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The Most Powerful Name in Corporate News

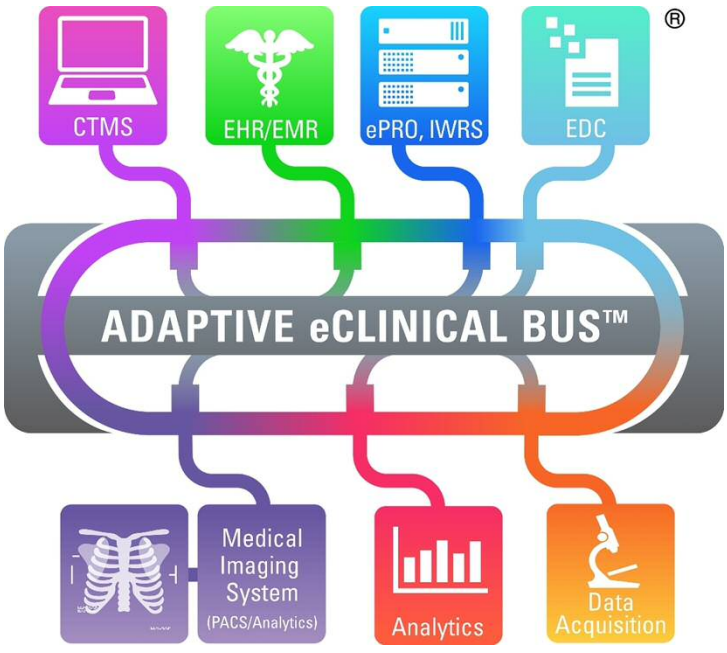
Cloud Based Clinical Data Interoperability Solutions with the Freedom to Choose the Best eClinical Informatics Systems

Sina Adibi
President & CEO
Adaptive Clinical Systems

CEOCFO: ***Mr. Adibi, your site indicates Adaptive Clinical Systems® provides a simple, validated and cost effective solution for clinical data integration. How so? What are the elements of your solution?***
Mr. Adibi: There are several elements to the service that we offer. One is that it is cloud based so it is highly scalable. Second is that it is constantly maintained in a state of full compliance with various regulatory requirements as it relates to clinical trial data management. The third is that the technology architecture is done in such a way that it is very easily integratable with almost all of the commercial tools in the market, as well as any proprietary tools that our prospects and clients may have.

CEOCFO: ***How is that different from other systems that may be available today?***
Mr. Adibi: Right now, in order for someone who is engaged in a clinical study to enjoy the capabilities that we offer they need to be either one of the top ten pharma, who have already made significant investments in technology over the course of many years or have purchased all of their software components from the same vendor for a similarly hefty investment. The problem with the latter is that not every vendor is best in class at everything. Some vendors are very good at EDC, which is Electronic Data Capture. Some vendors are very good at Clinical Trial Management or CTMS. It is rare to find the same vendor that is very good at everything. What we do is give our clients the freedom to choose the best commercial eClinical tools while continuing to leverage their proprietary back-office systems and leave the interoperability to us. They get all the benefits that big pharma enjoys without the cost.

CEOCFO: ***Are people looking for a better solution when it comes to Integration?***



Mr. Adibi: Yes, definitely. One point that I want to make is that we make a distinction between integration and interoperability in the sense that integration is very simple. It is moving data from point A to point B. It is something that we have been doing in this industry since I began my career. Interoperability is where you not only move data from point A to point B, but you also layer on clinical intelligence. What I mean by that is; think of having a situation where you have two locations with two clinical staff speaking different languages. One is accustomed to taking measurements in the metric system and one is accustomed to keeping height and weight in pounds and inches. In a situation like that where you actually have data that needs to be transformed as it is moving from one place to the next, that is where we excel. That is a very simple example. We also do things like calculating body surface area according to algorithms that the organization would like. We do things where we can actually look at a number of data points. Let us say that a patient comes in for multiple visits and during the course of those visits there are fluctuations in some of the vital signs. We have the capability of looking at all of that

data holistically and deriving clinical conclusions on behalf of the organization. Therefore, we do much more than integration and you are right - Not only are our customers challenged with integration; they also very quickly realize that the real value they get from us is that interoperability and the data transformation capabilities that we provide.

CEOCFO: ***You mentioned being compliant at all times. How are you able to monitor that, particularly when compliance regulations often change?***
Mr. Adibi: That is a big part of the service that we provide. Most obviously we stay abreast of those requirements and just as important is the way we have engineered our service; it is done in such a way where each functional component, if you will, is isolated so that once it is certified and we proceed to make changes elsewhere in the system, we do not undo the certification that was done for that module or for that component. It is something that takes a lot of time and vigilance – and something that may not be easy to accomplish for a pharma company that is focused on managing a product through to market. Fortunately for us, most of the regulations that we have to be compliant with come from the FDA and the FDA is very good at letting everybody know of any upcoming changes ahead of time.

