Decentralized Clinical Trials

HIGHLIGHTS FROM NEXT GLOBAL 2021

In This eBook

Medidata's global event series of the year—NEXT Global—brought together industry leaders, life sciences change-makers, and patient advocates to map the future of drug development. This global event included keynotes, live and interactive roundtable discussions, breakout sessions, lightning talks, customer success stories, and product demonstrations.

In this eBook, we've compiled highlights from the most popular sessions that focused on decentralized clinical trials (DCTs), including topics such as the pivotal role of technology in COVID-19 vaccine development, changes in the healthcare industry and regulations, the value of strategic partnerships in patient-centered technologies, and how a platform-first mindset is being embraced in clinical trials.

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Rosamund Round
VP, Patient Innovation Center and Decentralized Trials, Parexel

Anthony Costello
CEO, Patient Cloud, Medidata, Dassault Systèmes

To view these DCT-focused NEXT Global sessions on-demand, please visit:
https://www.medidata.com/en/next-decentralized-trials

In this session, Anthony Costello, CEO, Patient Cloud at Medidata spoke with Rosamund Round, VP, Patient Innovation Center and Decentralized Trials at Parexel about DCTs and the phenomenal progress being made in the industry.

Definition of DCT

ANTHONY COSTELLO ▸ When it comes to DCTs, there seems to be a thousand different definitions. The easiest way to think about it is that there are many ways we can help provide an opportunity for patients to do something outside the site setting. It doesn't have to be all of the technology. Even just ePRO studies, studies that allow consent or consent amendments to be done at home, as well as certain site visits that can be skipped or turned into video visits. These types of little changes to a protocol can have a big impact on patient burden. If we can work with our customers to design protocols and have access to these types of technological advancements to move trials into a decentralized framework—from the first visit to the end with data sharing—then I think we're starting to get somewhere.

ROSAMUND ROUND ▸ Absolutely. We've had such great feedback from patients and sites over the last year. Many patients are scared to go into hospitals. If you've got a preexisting condition, going into a hospital for a clinical trial may not be number one on your list, depending on how severe your condition is. So it's been a lifeline for a lot of patients.

When conducting our first feasibility for DCT, sites were repeatedly providing feedback that they were not going to do telehealth visits because that wasn't how a clinic is run. Now, that is just mainstream and how people operate. Things that were barriers before have completely changed. DCTs are here to stay and I'm excited to see where this takes us next.

> **Over the last year, DCTs have absolutely moved to the mainstream. I've never seen adoption of any innovation at a rate like this. Although obviously fueled by the pandemic, we've seen so much adaptability and enthusiasm from patients, sites, and our sponsor partners as well. It's definitely moved from something new and different to being embedded in the business and just how we deliver trials.**
>
> **Rosamund Round**
> Parexel

Minority populations and diversity in clinical research

ANTHONY COSTELLO ▸ There has been a healthy increase in focus around minority populations and diversity in clinical research. We need to be thinking about ways to design studies and engage patients to make sure that we're studying the same reflective population that's going to actually use the products in the real world once they're approved. You have done an enormous amount of work at Parexel focusing on diversity and you personally hold this as a very important part of your job.

ROSAMUND ROUND ▸ Absolutely, it is such an important topic. The last few years have shown us that focusing on supporting underrepresented communities in learning about and participating in research is absolutely critical. DCTs aren't the only answer, but if done well, they can definitely have a positive contribution to moving this area forward. Working with these communities to look at what it is they need and what hasn't been provided by research in the past. It is critical to examine how we can reduce the financial burden, the practical burden, and the geographical burden of participation.

We've been speaking to many people from different racial and ethnic communities, as well as the transgender and non-binary communities too. There's a large degree of fear within those communities about feeling comfortable in medical situations or in a clinic. If you have overnight stays on a trial, what does that mean in terms of which ward you'll be on? Are people going to be respectful? Are you going to be revealed to those around you?

Having a DCT can support patients because they can participate from home and not have to worry about some of those things. It can definitely help in terms of access and support issues, such as socioeconomic status, age, gender, and all these other differences that make us special. In talking with a professor about neurodiversity and people's abilities to understand an informed consent form—when done well, eConsent can be very helpful in terms of simplifying the information being presented.

