A Domain-Specific Framework for Collecting Data in Trials with Smart Mobile Devices

J. Schobel\textsuperscript{1}, M. Schickler\textsuperscript{1}, R. Pryss\textsuperscript{1}, M. Reichert\textsuperscript{1}, T. Elbert\textsuperscript{2}

1 – Institute of Databases and Information Systems, University of Ulm, Ulm, Germany
2 – Department of Psychology, University of Konstanz, Konstanz, Germany

Instead of using traditional paper-based questionnaires, more and more trials rely on electronic questionnaires running on smart mobile devices. However, existing survey tools do not allow deploying questionnaires on tablets or they lack substantial functionality. Other aspects not properly covered include user-guidance and the flexible enactment of digital questionnaires (e.g., skip questions depending on already given answers).

To enable data collection in clinical trials with smart mobile devices, a domain-specific framework supporting the entire lifecycle of an electronic questionnaire (i.e., its creation, deployment, enactment, analysis and evolution) is required. Such a framework has been developed in the QuestionSys project. First, based on methods known from end-user-programming, domain experts (i.e., psychologists or physicians) are enabled to create electronic questionnaires for their trials without need of any programming skills. Second, a process-driven approach is followed to enable a flexible and valid enactment of questionnaire instances on smart mobile devices. The framework also allows for the integration of external sensors (e.g., pulse tracker) to enhance the data collected. Third, the collected data can be analyzed based on user-defined rules to provide an on-demand evaluation.

Altogether, process-driven, electronic questionnaires on smart mobile devices will change the way of collecting data in clinical trials fundamentally.