



Press release – 1th September 2006

Signature Diagnostics Introduces the MARVIN EDC-CDM System in its Multi-Centre Diagnostic Colorectal Cancer Trial for e-Capturing of Clinical Data

Signature Diagnostics has selected XClinical's EDC-CDM system MARVIN to support a 6-year multi-centre diagnostic trial in colorectal cancer (CRC). This trial is sponsored and organized by Signature Diagnostics and involves presently 10 different hospitals throughout Germany. The trial will be extended to include more than 30 hospitals. Within this trial Signature Diagnostics is collecting high-quality snap-frozen tumour tissues, FFPE tumour tissues and blood cells from more than 3.000 CRC patients. An essential part of the trial is the collection and management of the vast amount of clinical data of the CRC patients including surgical, histopathological and follow-up data.

Prof. Rosenthal, CEO of Signature Diagnostics, states: "MARVIN is an internet-based database tool that allows the electronic capture of clinical data in the most efficient and convenient way: via the internet from all clinical sites. MARVIN is greatly facilitating the management of the clinical data of such a large multi-centre clinical diagnostic trial. MARVIN was chosen after careful analysis of a number of competitive systems. It offered the highest flexibility and ease-of-use for the best price."

Philippe Verplancke, XClinical's CEO points out: "Two particular factors make MARVIN ideal for this cancer trial: long term follow-ups can be easily managed without the risk of loss-to-follow-up thanks to the central storage of the patient's real identification data while strictly separating the identifying and the medical data according to the German Federal Data Protection Act. And the CDISC-based metadata version management makes mid-study protocol amendments an easy and auditable task."

Signature Diagnostics AG (www.signature-diagnostics.de) is a molecular diagnostic company dedicated to the discovery, validation and commercial development of novel diagnostic products that predict outcome and drug response in patients with colorectal cancer. Signature believes that patient selection and stratification based on gene signatures will soon become an important component of routine cancer treatment. Signature improves the quality of decision making in cancer treatment and patient care.

XClinical GmbH (www.xclinical.com) is an EDC-CDM system vendor based in Munich, Paris and Bethesda, USA. XClinical was founded in 2002 by a team of highly experienced software developers, clinicians and managers. Since 4 years XClinical has sustained profitable growth without external investors. MARVIN, XClinical's main software product, is an integrated Internet-based application for Electronic Data Capture (EDC), Clinical Data Management (CDM) and Clinical Trial Management (CTM). More and more biopharmaceutical corporations and medical devices manufacturers prefer MARVIN over competitive offerings, since MARVIN is designed to be an attractive working tool especially for investigators, the key people that drive the success of a clinical trial; moreover, MARVIN is fully compliant with the CDISC data standards and offers fast and flexible e-CRF set-up. Till today, MARVIN was used to collect and process data of more than 43,000 patients in 26 studies.

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