Sometimes, it's the simpler parts of a technology rather than the fancy processes going on in the background that have the most impact for patients. Thinking about when providing devices to patients, when does that help them? What about home nursing? Do they want someone in the home or should it be nearby? We have learned a lot and are deploying many different ways of improving that access and experience for patients, which I'm really proud of.

> **We always hear that half the hassle of being in a trial is the practical, not just the medical.**
>
> **Rosamund Round**
> Parexel

What types of DCT-related technologies are being used by Parexel?

ROSAMUND ROUND ▸ We have definitely seen a lot of new technology in this space. Aside from that, in terms of the actual functionality, virtual visits have been critical this year to trial continuity, patient safety, and data quality with so many hospitals closed to anything but emergency cases.

ePRO and eConsent have been very important too. Sensors continue to be of interest—particularly for exploratory endpoints and people thinking if something can't be done in the clinic, how can we do it in a different way? What sensors are available? There's obviously a lot of variation in those sensors and how they could be used. So we are very careful about how we select the right sensors and how we validate those sensors before we use them.

Patient registries have been useful as well, in terms of thinking about rare disease patients and some of those underrepresented communities. DCTs are so common now that it's just another way that we work.

Other interesting tools include micro-sampling, where patients can take the blood draws themselves, as well as the community care circle for things that can be done near the home and not necessarily in the home. With the pandemic, not everyone is comfortable having someone in the home for things like home nursing and there's also not enough nurses available because so many have been pulled into hospitals.

Build it around the patient, make their lives easier. If it's easier for them, it's more convenient for sites and you get better compliance, better recruitment.

Rosamund Round
Parexel

Data returns are something that we're hearing more about with patients who finished a trial. They want to know if they received the investigational product and if the drug was ultimately approved. Providing more consistent data for returns is something that patients feel is very important, as well as giving them a package at the end so they know exactly what went on. That optionality for patients is something that is hard operationally to achieve, but conceptually is important to meeting patient's needs and ensuring they have different choices.

KEYNOTE

Labcorp and Medidata's Sensor Cloud: Creating a Shared Vision to Transform Clinical Insights through Digital Health Technology

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https://www.medidata.com/en/next-decentralized-trials

SPEAKERS

Dr. Bola Oyegunwa
VP and Global Head of Decentralized Trials, Labcorp

Anthony Costello
CEO, Patient Cloud, Medidata, Dassault Systèmes

This keynote brought together Anthony Costello, CEO, Patient Cloud at Medidata, and Dr. Bola Oyegunwa, VP and Global Head of Decentralized Trials at Labcorp, to discuss their partnership in seeking to bring better sensor data ingestion and biomarker discovery to decentralized trials with the Sensor Cloud platform.

Together, they offered perspectives on the growing interest in sensor technology, the need for data standardization, their first collaborative project on the Six Minute Walk Test, and the benefits of incorporating sensor data into DCTs.

Why the sudden or rekindled interest in sensors in clinical trials?

DR. BOLA OYEGUNWA ▸ This has been driven by multiple factors that are coming together at the same time. If you look at the FDA and their stated interest in drug approval based on improvement in quality of life (QOL), there are limited objective measures to evaluate QOL. Currently, most of them are questionnaires. There is also a gap between results from subjective quality of life questionnaires and objective physiologic markers. If you look at the current landscape, COVID-19 has pushed the need to develop all measures of drug efficacy, especially for high-risk patients who did not go to the clinic due to their enhanced risk for contracting the virus.

Biometric data can be used for drug development approval and/or monitoring of clinical drug effects outside of clinical trials.

Favorable effects on survival and hospitalization rates are not required for FDA approval. The absence of a favorable effect on survivors or risk of hospitalization can actually be a basis for approving drugs to treat multiple indications. If you look at some of the guidance from the FDA, it is actually possible that if a drug provides substantial and persistent improvement in symptoms, especially for patients with New York Heart Association class three or class four, a decrease in survival would actually be acceptable. Together, all of that means the FDA will consider trials that use novel endpoints, including all the clinical outcome assessments, measures of functional capacity, and measures of daily activities.

The need for collection and standardization of medical grade sensor data

ANTHONY COSTELLO ▸ There's traditionally been a challenge with the load of data that comes from sensors—especially the high-fidelity, high-density data that comes off medical-grade sensors. A big part of the Sensor Cloud program is the ability to collect and standardize medical grade sensor data. How do you think the Sensor Cloud ingestion engine and our partnership together can find a better way to standardize data across different kinds of indications and medical grade devices?

