# Theorem Clinical Research's 'Little Advisor' Site-Level Reference Booklet for Medical Device Trials Now Available in French and German

The Associated Press

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)--Feb 19, 2013--Medical device expert Theorem Clinical Research has re-released its "Little Advisor" booklet into French and German. The booklet is an easy-to-read, site-level reference booklet about the International Organization for Standardization (ISO) medical device trial requirements. It highlights the qualifications, regulatory/ethics committee (EC) requirements, informed consent process, clinical investigation plan (CIP) compliance, resources, training, device accountability, documentation and safety reporting for clinical research sites.

Theorem, a full-service contract research organization (CRO) that provides core clinical research and development services, has developed a long-standing reputation in device and combination trials that includes external, implantable and active-implantable devices, resulting from years of focused experience in managing complex studies for all classes of medical devices.

Theorem's booklet is authored by medical device experts Judith Köhnen, senior project director of medical device development, and Dr. Lee Spurgin, senior vice president and general manager of medical device and diagnostic development.

The "Little Advisor" booklet specifically highlights the ISO 14155:2011 requirements and is available for purchase online in French and German.

ISO is an international standard-setting body made up of members who are recognized authorities on standards.

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 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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