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Addressing eClinical Data Challenges

by Andrea Charles

Scrip spoke to Fred Martin, Vice President, Engineering & Product Management and Johannes Hoech, Vice President, Marketing & International Operations about current eClinical data challenges at the DIA Europe 2018 conference in Basel in April. Medrio is focused on eClinical technology with a unique approach to electronic data capture (EDC), protocol and site compliance support, and eSource data. Patient data stored in its software are in compliance with the EU General Data Protection Regulation (GDPR) that went into effect in May.

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Q **Scrip: How do you feel GDPR regulations will affect the current clinical research environment?**

A F. Martin: The study is still going to be the same; the design, the data collection, and the analysis will be primarily unchanged; it's just now, you're required to know where the data coming from, what geography you're working in, who is looking at the data and how the data is stored. Most importantly, you must know where the data is being stored and who will be allowed to view the data and how. The back end is where we are going to see most of the challenges and changes, both good and bad.

Now, when you are combining data, and you want to look at data across multiple studies, across multiple continents, the change will be how do you take that data and view it in a holistic way? It's just going to require more creativity in making sure that you have the right processes, procedures and secure transmissions of data to be able

to view those data and bring the data sets together to ensure compliance with GDPR.

Q **Do you think pharma is ready to deal with those complex back-end challenges?**

A F. Martin: Probably not. And that's where the industry's going to have to support them; vendors will need to provide more innovative solutions, ways to view the data, bring data together, meet safety requirements and ensure compliance. That's going to be the big thing with PHI [protected health information]: how do we bring systems forward where they can manage multi-continent studies, but still see all the data in an aggregate way to do your analysis and submissions that still meets GDPR, but in a safe and secure way that you can view aggregate, de-identified data to be able to do those more complex analyses.

Q **What exactly are you doing to assure your clients that patient data are stored in compliance with GDPR?**

A F. Martin: Internally at Medrio, we've taken the most conservative view and interpretation of the ruling. We have servers on-site in Europe and in multiple countries to make sure that we are meeting not just the basic standard, but each individual country's interpretation. That's priority number one – making sure that we have servers on-site that are secure and meet the local regulations. Our datacenters use the typical industry standards for physical security, such as guarded ingress/egress points, CCTV, multiple levels of authentication/access (key card, pin, biometric), and windowless nondescript buildings. Communication between our datacenter locations is done via dedicated WAN links. The data for production is physically stored, at rest, in the EU, and our archiving/disaster recovery sites are also in the EU.

Beyond the local hosing of the data, when surfacing those data, we make sure that the data are separate; we have major protocols in the system about user provisions and configuration on who can see what data sets, based on rules ensuring that we work with each individual customer to make sure those are set up to their standards

and location protocols; making sure that our customers can only see the data for their regions, potentially for their countries, on the servers that their data are being kept on.

Q **How are you dealing with the complexity of a greater volume, velocity of data?**

A F. Martin: Large data sets have always been at the forefront of managing and enabling clinical studies, so that is not a new challenge. What has changed is an increasing need to accelerate studies, while simultaneously capturing, analysing, and storing data coming from multiple sources. This is the biggest change, interoperable systems are becoming more important, and being able to track where the data are coming from is critical. Did the data come through third-party systems, did they come via an API, did these come via a data upload? We need to be able to make sure that we can track data and understand the source of the data. This is a change in the volume of data.

Data can come from anywhere. We have to have the right trackers on there, to make sure we are interpreting the data along with our customers, to be able to say again, "Now once the data are in, where did those come from? Who gets to see the data? How can that data be used? What are the regulations around the data?" At Medio our system is focused on ensuring the quickest time to first patient and study close with innovation and intelligence that speed study set up time and enable higher quality data.

Q **Does "bring your own device" pose any unique challenges?**

A F. Martin: BYOD is becoming more of a standard operating procedure for most organizations. In today's world, organizations are global and employees are on the go. Being able to collect and access data from multiple locations is a requirement of the job that requires new tools and technology. This new era of remote, on-the-go access to data demands the creation of policies where organizations can ensure their BYOD procedures meet the requirements of the EU GPDR. For these policies it is paramount to address: how are you tracking the security of the device, does it have

dual authentication, how are you ensuring the data isn't stored on the device and isn't accessible by others. Establishing processes for managing issues such as lost or stolen devices and what to do when an employee leaves will need to be incorporated. As vendors, we have to guide and educate our customers, and help them think about the policies and the different ways employees will access data.

