ABSTRACT

Linking clinical research to healthcare is one of the FDA and industry’s key initiatives and, as such, is a strategic focus for CDISC. In an effort to support this initiative, CDISC has led the co-development of an integration profile with Integrating the Healthcare Enterprise (IHE). This profile, Retrieve Form for Data-capture (RFD), enables an external agency to surface data-capture forms within an Electronic Health Record (EHR). When applied to the clinical research realm, RFD offers an elegant, straightforward solution to the problem of capturing clinical research data inside of an EHR.

A handful of thought-leading pharmaceutical companies and technical implementers will pilot and grow the idea of using RFD to demonstrate the compelling possibilities that can occur when data sharing is facilitated between the worlds of EHR and clinical research. This CDISC-sponsored work was slated to be shown as a part of the Interoperability Showcase at the HIMSS 2007 Annual Meeting in New Orleans in February. The demonstration contained five unique scenarios, which represent examples of the potentially advantageous applications of integrated data capture. Each of the five scenarios is being sponsored by a CDISC member company.

RFD has four ‘actors’, each of which plays a key role in generating a form, completing the form within the patient-care environment, receiving and managing data from the data capture step, and archiving the electronic source documents. The SAS Drug Development platform participates in the demonstration, enacting both the form receiver and form archiver actors.

No paper was submitted for publication.

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