

Theorem Clinical Research Releases the ‘Little Advisor,’ a Site-Level Reference Booklet for ISO 14155:2011 for Medical Device Trials

The Associated Press

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)--Aug 28, 2012--Theorem Clinical Research released a site-level reference booklet that highlights the qualifications, regulatory/EC, informed consent process, CIP compliance, resources, training, device accountability, documentation and safety reporting for clinical research sites. Authored by Judith Köhnen and Dr. Lee Spurgin and illustrated by Michael Towse and Judith Köhnen, the booklet highlights the International Organization for Standardization (ISO) 14155:2011 requirements in an easy-to-read format.

The booklet is available for purchase online.

ISO is an international standard-setting body whose members are recognized authorities on standards. Most European Union member states, the United States and Japan are members of the voluntary organization. The ISO 14155:2011 — the equivalent of the ICH GCP for investigational medicinal products — is commonly called the modern GCP for investigational medical devices for human subjects.

Theorem Clinical Research’s reputation in device and combination trials, including external, implantable and active-implantable devices, comes from years of focused experience in managing complex studies for all classes of medical devices. In addition to experience in primary devices for orthopedic, oncologic and cardiovascular indications, Theorem is the go-to resource for implantable devices including drug-coated stents and device-based drug delivery mechanisms.

By bringing together teams of clinical, regulatory and study management experts, Theorem provides innovative development programs across the entire spectrum. The company has the development and regulatory expertise to execute successful trials across all risk classifications and approval pathways globally. Once a device is cleared for market entry, Theorem’s regulatory and health economics experts develop adjunctive reimbursement and safety surveillance programs and provide ongoing marketing support.

About Theorem Clinical Research Theorem Clinical Research 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 world 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

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Published on Medical Design Technology (<http://www.mdtmag.com>)

research partner, don't think twice. THINK THEOREM.

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SOURCE: Theorem Clinical Research Copyright Business Wire 2012 PUB: 08/28/2012
08:00 AM/DISC: 08/28/2012 08:00 AM
<http://www.businesswire.com/news/home/20120828005019/>

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