# The Future of Clinical Trials: Perspectives from BD and Exact Sciences

The pandemic pushed medtech to move faster, and leaders are riding that influence to discover sustainable efficiencies throughout the organization. Learn from two medtech experts on how they are enacting long-lasting change in their organizations.

There is always a demand for medical innovations to be delivered faster, but the COVID-19 pandemic accelerated trials to a new level as we've seen over the last two years. While this speed is likely unsustainable, this has been a catalyst for the medtech industry to embrace technology to do things faster and more effectively.

In a recent session at the Veeva MedTech Clinical Forum, clinical leaders from BD and Exact Sciences discussed how technology is transforming product development for devices and diagnostics. