INTIENT CLINICAL WEBINAR
VIDEO TRANSCRIPT

RAHUL KABRA: Hi everyone and welcome to this webinar series on INTIENT. My name is Rahul Kabra. I lead our INTIENT Platform business in Europe and I'm joined today by Patrick Warren, who's our INTIENT Clinical Lead. We're very excited to talk to you today about INTIENT Clinical. One of the foundational product suites within INTIENT.

And so, we're going to start with an overview from Patrick. And, Patrick, let me just start by asking you to give everybody a little bit of your own background. You've been working in this space for many years. And then perhaps we can just start with a bit of context around what are the real challenges that we see within clinical development? So over to you, Patrick.

PATRICK WARREN: Thanks, Rahul. So I'm a scientist by training with degrees in chemistry, biochemistry and biophysics and some post-doctorial training in molecular biology. So I came from the bench. I've worked in pharmaceutical industry for 15, 20 years or so. I joined pharma as a biopharmamatician, the old word for data scientist and worked in data analysis in several different therapeutic areas, including anti-infectives and oncology. I also worked through my time in pharma as a product manager, building software systems across the drug discovery pipeline, from research, to pre-clinical development, to clinical development. And before joining Accenture, I worked as a vice president of clinical systems supporting a major clinical research organization in the local Philadelphia area.

So clinical development is a really, really interesting and challenging area. Clinical trials are the most complicated of biological experiments. In a moderate sized clinical trial, one has to coordinate the physical observation and measurement of hundreds of patients across dozens of clinical sites and countries over many months and sometimes years and must collect and clean and analyze data from dozens of laboratories, devices and instruments from the select population of patients, all coming in asynchronously as patients visit the sites.

And it's growing, frankly, even more complicated. Recent advances in technology have lowered the cost and made it easier to make comprehensive molecular and physical measurements on patients remote to traditional medical centers. In addition, real world patient data can be assembled to complete our understanding of patient's environment and behavior, providing the clinician a full view of the patient's journey within the context of a clinical trial.

So the increased data and changing methodologies are really challenging the traditional roles and processes and software used in the current clinical trial context. What can we do about it?

As we're thinking about building out INTIENT Clinical, the goal, our goal, is to take advantage of current trends and modern computing to make it easier to collect and manage the increasing volumes of clinical data. By automating the ingestion and transformation of incoming data, integrating across all the data sources and presenting data in analysis ready formats, we want to be able to shift the balance away from the routine and help drive new insights into clinical analysis.

And as the cost of running the trials drop with this level of automation, more trials can be conducted driving new and better medications into the hands of our patients.

So where should the focus of INTIENT Clinical

be in reality? So our focus is really on building out that ingestion framework that allows us to bring in data from any source or any system in any format. From there, we can integrate and transform that data into the clinical repository in a standard form, similar or like the Study Data Tabulation Model, SDTM or other forms, depending on what kind of data or what domain you're looking at.

From SDTM, we can reformat that data into analysis data sets like Adam for biostats or many others like rapid medical monitoring or pharmacological modeling, for example.

NTIENT Clinical is meant to be an integration and analytics engine sitting on top of the traditional transactional layer like the EDC, the Data Management Systems, CTMS and ETMF, for example.

Next slide. So what are the product modules offered in the INTIENT Clinical suite. Our product suite is made of several solutions and modules as shown here. The solutions are underpinned by two main data warehouses, we call Evidence Repositories. One for study data and one for operational data. Our operational insights features rapid ingestion, flexible modeling and sophisticated data visualization and issue management capabilities. This allows you to effectively monitor and maintain the health of your clinical trial or your trial portfolio.

In addition, we offer several other applications, SDTM and SDTM confirmation application, we call the Study Data Engine to automate as much of the ingestion and transformation as possible on the patient data or study data side. And for those programming activities we find difficult to automate, we offer a powerful cloud native analytics environment similar, but superior to a traditional statistical computing environment.

RAHUL KABRA: So, Patrick, it's an incredibly complex area and you set out an ambition that we have with what we do with INTIENT Clinical to address it, which is fantastic. Can you just tell everybody a little bit about the approach that we're taking and why that's different to what has been tried in the past and the way we're leveraging the technology in order to take a different approach and how that's going to help drive some new benefits with what we're doing with INTIENT Clinical?

PATRICK WARREN: Absolutely, Rahul. So in my past and in my practice, I've been a part of building software in a number of different domains and I see many attempts to model all of the clinical data into one system or one model. And, ultimately, these models really become very difficult and overwhelming to maintain and become much too rigid to use effectively.

