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FOR IMMEDIATE RELEASE

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CIS Implements Tools to Benchmark and Develop KPIs for Good Clinical Practice Adherence

PHILADELPHIA, PENNSYLVANIA, March 22, 2010 – Compliance Implementation Services (CIS), a pharmaceutical compliance consulting firm, is pleased to announce that it is expanding its Clinical R&D Compliance services with additional tools for Good Clinical Practice (GCP) Benchmarking and Key Performance Indicator (KPI) development.

CIS applies metrics to GCP compliance areas, allowing clients to routinely monitor, evaluate, and remediate clinical compliance risks. CIS uses its proprietary *Inspection Readiness Profiles* and *GCP Regulatory Requirements Inventory* tools to internally benchmark the current state of a sponsor's GCP Quality Assurance and Quality Control systems and supporting controlled documents. This internal benchmarking identifies GCP compliance risks, provides a data-driven list of areas for improvement, facilitates rapid process enhancements, and enables application of root cause analysis and Corrective and Preventative Action (CAPA) planning for more complex compliance issues. Internal benchmarking is an early and essential step in establishing GCP Key Performance Indicators (KPIs), leading to a new measure of sponsor control and oversight of GCP compliance.

"CIS has been successful in assessing quality systems and developing KPIs for our pharmaceutical clients in their manufacturing processes, and we've found that a similar approach is transferable to our clinical clients," said Annette Horner, CIS Senior Director, Clinical R&D Consulting. "CIS' depth of experience consulting in the areas of Clinical R&D, Manufacturing, and Commercial allows us to take a product lifecycle view of compliance, leveraging our drug development knowledge, regulatory insight, and agency relationships. This lifecycle view is important as global agencies begin to collaborate and work towards a more universal compliance vision."

Annette Horner has more than 25 years of experience, including international accomplishments in the Pharmaceutical, Biotech, and Medical Device industries. She has directed several international consulting teams to design and implement clinical, regulatory, and pharmacovigilance quality improvement programs. For one Top 5 pharmaceutical company, she led the implementation of process and system reengineering changes impacting more than 2000 Clinical R&D end users in more than 25 countries. She has led more than 30 company-specific process design and SOP harmonization projects, designed a number of sponsor-specific GCP training programs, and led several metrics design teams to reduce clinical R&D cycle times.

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About CIS

Compliance Implementation Services (CIS) is a consulting firm specializing in compliance strategies for pharmaceutical companies, from Global Clinical Research & Development through U.S. Commercial Compliance and Government Programs. Founded in 2004, the firm's deep understanding of industry laws and regulations, innovative and practical applications, and custom solutions help its clients establish a "Culture of Compliance" that is both meaningful and practical.

CIS experts quickly identify exposure to compliance risks, help develop a strategic plan, and ensure its implementation and ongoing adherence to legal and regulatory requirements.

For more information, go to www.cis-partners.com

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