

Better Data Management is Key for Clinical Trials: Interview with Raj Indupuri, CEO, eClinical Solutions

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The digitalization of clinical trials and the adoption of artificial intelligence (AI) has been a hot topic for a number of years now. Below is my interview with Mr. Raj Indupuri, CEO of eClinical Solutions where we discuss some trends and use cases in this area, and how the company helps solve some of the hurdles of the industry.

eClinical Solutions is a Boston-based company, founded in 2012, with a mission to improve clinical trials -- by providing unique and high-quality solutions for the efficient collection, standardization, reporting, and role-based utilization of clinical research data. The company offers illuminate® -- clinical trial software that makes your job easier - a powerful clinical data platform providing data visibility, traceability, transformation, and clinical data analysis.

The original interview is available in video format, and the text below was edited for clarity and length.

Andrii: Can you briefly outline your career, and how have you joined the company, helping run a “clinical trial improving” business?

Raj: By educational background, I am a mechanical engineer and I came to the USA in 1997. My first job was at the biotech company -- I have been fortunate to be in this industry for most of my career. In the early phase of it, I started as a database developer and I used to help companies move from paper-based processes to electronic processes. If you are familiar with clinical trials, electronic data capture was a big initiative that helped collect trial data more efficiently -- it was a big thing in, I would say, the late 1990s and early 2000s. I always believed technology is a key enabler to help bring medicines for patients faster, and specifically -- data-related technologies. More recently we've been working with clients helping with digital transformation initiatives and helping modernize the technologies so it has been quite an exciting journey for me personally, but what is even more exciting for me is where we are right now and what is

ahead for the company and for the industry.

Andrii: What is the company doing? How would you describe your product and how it brings value to your clients?

Raj: We offer a cloud-based data analytics platform that helps modernize and digitize clinical trials via reducing inefficiencies, cycle times, and increasing collaboration. The platform also provides valuable insights in near real-time. We also have a services business which is a big component of our organization. elluminate® is our data analytics platform that actually enables companies to bring data from any source and any structure, in any format, into one central hub. We have capabilities that can elegantly and efficiently transform this raw data into something meaningful for insights and intelligent decision-making.

Over the past few years, clinical trials have been getting extremely complex and the amount of data that we are collecting has been increasing significantly. Companies are dealing with what I call “data chaos”, and our products and services help companies solve this data problem and start managing data in more smart ways.

Andrii: As I understand, you basically develop this centralized hub and you can integrate data from clients and, let's say, some other resources, like data suppliers or hospitals or something like that?

Raj: Yes. If you think about clinical trials, there are so many different sources of data to do cleaning and analysis, and that are required to be standardized for regulatory submissions. So what elluminate® does -- it enables this injection of data from any source, EHRs, labs, diagnostics results, biomarker values, pharmacokinetics, and pharmacodynamics, etc. Once the data is within the platform you can organize it in a way so that you can then transform this data into formats required by key stakeholders and users -- for efficient decision making.

Andrii: A very obvious question here is about data security. How do you comply with all these kinds of mounting new rules and regulations -- GDPR, some other rules about data security? It is a complex legal landscape, how does your company deal with various requirements?

Raj: One of the challenges, when you bring software to our industry and deploy it for commercial use, is both information security and data privacy and also regulatory compliance.

From the beginning, when we engineer the solution, we have different aspects within the platform itself to ensure that both information security privacy and compliance are given the highest priority in terms of engineering and transforming the business requirements into the software. We use leading industrial infrastructures, like Amazon Cloud, but also we have the highest levels of controls in place and leverage best practices when it comes to software development and storing data. We get audited by clients regularly, and with more than 100 clients, we have gone through all kinds of checks, and we review current regulations regularly to stay updated with new rules.

Andrii: You touched upon the matter that the clinical trials are kind of becoming more complex. Can you elaborate on that a little bit more? Like, what the current situation in this industry looks like, and how clinical trials are different from what they were 20-30 years ago? What are the trends now?

Raj: Well, first of all, last year changed a lot -- the pandemics forced more collaborations in the areas of clinical trials. Also, the coronavirus has become a catalyst for companies in our industry to embrace new technologies, take more risks.

