



Sebastian Mason, Office Manager for Professional Park Medical Services using RFD

November 2005, Libertyville, Illinois.

Landen Bain and Dave Iberson-Hurst of CDISC talk excitedly over dinner at a local restaurant, sketching out on the restaurant's tabletop an architecture that combines Landen's Single Source concept with Dave's vision of electronic source documents. They are in Libertyville visiting Allscripts, an electronic health record (EHR) company that is working with Merck on the Single Source concept, the notion of capturing clinical trial data within an EHR. Throughout the evening, Dave contributes his understanding of the regulatory environment of research to the nascent ideas of Single Source, and a messy but important set of drawings take shape on the paper table cover, in penciled notes and sketches juxtaposed with spatters of the evening's wine and pasta sauce. As they leave, folding the large sheet of marked up paper to take with them; two local ladies lean over from the next table and ask if they are going to launch a dot com company. Well, not exactly, but over the next three years these crude drawings have evolved into something quite real, first as PowerPoint slides, then as the Retrieve Form for Data-capture (RFD) technical specification, which passes through rigorous testing and high-profile demonstrations to lead, finally, to commercial implementation.

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December 2008, Carrollton, Georgia.

Three years and one month after the dinner in Libertyville, Sebastian Mason, Office Manager for Professional Park Medical Services in Carrollton GA, demonstrates the first commercial implementation of RFD to Landen Bain and representatives of Greenway Medical, the electronic health record company that, along with Outcome Sciences, produce the first commercial implementation of RFD.

Sebastian shows us *PrimeSuite*, Greenway's EHR solution, and demonstrates the enrollment of a patient into a research study managed by Outcome Sciences. So far the site has registered ten patients into the study, out of a pool of 260 eligible candidates. The lower left hand corner of *PrimeSuite's* facesheet lists four available forms for the study, and Sebastian selects the enrollment form. The form pops up instantaneously, despite the fact that it is being served up from Outcome Sciences offices in Boston, MA. The form includes sections for clinicals, medications, and demographics, and 75% of the data elements are pre-populated by RFD transactions between Greenway and Outcome. The workflow seems so natural that it would be easy to miss the fact that these data capture screens are not a native part of *PrimeSuite*, but come from Outcome Sciences's Forms Man-

ager, which controls the content and binding of the data. The *PrimeSuite* users at this medical group can fulfill all the needs of the study without leaving their native application, the EHR. Sebastian explains, "the only paper we have to keep is the consent form. There is no extra work to speak of." For the first time, due to the reduced impact on their workflow, participation in a research study makes business sense.

Sebastian shows the capabilities of RFD so deftly that it doesn't look like a breakthrough: it appears as if *PrimeSuite* does all the work. And, of course, that is precisely the point. The forms that pop immediately to the screen show no evidence that they had been served up from Boston. The data capture forms don't stand out as different from the rest of the Greenway screens, even though they are web forms (using iFrames) retrieved from afar. This is seamless integration, true interoperability, at a modest, practical, implementable cost and scale.

Sebastian explains that his group, a four physician practice, has heretofore avoided participation in clinical research precisely because of the difficulties of data capture. "Now with this approach," he



Daemon Whittenburg, Jason Colquitt, Tee Green
Greenway Medical

explains with a shrug, "there's nothing to it. We'll be doing more." Tee Green, President of Greenway, adds that, "the group can now participate in improving medicine, not just practicing medicine. Greenway will be in a position to match our *PrimeSuite* users to sponsors studies using our *PrimeResearch* application, giving our customers a way to easily add clinical research capabilities to their EHR investment." This business model that puts electronic health record vendors into a position as clinical research enablers has grown out of

the simple technical capabilities of RFD.

And this is exactly the outcome that Merck, Pfizer, and Lilly, three of the early sponsors of RFD development, have hoped for, that with the easing of difficulties of dealing with multiple data capture systems, more physician practices will engage in clinical research as a profitable, manageable extension of their patient care mission. The medical group in Carrollton are straightforward patient care practitioners who will only add research to their mix of services if it can be done 'on the margin', without disrupting their primary mission of taking care of patients. This is the sort of group that offers the best hope for expanding the pool of clinical researchers. The academic medical centers are tapped. The research focused sites already have work arounds for dealing with multiple data capture systems. It is the practical, down-to-earth business managers like Sebastian and the hard working doctors and nurses he represents who can expand the base of research sites around the country.

RFD Development

Ironically, the first companies to implement RFD - Greenway Medical and Outcome Sciences - were relative newcomers to the work. It began with Allscripts (it was a trip to their headquarters that led to Libertyville) and Merck, and George Cole of Allscripts became the lead developer of the IHE process that became RFD. Pfizer came on board with an important drug safety application, first demonstrated at HIMSS and then implemented at Partners Healthcare in Boston, MA. And Lilly, Quintiles and Cerner built the first clinical research data capture implementation for the Lilly S0001 trial. The implementation used real world data capture forms and successfully demonstrated several important innovations, but no live patient data were captured.

Many other groups participated in the development, testing and demonstration of RFD. RFD was developed by Integrating the Healthcare Enterprise and CDISC. The specification is available for download at:

http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Supplement_Retrieve_Form_for_Data_Capture_RFD_TI_2008-10-10.pdf

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