So in the INTIENT Clinical Practice, we decided to take a page out of the domain driven architecture and we've been following their principles and coined the term bounded domains and that's what we're using to build out our system. The principles of the architecture principles that we're following gives us a lot of freedom to model the data, like study your patient data, as I mentioned, or operational data, for example, independently, but interoperably. And so, it gives us that evolvability, if you will, that allows those models to continue to grow and evolve as the data types grow and change over time.

RAHUL KABRA: Thanks, Patrick, for taking us through the overview of what we're looking to do is pretty ambitious and I know we have an ambitious roadmap for forensic clinical. Can you talk to us a little bit about the approach we're taking and how it's going to be different to what has been tried before and why we think that's going to drive the benefits we're aiming for?

PATRICK WARREN: Absolutely. So in the past, there have been a lot of attempts to try and model all clinical data into one big model or one big system. Ultimately, these models have become overwhelming to maintain and much too rigid to use effectively. So we've adopted a domain driven architecture principles or what we call the bounded domain principles to model and build out our applications within a given domain. This gives us the freedom to model the data like study and patient data, the measurements and observations of our clinical trial participants independently of say, trial operation data which are the metrics, milestones and cycle times of the given trial or portfolio of trials.

We can rapidly then evolve these data within a given domain to meet the growing complexity of the modern clinical trial. And, of course, keep interoperability in mind. So as we model these given domains independently, we maintain the interoperability between the domains, so clinical researchers and analytic folks can actually get

access to both those domains simultaneously to do the work they need to do.

So why does this matter? Why does this bounded domains actually practicing? What does it really give, what advantages does it actually serve for us? So in addition to the models being evolvable, we also allowed the opportunity to build out domain specific languages that avoid much of the traditional maintenance overhead, the current ETL tooling. The domain line which is we're building provide a high level business friendly solutions to accomplish work previously done by complex data and metadata management software.

Along with our domain specific languages, we're adding in data vault technology to further increase the level of flexibility and reproducibility required for effective data integration and analytic support. This is really the basis for the evidence repositories both our operational, as well as our study evidence repositories and the applications that we're building.

RAHUL KABRA: So, Patrick, that's really interesting and it's good to understand how we're doing this differently and how that's going to help drive these benefits. I'd like to bring us back to where we started and you talked at the beginning about what we're doing around automation, integration and, ultimately, trying to drive innovation. And let's think about the people involved in this, can you tell us a little bit about how you think that's going to really impact the people in the field, working in this area, the clinicians, researchers, project managers and then, ultimately, how do we think about this impacting with lives of patients?

PATRICK WARREN: Yeah, so this is – thanks, Rahul. So this is something we're really excited about. By effectively automating a lot of the routine behavior in the clinical trial practice, just literally bringing data in, reformatting it, cleaning it and trying to pass it onto actually get to the analysis. The software that we're building starts to actually take some of that routine and automate some of that routine behaviors away and that is going to really give people more opportunity to actually conduct the analysis and really think hard about the trial itself and the impact of the trial and that's ultimately going to help drive the cost and time down conducting the trial and allow us to like do more of these precious experiments and, ultimately, get

medications out to our patients faster.

So it's a really exciting opportunity to start to really allow people to focus on that analysis and do more of these trials to reduce the overall cycle times of clinical development from say the routine 15 years to say down to 7 to 10 years, which is going to have a huge impact on our clinical trial population and our patients themselves.

RAHUL KABRA: Yeah, how do we ultimately see that impacting the larger patients, Patrick? What do we think about that?

PATRICK WARREN: Yeah, so like I said, as you start to reduce the cost and time it takes to run a clinical trial and the ability to consume these new data types that give us a lot clearer view of the patient in their native environment and over a longer period of time, as opposed to an artificial environment, for instance, in a clinic. This really gives us the opportunity to tailor the medications to the patient to really build up precision medicines for those patients and actually conduct more of these experiments in a much shorter period of time. And that is a massive impact in a clinical trial development cycles right now. As the vast majority of the money and time is spent in clinical development. So if we're able to reduce those times and actually make better measurements, it's going to be able to deliver medications, more medications to more patients faster.
 And that's incredibly exciting and what we're doing here and what you're doing with the team and we think about using the word game changing sometimes, but it really feels like we're making a step change and enabling something here in the industry which is really going to bring benefit to people working in the industry and, ultimately, to impact more patients which is just fantastic. So thank you for taking us through that, Patrick, really appreciate it.

PATRICK WARREN: Absolutely.