DR. BOLA OYEGUNWA ▸ The key obstacles to adoption have been the lack of effective infrastructure to integrate, collect, standardize, visualize, and report the data. Now that we have the ability to standardize and ingest the data, as well as an infrastructure for managing that data, we can use data to bridge the gap between objective physiological metrics and quality of life assessments. Our partnership is also providing an ability to measure physiologic parameters during daily life activities—particularly now that we have an infrastructure for capturing that large, clinical grade data set, and then standardize across utilization of several sensor devices.

I think our partnership definitely shifts the dynamics in terms of benefits along the cost, time, and value continuum.

Dr. Bola Oyegunwa
Labcorp

We have an ability to monitor patients long-term. Historically, patients would go in for a few minutes or a few hours, but now we can also provide results across a more protracted period of monitoring the patient. It also gives us access to novel physiological metrics that were previously unobtainable in large populations over long periods. These metrics include sleep quality, energy use, and heart rate variability. Theoretically, we'll be able to provide our own assessment of standardized exercise studies as well, in place of a patient going to the office to conduct these studies. This provides a way to start exploring drug effects previously undetectable by bridging the objective and subjective results into synchronization.

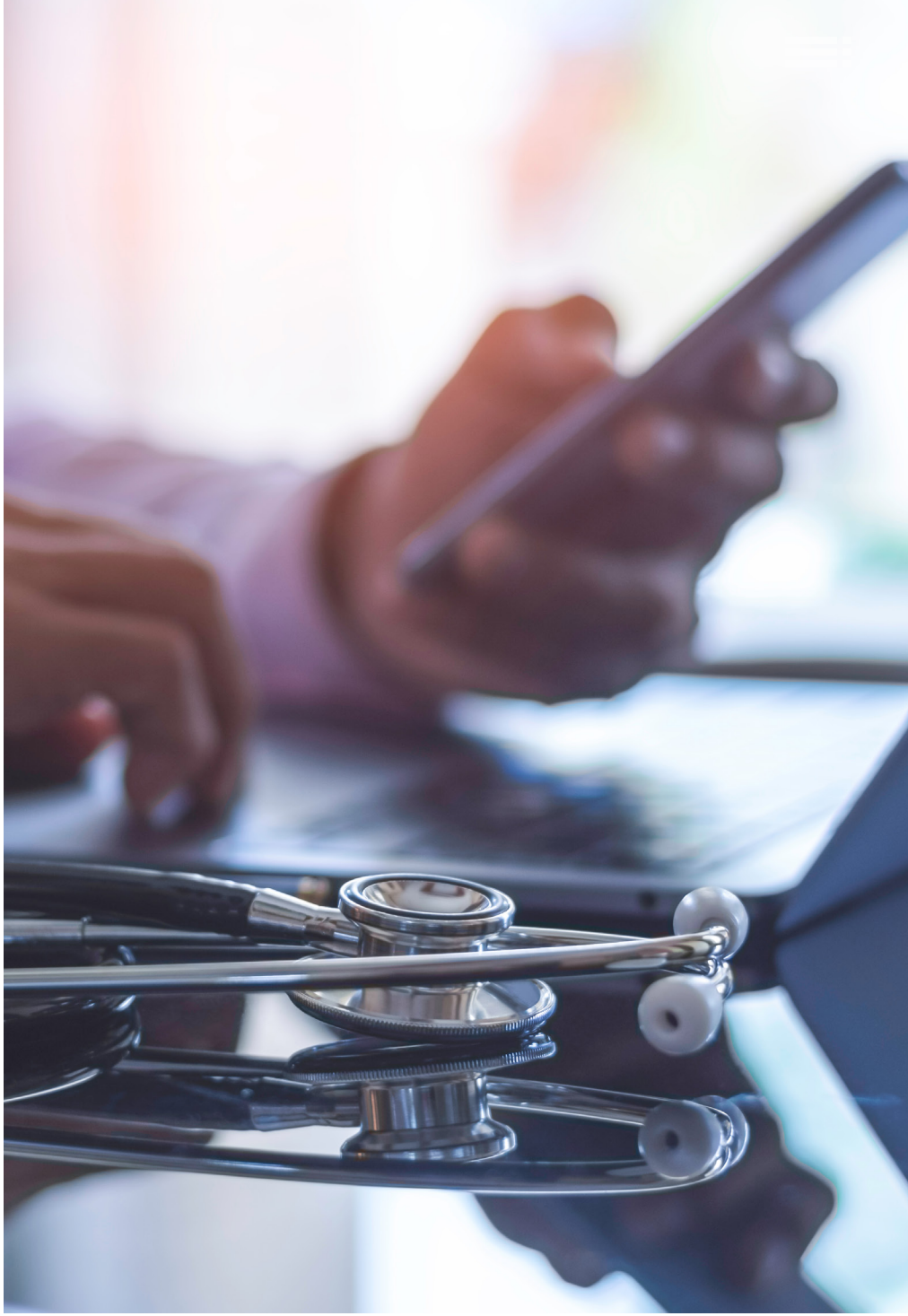
Bringing sensor data to DCTs

ANTHONY COSTELLO
We have to see this in the context of a broader decentralized trials approach, where we're looking for all kinds of different ways to bring data into the mix and understand a multidimensional way of seeing that patient. Sensor data can be an important part of that. The team at Labcorp are leaders in this space, and we're thrilled to have you be a flagship customer for Sensor Cloud and the ability to tie that together with other types of DCT technology to address some of these critical needs in the industry.

In our partnership, we are starting with the Six Minute Walk Test which is a key metric for a lot of clinical research studies. Can you talk a little bit about why we want to start with this test? And then if that works, where are we going to go from there?

DR. BOLA OYEGUNWA
In the context of DCTs, the Six Minute Walk Test can now be decentralized. It doesn't have to be conducted in the physician's office. By starting to combine digital biomarkers with DCTs, Sensor Cloud lets us capture this data at a rich level over a protracted period of time, and even execute that beyond the investigator's office.

