

# PODCAST TRANSCRIPT

## Integrating Eclinical and EDC

**Guest: Landen Bain**

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Will the enclave of industry-sponsored pharmaceutical research ever be connected to physician and hospital health care systems in society at large? No one is better equipped to assess that question than Landen Bain, health care liaison to the Clinical Data Interchange Standards Consortium (CDISC). His projects suggest a clear, feasible way to connect the two worlds. If such linkages move beyond the pilot stage, significant quantities of electronic health record data could load in industry's trial systems automatically. That would lighten investigators' workloads and expedite regulators' abilities to confirm drug safety issues. ClinPage editor Mark Uehling interviewed Bain.

**Uehling:** Welcome, Landen

**Bain:** Thanks, Mark.

**Uehling:** I hate to put you on the spot. But is the integration of electronic health record (EHR) systems and electronic data capture (EDC) systems inevitable—a foregone conclusion, from your perspective?





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**Bain:** Yes, I think it is. I have an engineering background. If I look at the way data are captured today for health care and then captured a second time for clinical research, it is such an inelegant approach that I think it is inevitable that that will change into something more efficient, more agreeable to the people who actually create the data to begin with—the investigators and the study coordinators.

**Uehling:** Some people in the industry have dismissed or downplayed pilot projects that connect electronic health records with clinical trial systems. They say those two worlds, those two types of systems, are too complex to tie together. Do you think that every EHR has to completely integrate with every EDC system?

**Bain:** If you look at the entire project of computable semantic interoperability between health care and clinical research, I would probably agree with the critics that it's going to take a very, very long time for that to happen. But what we have done, and by we I mean CDISC under the heading of a project called Health Care Link, working with the EHR community in different forums, what we have done is try to take a very modest set of approaches to first of all bring the representatives of the two technical communities—health records and clinical research—together to start solving very modest problems. And to constrain the problem so that we can make useful progress without sort of looking to the whole endpoint. But just doing what we can do today. And we feel we're making useful progress.

**Uehling:** I understand that in a pilot project being supported by Lilly, Cerner, and Quintiles that you've really done some interesting things in populating a case report [form] (CRF) using an electronic health record system. In fact, in a live CRF, you used the CDASH standards, which apply to case report forms, that are from CDISC, and you were able to populate 25 out of the 33 data elements in that form. I have to ask you, was an act of Congress involved? Millions of man-hours of programmers in India?



**Bain:** Again, it was a very, very modest project. Eli Lilly has been working with the Health Care Link initiative of CDISC for a couple of years now. We asked them for an opportunity to work with a real clinical trial. They selected a small trial run in the



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Lilly clinic in Indianapolis. Using the case report form, we did, as you said, hit 80 percent of that.

One of the things that we learned is that CDASH is an integral part of Health Care Link. What CDASH does is by identifying the data elements that are common to all case report forms, it gives the electronic health record community a known target. So in other words, in this case, Cerner was able to identify the data elements and hand them off to what we call the form manager, to prepopulate that form.

I can't speak for Cerner. But I know that Cerner is very engaged in this, very optimistic about the electronic health record's role in clinical research. They put some top notch technical resources on the project. But the work was done in a matter of months, not years, not decades, and proved the point very handily. We've demonstrated that a single trial, a

single site, a single EHR, using the health care link tools, CDASH, and the RFD profile, that that's a solvable problem. What we need to do next is find a larger study, multiple sites, multiple EHRs, multiple CRFs, and demonstrate again that this approach can start to scale up.

**Uehling:** Do any EDC systems talk to EHR systems out of the box now? Or are there things happening already that people may not be aware of? Or are these all custom projects to some extent at this stage?

**Bain:** We are talking about very new work. Emerging technology. So there are aspects of any trial implementation that will be unique or developmental. Our goal, of course, is to have it be standardized so that an electronic health record can express data in their vernacular, if you will, as a medical summary or a continuity of care document. Those are formal, standardized documents from the health care side. And a form manager on the clinical research side can take those data, prepopulate a form, and give the form back to the electronic health record to display. The basic underlying mechanism to do this is very simple. It uses basic web technology that we think anybody should be able to use. So we're hopeful that we've created a point of contact, a single point of contact [that is] very simple between the eclinical





world and the EHR world. Every time we do a demonstration or a trial implementation we discover something new. It makes it very exciting. I liken it to two different groups of people who speak different languages. At the frontier between these two groups, they start to engage in trade among themselves. And they learn to communicate in some very very simple ways so that they can trade goods among them.

It's sort of like that. We are starting at such a modest point that the electronic health records and the eclinical people can say, OK, if I can do this, why can't I do this? As every project we do—and CDISC's role is often just pairing up willing health record [companies] with willing EDCs with willing sponsors—around a particular problem, turn them loose in the general framework of Health Care Link. And see what emerges. We've had some very pleasant surprises in terms of the capabilities. We have had to go back and modify some standards and extend the technical considerations. But overall it is a healthy process that is starting to bear fruit and I hope will become commercially viable.

'It is a healthy process that is starting to bear fruit.'

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**Uehling:** It sounds like things are really moving along. We've been talking a little bit about data gleaning. I wonder if you could say more about that. The basic concept is that EHR systems don't have to worry about all of the minutia of 21 CFR Part 11 compliant systems. But can you go into more detail and explain the concept of data gleaning? It's a reference to an agricultural metaphor that I know you'll share with us.

**Bain:** Sure. Well, gleaning is an ancient practice. All the way back in Biblical times, the owner of a field was enjoined not to reap every grain but to allow some for poor people to come and gather on their own. But there was an arrangement made so that the farmer left enough grain to be helpful. But the gleaners had enough sense to stay out of the way. There are actually laws on the books in France that define, I understand, that's it's ten meters or something that the gleaners have to stay back from the harvesters. We've kind of taken that as a metaphor. The EHRs are the farmers. They're the ones that have the resource, the data. They don't mind, and in fact they are very willing to help. This was a surprise to





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some people. By going to the EHRs in their forum and saying, "we would like to be able to capture data in this following way"—they were very open to that. But they said, "we want you to stay out of our way, i.e. not interfere with the core use of the EHR, which is to support patient care. And we want you to buffet us from the regulatory aspects of clinical research so that we don't have to become 21 CFR Part 11 compliant. We already have to worry about HIPAA, and that is enough for us." We tried to develop Health Care Link in such a way that it has minimal impact on the EHR technology and a minimal impact on the EHR user, whether that be

a physician-investigator or a nurse who is also working as a study coordinator. And to keep this courtesy arrangement of the ancient practice of gleaning in place.

**Uehling:** It's a wonderful concept. I wonder if you could say a little how that works, technologically. It is a separate file or an application that runs along side the EHR system that eventually could be validated in a clinical site in accordance with GCP?

**Bain:** I will explain it to my level of understanding. David Iberson-Hurst is the individual who is much more knowledgeable than I, and who has designed what we really do with this guest form that is actually supplied by the eclinical system. When that form is completed by the automated EHR or by the direct data entry of the EHR user, that form becomes at that moment the source document. Then that document is exported into a form archiver. And that form archiver stays under the sphere of influence of the investigator and becomes the electronic source document. This is a very important point. The electronic source document is *not* inside the electronic health record. It is in the form archiver. The data are brought from the EHR and prepopulated in the form. But the investigator eyeballs that electronically and verifies it and submits it. At that moment, it becomes the electronic source document.



**Uehling:** Thank you so much, Landen.