In addition, organizations need to think about how these devices are accessing networks. Security, once, again must be the primary consideration. Networks need to be secure, the creation of granular control over access should be considered, whereby companies can monitor and manage mobile device sessions both on-premise as well as over a secure SSL VPN.

Q **Aside from GDPR, what are other key challenges to the eClinical environment?**

A F. Martin: There are the standard issues that eClinical technology companies face: so, the cost of a trial, the speed of a trial, site recruitment, and recruitment of patients will make or break any study that's being done. The need to get to market faster, with fewer resources, is of paramount importance. Medrio is laser focused on meeting this need, providing our customers with the tools to accelerate their studies. We can get studies up and running between two and four weeks for a brand-new customer and then, if they are doing another study with us, on average just a little over two weeks. We help our customers speed up enrollment and the first subject live in the trial. This will enable them to close the trial faster, which in turn reduces the cost and shortens time to market.

Additionally, driving costs of a study down. When you're looking at managing costs and working with sites, and if you are outsourcing, with CROs, how do you decrease your site data verification (SDV) costs? At Medrio we are the leaders in providing e-source solutions, where sites can enter the data right into the system in real time –the system is integrated into our EDC system – so it's simplifies the data collection process and data transfer; but more importantly, it simplifies the audit and validation processes. So, again, we're driving costs to some extent, around 35% in decrease in the SDV costs.

I think that's really the challenge in the market place – to find the right technologies and solutions that speed time to market and decrease costs. Really, as I like to say, it's democratizing clinical studies. Most systems hold their customers hostage due to the complexity of their systems. You need coders, you need programmers, you pay for simple changes, and you need experts who can really get into the back end of the system. Medrio has changed the paradigm by introducing a solution that is web based and easy to use. We've eliminated one of the primary the barriers that has traditionally slowed down studies: unwieldly software that requires expensive programming for study build and mid study changes. With Medrio, anyone can set up your study and partner with you, which makes it a much quicker process because you're not dependent on a sub-set of people, you're now across multiple clinical organizations that can do that study.

J. Hoech: I will add one more layer from a macro-economic point of view, about the kinds of cost reductions and technology trends that Fred has described. Companies are grappling with three fundamental market trends: 1) geographic shifts, 2) technology innovation, and 3) increased regulatory requirements. On the first point, the geographic shift is clear. When you look at the market data on where clinical trials are taking place you see: the American market is growing slightly; the European market is flat or trending down; and then the vast growth is in the Asian market, with more clinical trials being done increasingly out of places like China and Taiwan, and India. So, there's low-cost competition coming in. They also have large populations of treatment-willing patients and they can really handle the bulk. China's building up its own pharmaceutical industry and as you know, IP protection is not taken as seriously there as it is here.

Second, you have technology innovations that are driving a digital transformation in this industry. The days of paper-based clinical studies will soon be behind us, as adoption of new solutions like eSource and eConsent become mainstream, like the usage of EDC over the past decade. These innovative technologies continue to gain traction as a direct response to the need to accelerate trials and reduce costs.

Third, the regulatory environment continues to evolve, with increased scrutiny on data security particularly in Europe. It is critical to understand the nuances and intricacies of the regulations. Because you have this competitive threat from Asia and you have the regulatory requirements here, technology-driven innovation and cost reductions provide another way to get out in front of those issues. For example, where the entire data capture is completely automated, and you can bypass associated manual processes, that's a massive cost reduction because the monitoring alone of such trials is often 50% of the overall cost. If you can take that out of the system, it's a way to be cost competitive and improve the quality of the process. There are multiple levels at which the challenges occur, just to build on what Fred was saying.

F. Martin: Absolutely, I think that's the other complexity in the market place now as these systems are growing and you need to get data from external devices and EHRs, and the list goes on and on and on. Interoperability is becoming more and more important, so I think that having a system that has the right connectors and hooks into the market becomes incredibly important. Systems have APIs, open-source APIs, to be able to connect out to data sources both bringing data in but also bringing data out. A lot of customers want to do their own analyses on the data, they want complex learning, complex cross-data analysis. Many vendors are trying to build those capabilities into their own systems, as we are, but a lot of customers already head to the marketplace. We must be able to build smart systems that have those hooks out there and understand not where the market is today but where the marketplace is going in the future, so that we're building the right hooks for tomorrow's technology that we haven't even thought of today. New clinical trials are going to be brought out, and how do you bring more of their data into the system?