Theorem Clinical Research Inc. Optimizes its Services for Regulatory and Clinical Issues

The Associated Press

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)--Oct 10, 2012--Theorem Clinical Research Inc. a full-service contract research organization (CRO) that provides core clinical research and development services, also helps clients identify and strategically address early and ongoing device-related regulatory and clinical issues.

Theorem develops clinical study protocol and design for pre-Investigational Device Exemption (pre-IDE) activities, IDE submissions, and Institutional Review Board (IRB) review and approval.

Theorem’s Vice President of Medical and Scientific Affairs, Medical Devices and Diagnostics, Evan L. Rosenfeld, M.D., J.D., F.C.L.M., said that the goals of these services are both to optimize medical clients' pathway to marketability and to ensure their high-quality adherence to all post-marketing requirements.

“The traditional CRO doesn’t offer a full spectrum of regulatory services,” Rosenfeld said. “At Theorem, we go above and beyond to help our clients focus on the regulatory processes in addition to tactical protocol development and then running their clinical trials.” Theorem offers a strategic clinical and regulatory approach to pave the best pathway for such efforts, from original trial design, to study start, through FDA and IRB review and approval, and ultimately to market entry.

With the FDA’s greater emphasis on post-marketing surveillance and trials, Theorem also provides additional trial setup for its clients and saves time in those respects, as well.

“We help our clients meet both the FDA’s requirements for post-marketing surveillance and also the evidentiary requirements that insurance companies may impose for product reimbursement,” Rosenfeld said.

Theorem’s process for pre-IDE services includes a thorough review of the relevant regulatory provisions and guidance documents, analysis of relevant research in the field, review of the past outcomes for similar devices and a determination of the studies that may be required for both regulatory market entry and subsequent insurance coverage.

About Theorem Clinical Research Theorem Clinical Research Inc. is a leading midsized provider of comprehensive clinical research and development services with offices in more than 30 countries and a customer base comprised of some of the world's leading pharmaceutical, biotech and medical device companies. A leader in the most complex medical device and drug-device combination trials in addition to a notable capability in pharmaceuticals and biologics, Theorem has deep

expertise in a broad range of therapeutic areas and in all phases of development. Some of the industry's top scientists and most advanced clinical analytics capabilities help ensure smooth-running, successful trials. For a full-service, right-size global research partner, don't think twice. THINK THEOREM.

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