Innovation In Clinical Trials: Is It Time To Change The Paradigm?

By Ed Miseta, editor, Clinical Leader

"People hate change. This is true in the life sciences industry and everywhere in the world. I think it’s a major, major problem."

That statement, by Glen de Vries, president of Medidata, seems to sum up the challenge many have with trying to bring down the cost of clinical trials. To bring down costs we need to implement new, efficient, and available technologies. Unfortunately implementing new technologies involves change, which many people in this industry do not seem to want to embrace.

Hopefully, that attitude may soon be changing. One of the trends de Vries has seen in the past year is a focus on innovation originating at the executive level. More managers, especially those in the C-suite, are saying we need to figure out how to do things differently.

“We’re not getting the return from our investment in clinical development that we should be getting,” de Vries says. “So it’s only natural for people to question what can and should be done differently. The good news is this demonstrates there is a real potential for momentum in terms of people rethinking how they plan and run their studies. Until recently, we haven’t had a lot of great technology. It may now be time to finally take a good look at how we’ve been doing things for a long time, especially bio statistics, clinical operations and data management.”

Even with support at the management level, implementation can be a challenge. Execution can drop off a cliff as you get further and further into an organization. For real innovation to occur, the executive teams will need to ensure they are properly communicating, incentivizing and measuring the people who are actually at the ground level planning and running the studies. Unless they do, de Vries believes they will find their desire for new innovation resulting in very little returns.

NEW SOURCES = NEW OPPORTUNITIES

Another trend de Vries sees is new sources of data in clinical trials. It will be incumbent on the industry to figure out how to take advantage of these new sources. For example, a patient used to have to visit a healthcare professional to have objective measurements taken. Today, they can be connected to a database at any given time simply by wearing an activity tracker.

“The entire technology world around clinical trials is moving towards better instrumentation of people,” notes de Vries. “Our industry is now beginning to take advantage of available technologies. There are pilot studies going on where people are pulling more of this in-life data into what they’re looking at from the clinical trials perspective. That is going to be an incredibly exciting part of what’s going on in our industry. The best part is that we don’t have to build it. Companies like Samsung, Apple, and Google are the ones creating the infrastructure. We in the life sciences just have to figure out how to best take advantage of that infrastructure.”

Technology will never put an end to the site/subject relationship. de Vries is quick to note the relationship between the valuable data assets and trying to make them even more valuable.

“When we collect data, we do it in an incredibly disciplined way,” he says. “We have high-quality data, but it has been looked at with the blinders of a single trial. Now what we’re starting to see is people say, “How can we look at this more broadly? How can we look at data across multiple studies and figure out how to manage sites better? How can we look at data across multiple studies and figure out if there’s a way to reduce the number of patients who would be exposed to harmful or ineffective doses of drug? How do we share what people like to call precompetitive information?”

In the past, no one has ever really taken advantage of the data because there wasn’t a demand for it. Today, that demand is there. Everyone is feeling the need to take the data they have and get more leverage from it. When companies learn to properly take full advantage of the data, de Vries believes the result will be a huge savings of time and money, as well as lower risk and a higher quality of work. It is also a way for vendors and CROs to provide more value to clients.

DATA SHARING CAN DRIVE INNOVATION

Getting everyone in the organization to change their attitude and outlook is never an easy task. After all, people do hate change. de Vries believes it is best to put people in a framework where they understand why it’s important for them to change. “People are going to have to figure out how to make sure these innovative ideas are coming to fruition,” he says. “It seems people are more willing to innovate, but we still need to make sure we take advantage of the willingness. One of the trends that I think will help drive this is that we seem to be at the dawn of a new age of data sharing in the life sciences industry.”

As examples of this trend, de Vries points to TransCelerate and Project Data Sphere. Companies are now taking their valuable data assets and trying to make them even more valuable.

"P"eople hate change. This is true in the life sciences industry and everywhere in the world. I think it’s a major, major problem.”

That statement, by Glen de Vries, president of Medidata, seems to sum up the challenge many have with trying to bring down the cost of clinical trials. To bring down costs we need to implement new, efficient, and available technologies. Unfortunately implementing new technologies involves change, which many people in this industry do not seem to want to embrace.

Hopefully, that attitude may soon be changing. One of the trends de Vries has seen in the past year is a focus on innovation originating at the executive level. More managers, especially those in the C-suite, are saying we need to figure out how to do things differently.

“We’re not getting the return from our investment in clinical development that we should be getting,” de Vries says. “So it’s only natural for people to question what can and should be done differently. The good news is this demonstrates there is a real potential for momentum in terms of people rethinking how they plan and run their studies. Until recently, we haven’t had a lot of great technology. It may now be time to finally take a good look at how we’ve been doing things for a long time, especially bio statistics, clinical operations and data management.”

Even with support at the management level, implementation can be a challenge. Execution can drop off a cliff as you get further and further into an organization. For real innovation to occur, the executive teams will need to ensure they are properly communicating, incentivizing and measuring the people who are actually at the ground level planning and running the studies. Unless they do, de Vries believes they will find their desire for new innovation resulting in very little returns.