Multiple failures in clinical trials are likely due to incorrect patient segmentation. Capturing, standardizing, and closely evaluating such a large volume of data will lead to improved patient segmentation, enhancement of predictive and prognostic enrichment, and targeting more suitable patient segments. There will be increased access to new patient populations that originally would not be able to go to the site, which is the DCT component, but also new patient populations that historically would not have been able to participate because we couldn't capture the rich data that would indicate their suitability to perform in clinical trials.



KEYNOTE

Impact of the Changing Industry and Regulatory Landscape

SPEAKERS

Scott Gottlieb, MD
Former Commissioner,
Food and Drug Administration

Glen de Vries
Life Sciences & Healthcare Vice
Chairman, Dassault Systèmes

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This keynote session featured former FDA commissioner, Scott Gottlieb, and Medidata co-founder, Glen de Vries. Together, they explored how changes in the healthcare industry are creating a "Brave New World" for clinical development.

The FDA remains the gold standard regulatory body. Dr. Gottlieb's knowledge and experience uniquely position him to reflect on how maintaining this gold standard will require the FDA to have greater and earlier global collaboration in a more iterative process, especially in cases of public emergencies. The discussion covered a number of related questions that can be broadly fit into the following topics:

- The role of the FDA moving forward
- Decentralized clinical trials and data-powered insights

The future of the FDA

GLEN DE VRIES ▸ With COVID-19, the FDA has come under scrutiny—both from physicians and scientists, as well as the court of public opinion—in terms of what "good" looks like from an evidence perspective. How does the future of the FDA look? Is the agency and its place in the world changing? Or are we still in the same business of evidence that we're presenting to the FDA, as we were in the past?

SCOTT GOTTLIEB ▸ I don't think the FDA has undergone any kind of fundamental change. I think that you've seen the agency use certain authorities in a more aggressive fashion, and that has probably had some secular impact on how the agency thinks about its approach going forward. Particularly with the use of real-world evidence to inform regulatory decisions, with the use of different forms of data collection, allowing patients to collect data, shipping drugs to patients, and allowing them to self-administer drugs. Some of the innovation in how clinical trials are conducted to deal with a pandemic situation are probably going to become more routine.

Thinking about the more secular trends that are underway in the regulatory scheme, you're going to have increasing scrutiny of some of the accelerated approval pathways that the agencies used to try to get drugs to patients more efficiently targeting unmet medical needs.

