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CDISC and PSI Announce Partnership to Improve Patient Safety

Austin and Plano, TX – 28 September 2005 – The Clinical Data Interchange Standards Consortium (CDISC) and the Patient Safety Institute (PSI) announce a new partnership to improve patient safety related to investigational and approved biopharmaceutical products. With international concern growing around improving safety monitoring and reporting for new medical treatments, this CDISC-PSI partnership represents an important new initiative.

An initial PSI - CDISC project will focus on facilitating post-marketing safety reporting and streamlining investigator participation in an IND-regulated Phase IV project to monitor biopharmaceutical product safety. CDISC and PSI are now evaluating and selecting the trial/sponsor(s) to participate in this project. The proposed joint project will address a missing link that exists between post-marketing and pre-approval safety monitoring.

David Hardison, PhD, VP, Life Sciences, SAIC and Chair-elect of the CDISC Board was responsible for conceiving the partnership. "I have been involved in both organizations for years, but now more than ever, the synergy is obvious. PSI has an elegant means of aggregating disparate safety data, and CDISC can provide the standards that are needed to increase the value and meaning of these data."

Jack Lewin, MD, Executive VP/CEO, California Medical Association and PSI Board Chair said, "In the current challenging environment, FDA and the biopharmaceutical industry can both benefit from the work of the PSI with CDISC to ensure patients receive quality care from providers who have ready and permitted access to the patient's safety data, from all sources."

About PSI

Patient Safety Institute (PSI) is a national, non-profit, patient-centric 501(c)(3) open membership organization that is dedicated to supporting communities across the nation in their development of clinical information sharing networks.

PSI is governed by leading consumer, physician and hospital advocates. It was formed to provide the healthcare community with a commonly owned, inclusive, multi-stakeholder network utility to improve patient safety, quality of care and lower costs.

PSI is not a vendor and does not promote a proprietary technology or product. PSI offers national connectivity of clinical information through a representative, collaborative organization, like VISA®, that allows communities and organizations to achieve success together, that they could never achieve individually.

For more information on PSI, please visit www.ptsafety.org.

About CDISC

CDISC is an open, multidisciplinary, non-profit organization committed to *develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare*. CDISC standards are vendor-neutral, platform-independent and freely available.

CDISC is made possible through the generous support of its members, sponsors, and volunteer participants. These include academia, biopharmaceutical companies, technology and service providers, HL7, NCI, institutional review boards and anyone interested in streamlining biopharmaceutical product development and clinical data quality.

Additional information on CDISC can be found on the CDISC website at www.cdisc.org.

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