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Keynote Presentation: Standards for Clinical Research from Protocol Through Submission: CDISC Business Case and Progress Report

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ABSTRACT

Working with Gartner and with support from The Pharmaceutical Research and Manufacturers of America (PhRMA,) CDISC recently completed a business case for clinical research standards. The results stress the value and importance of implementing these in the start-up stage of a clinical study, in terms of cost and time savings, and also point to additional value of standards in clinical research in terms of data quality, team communication, real-time integration and a strategic link to healthcare information.

This session provides specific information on this business case and describes 2007 initiatives toward realization of the CDISC mission to develop and support platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. These initiatives include the Clinical Data Acquisition Harmonization Standards (CDASH) project (an FDA Critical Path Opportunity), a demonstration of the use of electronic health records in clinical research, the Protocol Representation standard, and a World Health Organization (WHO) clinical trial registration and reporting project.

No paper was submitted for publication.

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