And the other secular trend that's underway is this movement towards using real-world evidence and different forms of evidence generation, as opposed to just the empiric model to inform regulatory decisions. I think you're going to see those methodologies get better over time and become more validated in scientific circles, leading to regulators relying more on them. The old, frequent test model for how we generate evidence is optimal for certain settings, but in certain situations it's suboptimal—especially when you have the ability to collect very large data sets and interrogate them very effectively.

What are the new parameters for evidence in the regulatory approval process?

GLEN DE VRIES ▸ The incorporation of more data from different sources allows us to be more precise in terms of a rare disease or looking at patient populations more specifically than in the past. The FDA has long been the global gold standard for what "good" looks like from an evidence presentation perspective. It sounds like maybe that gold standard will change, but we shouldn't be thinking that the gold standard is going to be eroding or moving around in a more dynamic global perspective or a more political perspective.

SCOTT GOTTLIEB ▸ In the context of COVID-19, some things have been accelerated where there might have been a higher level of uncertainty around a certain construct or approach; but in the setting of a public health emergency, it needed to be adopted and incorporated. The agency has made use of real-world evidence to try to accommodate missing data in clinical trials. Some of these approaches have been accelerated, but the reality is that the adoption of new approaches is only going to happen after there is a consensus in the scientific community. The question is the speed at which that consensus is reached; the agency leads this discussion, but it doesn't lead out in front of where the scientific consensus is.

It might feel slower than it should, relative to our appreciation for what the capabilities of some of these methodologies are. It also gets to issues of synthetic control arms and using historical controls and clinical trials as more therapeutics target significant, unmet needs, where it's hard to randomize placebo. You're seeing this in oncology where they have said, "we're not going to be doing placebo trials anymore, except in the narrowest of circumstances." You're going to see more and more use of these kinds of approaches, as well.

Decentralized clinical trials and real-time data monitoring

GLEN DE VRIES ▸ We're in this world where you previously had to be a clinical trial site and an investigator to participate in generating evidence. Now, we're going to have more data that just comes from physicians, who aren't necessarily part of a trial. We'll still have volunteers and research, but patients are contributing to bigger sets of data.

SCOTT GOTTLIEB ▸ That's what the electronic capture of information allows. It allows an electronic audit trail that can be more rigorous than physical inspections because you could do real-time monitoring. You can interrogate data in ways to make sure it was collected rigorously and that there wasn't inappropriate conduct. This is in contrast to physically inspecting the site and going through paper records, which could be highly inefficient. I think COVID-19 has also demonstrated this for regulators. Now, you have an electronic record that can be interrogated much more effectively. If you're having a patient self-administer the drug on Zoom, you now have a video record of the drug being administered, as opposed to a check in a paper manifest. That's much easier to interrogate. There's a perception that somehow you're weakening controls, but in some respects, you've actually strengthened them.

GLEN DE VRIES ▸ In some cases, this means getting better data. If I'm using a sensor or I'm asking a patient to report any symptom or side effect in real-time on their phone versus calling it into position, we'll get better data. How do you think this is going to have a positive impact on access? Is this medicine of the future that is getting designed now in clinical trials—where we can figure out how to treat people more broadly, more remotely? I certainly hope this has implications for how we can take therapies to more challenged populations, whether it's economically, socially, and geographically, and treat them.

SCOTT GOTTLIEB ▸ We've incorporated some of the technology into the conduct of clinical trials and accelerated the adoption curve. The leading edge of this will be what happens in the clinical space. That's now going to continue to evolve more quickly than what happens in the clinical trial space. The initial inflection point happened maybe in the conduct of clinical trials, or maybe it was simultaneous in terms of what we had to do to accommodate COVID-19. But now you're going to see the care delivery space innovate more rapidly. How we deliver clinical trials is going to be pulled along to take advantage of the opportunities that get created.

Because there has been a cultural change, societally, where we now embrace this. Previously, if my pediatrician would have said to my wife, "don't bring your child in if your child has a sore throat. Let's do a Zoom call." We would have said, "why doesn't this doctor want to have an office visit?" Now, if they say, "bring your child into the office," we'll say, "can we do a Zoom call first? Can't you send a home diagnostic test, so we can self-swab and get a diagnostic, and then you can do a virtual visit?" The whole culture of how we want to receive medicine is starting to change.

The whole culture of how we want to receive medicine is starting to change.

