



PRESS RELEASE

DCS and Kestrel Consultants join to offer recorded webinars starting with DILI

Ann Arbor, Mich.— May 18, 2010 - Kestrel Consultants, helping to achieve goals for efficient, high-quality, cost-effective clinical trials by providing innovative approaches to clinical data standardization, teams with Distributed Compliance Solutions, LLC (DCS), the premier compliance hosting company of staff, technology and business process for business.

“Our partnership with Kestrel gives customers a chance to stay current on information they need while managing their day; work, home and free time as needed,” notes Distributed Compliance Solutions Managing Partner, John Nidelcheff. He goes on to say “Kestrel offers an important complement to our Clinical Hosted Solutions.”

Kestrel’s first presentation offered by DCS is “**Minimizing the Impact of FDA’s Drug Induced Liver Injury Guidance on All Preapproval Clinical Trials.**” In July 2009, the FDA’s CDER and CBER issued the "Drug Induced Liver Injury Premarketing Clinical Evaluation" guidance that potentially requires a large increase in data captured in all clinical trials on unapproved drugs. Drug Induced Liver Injury (DILI) is severe liver damage potentially induced by a drug and occurs in about 1 in 10,000 clinical trial subjects. It is unpredictable and all subjects must be monitored. Some of the required data are collected in most trials, but some are not, such as time of study medication. This webinar reviews the key parts of the guidance and the additional data required, and suggests data capture approaches to minimize the impact on sites and sponsors. It also helps to evaluate the risks of different approaches rather than assuming that all data are required for all subjects.

DCS will start offering registration on their web site for the first recorded session May 24, 2010. The full library will be available by mid July.

[About Distributed Compliance Solutions L.L.C.](#)

DCS is the premier compliance hosting company of staff, technology and business process for the small to medium size business. DCS is making it easier for business to focus on their goals, collaborate with their partners and bring products and services to market earlier.

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