CEOCFO: ***What has changed as your product has been available? What have you learned? What is different today?***
Mr. Adibi: Increased dependence on automation has been a very positive change for us. When we started the number of systems that a typical organization was using during the course of a clinical trial, was a handful. They would use one system to manage the financial aspect and another system to manage the clinical data and that was it. What we are seeing now is that by some estimates upwards of twenty five or so systems come into use by the time a clinical study is completed. That is because clinical studies have become so complex that our clients have had to introduce highly specialized systems for a typical clinical study. These are often developed by niche vendors that do a very good job at what they do. However their systems do not interoperate with the other systems. That is where we come in. We become the intelligent glue that knits all of these together.

"What we do is give our clients the freedom to choose the best commercial eClinical tools while continuing to leverage their proprietary back-office systems and leave the interoperability to us." - Sina Adibi

CEOCFO: ***How are you reaching out to potential customers? How might they find you? Would someone know where to look, what to search under to come up with Adaptive Clinical?***
Mr. Adibi: That is a marketing question. What do we do? How do we market? Obviously, inbound marketing is a big part of what we do. We belong to many associations. In fact, we were invited by a major standards body to attend a conference that they were hosting with the FDA on the subject of interoperability in clinical trials. We develop and publish white papers as we learn. We publish case studies and basically, by sharing the wealth and the knowledge, if you will, we spread the word about the challenges that people are facing. That is how we get many of our connections. We also have an established customer base. We get referrals, so folks are very happy with us. We attend conferences. We are speaking at the SCDM, the Society for Clinical Data Management, which is in September. We attend major conferences like the DIA, the Drug Information Association. That is how we get the word out. Of course we spend a healthy dose of our sales and marketing dollars on networking and calling on prospects.

CEOCFO: ***What is involved with an implementation?***
Mr. Adibi: It is actually pretty straightforward. An implementation is two things. One is what type of study is being conducted and the second is what are the systems that are involved? The first thing that our clients tell us is what commercial or proprietary tools they are using. . Often times we already have what we call "connectors" in our library for the commercial vendors and we also have template connectors that we use for any proprietary system. Therefore, from beginning to end, within typically a couple of weeks we are able to interconnect most of these systems. Then for the balance of the time, which is probably another couple of weeks, we sit with the data management, operations and clinical staff to optimize their workflow. We look at the study and how the data should be manipulated as it is moving from system A to system B, for example. We gather information on how to apply content processing rules using one of our components known as the "Adaptive Rules Engine" to effect the data transformation I talked about earlier. When we first started out our ramp up time was longer. However, over time as we built out a robust library of connectors and clinical rules, our deployment times have gone way down so our clients benefit from all the past projects that we have done.

CEOCFO: ***Do idioms or regional distinctions come into play? Are there regional differences in some of the medical terms? How do you transfer the interoperability idea in this situation?***
Mr. Adibi: That is a very astute question! Often people do not think to ask that, because there is an assumption that English is the language of medicine. Anywhere in the world that you go, for the most part, the practicing investigators and

physicians speak English fluently and the terms, obviously, are in Latin. There is all of that commonality. However, the thing that everyone leaves out is that their associates and the people under them that are actually doing a lot of the work with these systems, often times do not speak the same language. In the example of the units that I was talking about; units of measure; sometimes they do not use those units of measure. Sometimes dates are different in the way they are looked at and referenced. Therefore, a big part of that data transformation that I was telling you about are those mappings. We call that localization. There is a government sponsored research institution in one of the former Soviet Union Republics that is using our system. One of the things that they like about it is the fact that we were able to allow the systems to have a bilingual interface. They could view the same questions both in Russian as well as in English, so that if they had any doubts about their comprehension of the question in English they could read the Russian version and that way there was no doubt as to its meaning and intent. However, the data is collected in English. If they wanted to collect the data in a different language we also have that capability, but we do not actually get into translation. We just move and transform whatever data has been entered.

CEOCFO: ***Why is Adaptive Clinical Systems such an important company and concept?***
Mr. Adibi: First of all, for anyone in the clinical trial space, they are under tremendous pressure to expedite their study. Things that slow down a typical clinical trial are data errors, time involved in moving data from one system to the next and then the sheer number of people that have their hands in the data collection and data manipulation. We address just about all of those in the sense that we effectively deliver electronic sourcing or eSourcing of data. That means that the data that emanates from a medical device comes directly into the data base, so there is no longer a, “lets print out the output from the machine and then type it into the system.” As you can well imagine, those three steps require someone to work with these three systems and then someone to sit there and type the data. You run the risk of introducing errors. You run the risk of having inconsistencies. These are challenges that surface during the course of an audit. Therefore, by eliminating these weaknesses or these hand offs we have managed to speed up a number of clinical studies for our clients. In one case we quantified how much less time they were spending doing their daily jobs and it came up to about twenty five percent. You know, when one is under pressure to manage volumes of data and push a study through for a critical clinical drug, twenty five percent makes a huge difference. We have done cost savings of systems, something to the tune of seventy percent. We have some results on our website that we would be happy to share. There you can find the detailed case study that I cited earlier.

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Adaptive Clinical Systems

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