Over the last two-three decades, science has evolved significantly, but I would say the clinical trials process did not change much in terms of technology adoption. I can give you a simple example -- before COVID-19 we have been talking a lot about how it is critical to transforming clinical trials where we make it easier for patients to be part of trials. You heard a lot about virtual trials and decentralized trials, but the

change is slow. What is exciting is that COVID-19 pandemics seem to have accelerated this whole technology adoption rate, where companies are investing in technologies and modernizing the technologies and doing some progress across the entire value chain. New technologies are being implemented to gain efficiencies and to reduce cycle times which was needed to get regulatory approvals quicker.

Another important trend is that there is a lot of intent and also research and adoption around artificial intelligence and machine learning technologies.

Speaking about data complexity, every trial is different, every therapeutic modality has its peculiar contexts and data types, so the challenge here is you have the variance of data structures across trials -- how do we apply technology and how we should train machine learning models in the right way to be efficient at capturing the right kind of insights from data. But I think we are making huge progress and e-clinical solutions are on the rise.

Andrii: Can you give some examples where your system brings efficiency for a user? A specific use case where your company helps improve the clinical trials?

Raj: We help life sciences companies with modernizing and digitizing clinical trial processes. The number of sources for each clinical trial on average is maybe around 10-15 sources. When you are getting all this data as part of the clinical trial process, clinical data managers are responsible for its review and cleaning so that analysis can be done, and also this data can be packaged for submission.

Data cleaning is incredibly inefficient without systems like *illuminate*® where you can review this data, analyze it, and clean it in near real-time, providing capabilities for reviewers to quickly take action. You can have workflows where they can collaborate with data providers to resolve the data issues and in the end, can expedite this cleaning and monitoring processes. This helps statisticians and people who do analysis with achieving results quickly and submitting data to regulatory bodies fast, maintaining a high quality of data and analysis.

Andrii: I see that your system helps clean and essentially prepare data for analysis, but does your system actually perform the analysis?

Raj: We don't do the analysis as such but we enable the analysis at scale. One use case is when our models use machine learning to identify data issues or anomalies to alarm the reviewers. The amount of time needed for review drastically reduces. Similarly, we have another use case where machine learning models can provide or detect outliers -- and also predict scores to detect any sites where there are certain issues or where the sites are not operating efficiently. Machine learning models can help to predict risk scores so that if you are part of clinical trial operations you can quickly take action.

Andrii: What do you expect in the future of the clinical trial industry?

Raj: There is a huge opportunity ahead of us and definitely there is no going back in terms of how clinical trials were done before COVID-19. I suspect three to five years from now there will be significant adoption of technologies like AI and machine learning across the complete clinical trials value chain. Also, we will make use of real-time data coming directly from patients, like from smart devices or apps. And there is no way you can actually tap into this data and generate value out of it or get insights into it without leveraging advanced analytics and machine learning models.

At the same time, there are several use cases within our space which is a small data problem. The data variance across trials and the structures is quite complex to deal with so again even with that AI will play a big role. I believe for everyone involved in the value chain whether it is software companies or the sponsors, the competitive advantage will come from a successful combination of both human intelligence and automation -- what we call augmented intelligence. Besides, there will be even more convergence between technologies like cloud, machine learning, and digital tools for clinical trials in the future.

Andrii: Would you agree if I say that clinical trials is the area that might have the biggest short-term impact by adopting artificial intelligence? I mean, compared to, say, basic research, preclinical discovery, and so on?

Raj: I don't know if I can say that it would be the number one space, but like you said there is a huge opportunity for AI in the clinical trial space. What is certain, AI will help industrialize the drug discovery process. And definitely, AI can significantly help automate and scale clinical trials -- but importantly, it is not just about AI and machine learning, it is about data platforms in general, including modernization of the data infrastructures, etc. You need mature data pipelines to efficiently apply AI. Modern data infrastructures along with AI and machine learning will be key enablers that can dramatically transform clinical trials and help expedite overall research.

As they say, artificial intelligence is as good as the data behind the models.

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