

A New Contextual Language to Improve Prevention and Treatment of Disease

Before CLOUD

The notion of a clinical trial conjures two powerful and immediate images. On the one hand, it means that a biotech or pharmaceutical company is close to some groundbreaking drug or therapy that has the capacity for healing and survival of people afflicted with a particular disease. This is a truly exciting and powerful prospect. On the other hand, the very people that can be helped are experiencing a very different emotion. If someone is a candidate for a clinical trial, this means they both have the disease being targeted, and it also means nothing else is working. Bottom-line, they might die. Mortality is clearly in front of them.

Clinical trials are part of a larger whole. They are part of a continuum of health and the delivery of care, and the system for reconciling the goals for patient, provider and researcher is broken. It isn't about standards. It is about connections. As one of the founders of CLOUD, this part of our mission is very personal for me. Nine months ago, my wife was diagnosed with a recurrence of her breast cancer. Fortunately, she is now back in remission, but along the way, we became acutely aware of how tenuous the connection to life-saving therapies can be. And here's why. But for our oncologist in Austin, Texas introducing us to the right oncologist at MD Anderson in Houston, Texas and but for that oncologist discussing 'our tumor' at their Tuesday tumor board... and but for the almost 30 oncologists that attend that Tuesday tumor board including the principal investigator for a clinical trial in its second phase... we would never have known of the therapy... and the PI would have missed the 'perfect candidate.' Fortunately, the FDA-approved chemotherapy that we were already receiving worked. If it hadn't, we would have been searching for this exact clinical trial.

Although there have been standards efforts underway for over a decade in both health information exchange and clinical data interchange to get at this problem, the groups responsible for these efforts (HL7 and CDISC) have acknowledged the following reality, "Policy issues, including privacy, are . . .

impeding the transition. Before we can be successful with our most important opportunity to make fundamental use of data, we need to address those policies.”Therefore, to unleash the true power of these important data standards, there has to be a people’s standard, a new contextual language. There needs to be a new CLOUD.

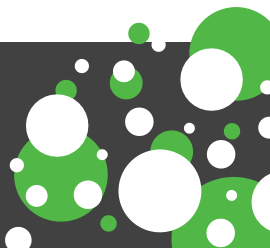
After CLOUD

How might this clinical trial process play itself out differently in a CLOUD-enabled world? The critical first step is to separate identity from our data in all of the different silos it exists. The privacy problem addressed by HL7 (Health Level 7) and CDISC (Clinical Data Interchange Standard Consortium) is driven by the fact that wherever our health data exists, we also exist. It does not have to be this way. Our records could exist separately from our personal identifiers, and more importantly, our data can exist in a decentralized way. Simply trying to aggregate all of our data that is now in separate silos into one silo simply relocates the problem. It doesn’t solve it.

There is nothing wrong with our doctors, our hospitals, our testing organizations and our prescribers holding our records. It is how they hold and store them that makes the difference. Whether the medical office systems host our data locally or through some cloud computing technology is not the relevant issue. The way this data ends up being CLOUD-enabled will be the determining factor in its utility. If all we do is simply move the paper records from a dead tree format to a digital version, we have made no actual progress. Whether on paper or silicon, disconnected data is still disconnected data. It is the fabric that weaves it all together that matters, and that fabric must be focused around you rather than just the data, so as to unleash the power of all of our other technology and standards investments.

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In a CLOUD-enabled world, the clinical trial example transforms itself completely for patient and investigator. How? Well, think about how it works now. In a silo-driven world of data, both the patient and the investigator must have made the same decision to enter their data and their identities into the same web site. Obviously, the likelihood of this is low, and thus, the likelihood of useful connections is lower still. Bad for patients; bad for investigators; bad for possible new life-saving therapies.

In the world of CLOUD, an investigator could pull up an anonymous mosaic of potential study participants, weaving their way through a completely private set of data targeting the exact disease at the exact right stage to rapidly accelerate their research and equally importantly connect patients with life-saving therapies without the myriad of chances occurrences my wife and so many others face today.

The vision for CLOUD is to understand that the standards for data can only be unleashed if there is a standard for people. A world of ME 1.0 allows two very important things to happen. First, it doesn't require information be moved. The data can stay right where it is, and with a sort of two-sided Velcro wrapped around it, it can interact not only with my identity profile, located elsewhere, but it can interact with other data that is just like it wherever that data resides. This means that all of the hard work put into HL7 and CDISC can be fully realized, because YOU are now fully enabled and not just your data. And by untethering your identity from your data, it means your data is anonymous, which means that the privacy problem cited by the Applied Clinical Trials journal article no longer stands in the way. And by putting YOU in the center of the equation, it means that there aren't silos of data standing in the way either.

And, at the end of all this lingo about data and standards and ME, it also means that we have a new way to connect on the Internet that is no longer dependent on HTML but is dependent on a new contextual language for people, a language that let's us connect not only the various parts of ME with ME but can also connect others with those parts of ME that matter most. In the case of clinical trials, this new CLOUD-enabled world can really mean the difference between life and death.

