007: FDAAA and PDUFA IV) and Agency initiatives (e.g., The Critical Path) are shaping new directions for product development, science, and regulatory processes. The Agency is pushing forward simultaneously to assure quality, expedite drug development, and to enhance the submission and review of applications for new drugs, biologics, and devices. Motivated by many pressures to change and improve, we are working to develop new standards for collection, submission, and review tools. SDTM, SEND and ADaM, and Janus are real. Health Level 7 (HL7) and the Clinical Data Interchange Standards Consortium (CDISC) are important partners in this effort.

What is the vision? How are we going to get there? What is the “roadmap”? You are part of this. We need to be on the same “path.” It’s important for all of us to talk, to listen and to learn.

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