NEW SOURCES = NEW OPPORTUNITIES

Another trend de Vries sees is new sources of data in clinical trials. It will be incumbent on the industry to figure out how to take advantage of these new sources. For example, a patient used to have to visit a healthcare professional to have objective measurements taken. Today, they can be connected to a database at any given time simply by wearing an activity tracker.

“The entire technology world around clinical trials is moving towards better instrumentation of people,” notes de Vries. “Our industry is now beginning to take advantage of available technologies. There are pilot studies going on where people are pulling more of this in-life data into what they’re looking at from the clinical trials perspective. That is going to be an incredibly exciting part of what’s going on in our industry. The best part is that we don’t have to build it. Companies like Samsung, Apple, and Google are the ones creating the infrastructure. We in the life sciences just have to figure out how to best take advantage of that infrastructure.”

Technology will never put an end to the site/subject relationship. de Vries is quick to note the relationship between the valuable data assets and trying to make them even more valuable.

“When we collect data, we do it in an incredibly disciplined way,” he says. “We have high-quality data, but it has been looked at with the blinders of a single trial. Now what we’re starting to see is people say, “How can we look at this more broadly? How can we look at data across multiple studies and figure out how to manage sites better? How can we look at data across multiple studies and figure out if there’s a way to reduce the number of patients who would be exposed to harmful or ineffective doses of drug? How do we share what people like to call precompetitive information?”

In the past, no one has ever really taken advantage of the data because there wasn’t a demand for it. Today, that demand is there. Everyone is feeling the need to take the data they have and get more leverage from it. When companies learn to properly take full advantage of the data, de Vries believes the result will be a huge savings of time and money, as well as lower risk and a higher quality of work. It is also a way for vendors and CROs to provide more value to clients.

DATA SHARING CAN DRIVE INNOVATION

Getting everyone in the organization to change their attitude and outlook is never an easy task. After all, people do hate change. de Vries believes it is best to put people in a framework where they understand why it’s important for them to change. “People are going to have to figure out how to make sure these innovative ideas are coming to fruition,” he says. “It seems people are more willing to innovate, but we still need to make sure we take advantage of the willingness. One of the trends that I think will help drive this is that we seem to be at the dawn of a new age of data sharing in the life sciences industry.”

As examples of this trend, de Vries points to TransCelerate and Project Data Sphere. Companies are now taking their valuable data assets and trying to make them even more valuable.
doctor/nurse and patient is incredibly important. Instead, he believes technology may simply be one way to better scale that relationship.

**STANDARDIZE THE DATA**

One thing the industry does need to improve on is data standardization. If we can better standardize the data collected in clinical trials, the industry will be better able to predict the operational performance of site enrollment rates for subjects based on protocol designs and clinical outcomes.

The issues faced in life sciences are not insurmountable. In fact, de Vries believes the data issues faced by most companies are problems that statisticians and mathematicians are well-equipped to solve. But in some cases there are a lot of SOPs that keep getting in the way of doing it.

“This is where that executive who wants us to think and work in different way needs to get involved and clear those SOP roadblocks out of the way,” says de Vries. “In some organizations, when you drill down two or three levels into the management infrastructure, you find people hiding behind those SOP books. This prevents us from doing many of the things we want to do.

One example de Vries likes to give is adaptive designs in clinical trials. He believes there is no reason why adaptive dose finding studies shouldn’t be performed in the vast majority of clinical development programs, and yet we do not see them happening.

“It’s not happening because the way we have always done trials is without adaptive designs,” he notes. “The SOP books are responsible and that is a log jam that we really need to get out of the way.”

**DON’T LET FPI CONTROL YOUR TRIAL**

Although we want employees in our companies to always be looking for the next game-changing technology, and to focus on what will save the company time and money, we may not be properly incentivizing them to do so.

“We want people to look around them and think about what is the big goal is for the company,” says de Vries. “First patient in (FPI) is something we hear about day in and day out, especially when speaking with clients. Once a client gets to FPI, they are anxious to get the study going. Often times, companies will start studies because they’re trying to get FPI by a certain date that was promised to somebody. They must realize they will end up getting measured on that. They will have to live with a study that will inevitably have protocol amendments that haven’t been thought through. Worst case scenario, they may end up with a protocol that subjects will not be willing to participate in.”

Clearly, everyone wants to manage their studies in a low risk way. But rushing to FPI may not be the best way to accomplish that. de Vries recommends figuring out all the operational details in the way that’s not going to put the study at risk. For example, if you want to finish a study in 24 months, are you better off starting it today? Would it be better to wait three months and make sure you have a better study design? Which option will allow for faster enrollment? Many factors should be considered.

In conclusion, changing some of the existing paradigms in clinical trials is something everyone in the industry should focus on. “You can keep your head in the sand and do it the way you always did,” adds de Vries, “or you take that new information that you didn’t have access to before and turn it into actionable knowledge. I like to think we’re in the insight business, not the data business. Data’s easy to get in 2014. It’s everywhere. The trick is to get somebody to have wisdom or insight.”