



PRESS RELEASE – 2 June 2010

XClinical introduces eCRF design tool

XClinical introduces ODM Study Composer

XClinical GmbH, Munich, Germany – 2 June 2010 – Today XClinical, a European vendor of innovative software products for eClinical trials, announced the introduction of the ODM Study Composer, a validated software tool for accelerating and simplifying the design of case report forms and data validation plan.

Alongside its successful EDC System MARVIN, XClinical will now also be providing the ODM Study Composer as an intuitive graphical point-and-click tool for quick and easy study set-up regardless of the EDC/CDM system in use. “The Study Composer is a replacement for MS Word and Excel. Using this tool, study managers, clinicians and data managers can collaborate and achieve considerable time and cost savings,” said Dr Philippe Verplancke, CEO of XClinical. “It supports a lot more than just eCRF design. The annotated CRF, data validation plan, database specs and other key documents can also be exported from the tool, which uses a single, central, XML-based set of metadata.” In addition the ODM Study Composer allows users to build and use an item, as well as a CRF library to re-use existing items and CRF definitions including both legacy and CDISC metadata.

Last but not least, the ODM Study Composer supports the automatic set-up of the database and eCRF. “As an EDC software provider we are confronted on a daily basis with legacy inefficiencies in clinical data management processes. The use of data standards is an important factor,” said Dr Verplancke. “That’s why we developed a tool which enables users to easily generate a CDISC ODM-compliant file ready for importing into a variety of EDC systems. The use of the CDISC ODM data standard greatly improves the quality of communication between different teams and organisations involved in a study.”



Three weeks ago XClinical presented the ODM Study Composer during an end-to-end workshop the company hosted for pharmaceutical companies, CROs and freelance data managers. The workshop included a practical demonstration of an efficient end-to-end process and an introduction to the study set-up using the ODM Study Composer. It was very well received by its 25 participants from the industry.

XClinical will also be presenting the ODM Study Composer at the 46th DIA Annual Meeting taking place in Washington, D.C. from 13-17 June. To learn more about the product and our data management partnership program, be sure to visit XClinical's experts at booth n°. 926.

If you are interested in further information on the ODM Study Composer or would like to have a presentation of the tool, please contact Dr Merten Menke (mm@xclinical.com).

About XClinical

XClinical GmbH (www.xclinical.com), an innovative EDC-CDM system vendor based in Munich, Paris and Boston provides solutions for the electronic conduct of all types of clinical trials, post-marketing studies and registries.

XClinical develops and markets MARVIN, a CDISC ODM-certified online platform for Electronic Data Capture (EDC), Clinical Data Management (CDM) and Clinical Trial Management (CTM) and the ODM Study Composer, a graphical user interface for study set-up including CRF design and data validation plan.

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