Scott Gottlieb
former FDA commissioner

KEYNOTE

Pioneering Next-Gen Medicine: How Moderna Delivered a Vaccine in Record Speed with a Strategic Partnership in Patient-centered Technologies

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SPEAKERS

Marcello Damiani
Chief Digital & Operational Excellence Officer, Moderna

Glen de Vries
Life Sciences & Healthcare Vice Chairman, Dassault Systèmes

Moderna has developed a new class of medicines at an unmatched speed the industry has never seen. Delivering more than 100 million doses in less than 12 months and forecasting to manufacture up to 1 billion doses in 2021 is a remarkable achievement that sets a new bar for the potential of future scientific innovation.

In this keynote, Glen de Vries was joined by Marcello Damiani from Moderna to talk about the technology and innovation that powered the digitized delivery of a highly-anticipated vaccine.

Moderna and Medidata's strategic partnership focused on bringing together a scientific mRNA platform with a clinical technology platform to address complex variables that needed to be harmonized to bring a COVID-19 vaccine to a global community.

Success is not overnight.

Marcello Damiani
Moderna

Clinical trial site selection

GLEN DE VRIES ▸ Speed of execution is always important in clinical development. From a population perspective, there have never been as many people waiting for an unmet need—in this case, protection from COVID-19. From a decentralization perspective, what were your approaches to making sure you could get data from patients everywhere? What was your philosophy in terms of using analytics? And how do you, in your modern approach to things, think about the site selection process?

The data is always changing. It's dynamic and you need to adjust with it. If you don't, your outcome will not be as optimal as you want it to be.

Marcello Damiani
Moderna

MARCELLO DAMIANI ▸ What we've done is we've partnered with both PPD (CRO) and the NIH to use existing data around sites and to identify the best places to go to from a site selection perspective. We actually looked at public data around the sites, such as the distance needed to travel, the type of population, which diseases are near the sites, and so on. All of this is key when you are doing clinical trials because they are conducted over a long period of time.

As the clinical trials were moving forward, this is where we have made decisions on increasing the number of people and adding other sites. This was purely based on data from databases.

Optimizing the process

GLEN DE VRIES ▸ Digital technology was used to make a difference. What were you able to spot and fix along the way?

MARCELLO DAMIANI ▸ I don't think it's about fixing, but it's about optimizing. How you go and use the data to optimize the outcome. To do this, you need to be very analytical. It cannot be by chance or by mistake; it needs to be deliberate. You need to read the data, analyze the data, and make sure you're taking the right insight from the data. That's the key piece when you go to clinical trials. It's not only the digital piece, but it's all our clinicians and our team that worked on this to ensure that we're getting the best outcome from that clinical trial. The vaccine was key at that time, as there was nothing to fight COVID-19. We wanted to make sure we had something that could help the world and that's what we've done.

Decentralization and the patient-centric perspective

GLEN DE VRIES ▸ From a patient-centric perspective, you also performed data capture directly from the patients themselves?

MARCELLO DAMIANI ▸ We used mobile tools from patients so we could understand what was happening. That's critical in any clinical trial. We've been extremely happy to have a high rate of engagement from the healthy volunteers during those clinical trials. That was key from a clinical standpoint and crucial to the outcome.

GLEN DE VRIES ▸ You were right on so many things that really helped deliver your vaccine. What are your thoughts about what comes next? What's in the future for our industry, from a digital perspective, and what defines operational excellence?

MARCELLO DAMIANI ▸ We have 37 programs now, and 22 of those are in clinical trials. To be able to manage all of those programs at scale, digital is becoming key to analyze and capture the data and make sure that you are getting the best of the clinical trials.

In addition to the COVID-19 vaccine, we are also working on a cancer therapeutic, where the data is more complex. When it comes to personalized cancer vaccines, the data is also sometimes personalized. The data environment that we need to build for this needs to be 10 times more intensive than the one that we have today.

Another element that is key to us is the external data that exists within the healthcare systems, hospitals, or any other health environment. That data can help in drastically improving what companies do from a clinical trial perspective to achieve the best drugs to help cure any disease. This is what we're focusing on. Add to this some of the sophisticated algorithms that we have today to help curate and take insights from the data—a human mind cannot achieve that.

BREAKOUT SESSION

Moderna and Medidata: Solving the Impossible for COVID-19

SPEAKERS

Laurie Callen
Senior Director, Clinical Data Management, Moderna

Jackie Kent
EVP, Chief Customer Officer, Medidata, Dassault Systèmes

Jason Dacko
Client Services Principal, Medidata, Dassault Systèmes

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The COVID-19 crisis emphasized the pivotal role of technology in accelerating safe clinical trial development. Medidata technology helped Moderna bring a COVID-19 vaccine through the full clinical trial life cycle in under one year—enrolling 30,000 subjects in just 12 weeks.

For this effort, Moderna used a suite of Medidata technologies, including Rave EDC (electronic data capture), eCOA (electronic clinical outcomes assessment), and Detect (centralized statistical monitoring). These tools allowed study teams to course-correct before trial quality and timing were affected by potential risks.

In this session, experts from Moderna and Medidata discussed their phenomenal achievement, as well as the critical role that decentralized trials played in helping bring Moderna's vaccine to market.

moderna

Through the use of these various tools and solutions, we believe this helped enable a very rapid clinical database design and eDiary deployment, as well as greatly streamline the ability to collect and clean the data throughout the conduct of the clinical trial.

Laurie Callen
Moderna

The challenge of a large-scale COVID-19 vaccine clinical trial

When it was first understood that Moderna would be conducting a clinical trial of such magnitude for the COVID-19 vaccine, we knew that we would need to think strategically and innovatively on how to support such rapid, high-quality data collection. Based on our existing relationship with Medidata, we reached out to evaluate our solutions. Some of the possibilities that we discussed together included leveraging our already-existing global library of case report forms (CRFs). This global library also included components of our electronic diary.

Additionally, we looked at the utilization and further deployment of Rave Safety Gateway for the collection and processing of serious adverse events, as well as the use of the Detect tool for visualizing error and trend detection within the data.

Does the eCOA approach used with COVID-19 give Moderna confidence for other large programs like Flu, RSV, and others?

Moderna is extremely keen on standardization, efficiency, and reuse and use of global libraries wherever possible. This includes standards for our electronic diaries which help support and drive high-quality data collection, as well as the ability to analyze and report on the data.

The development of the standard eDiary specifications over the years has streamlined the deployment of these tools for our trials. The standard supports the entire clinical trial conduct and has enabled us to have a rapid database build and also allowance for more streamlined data collection. This includes data reporting and analysis, as well as all of the other downstream data flows. As a result, Moderna has high confidence in the continued use of our standardized electronic diaries in the various upcoming clinical trials.

How did tools and technology help with the data analysis and decision making leading up to the emergency use authorization in December 2020?

We used Medidata Detect for our COVID-19 trial. We knew this data analytics solution would help us identify potential errors and trends within the data. This would then allow us to improve data integrity and reduce trial risk.

The use of Detect allowed cross-functional members across our team, including clinical operations, data management, and clinical research, to determine where there might be challenges or gaps in the data and where potential actions may be needed. Those actions could include follow up or further training to the clinical sites and further explanations of the clinical protocol to various partners. Making use of a data analytics solution allowed us to pull together various data sources, which enabled a rapid, robust, and rigorous data visualization to determine what possible steps might be needed throughout the data collection process.

What elements of the Moderna-Medidata partnership were critical to the program's success?

We knew that we could rely on and trust the partnership that Medidata and Moderna have built over the years. We knew Medidata would put forth their most innovative and thoughtful solutions to support whatever the need was. The Medidata team truly was—and still is—very much an extension of Moderna. Each Medidata team member was called to action and supported this very important trial and showed dedication and commitment to a greater cause.

Will the innovations implemented for the COVID-19 vaccine trials change how future trials are conducted at Moderna? What about data management across the entire industry?

The task is now before us to assess, consider, and reflect on best practices and best processes.

- **We must identify the technologies and solutions that we utilized to help support such large scale, rapid clinical database development and builds, as well as high-quality data collection.**
- **We must examine what worked and what we should continue to consider innovating and building such that we can continue to drive clinical trial processes forward.**

By working with Medidata and assessing their various solutions, such as decentralized clinical trials and tokenization, we can see how to utilize these technologies for future clinical trials so that we can deliver high-quality medicines and therapeutics for patients worldwide.

COVID-19 has made us all patients.

Jackie Kent
Medidata

DECENTRALIZED CLINICAL TRIALS: HIGHLIGHTS FROM NEXT GLOBAL 2021

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,800 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at **www.medidata.com** and follow us **@medidata**, The Operating System for Life Sciences™.

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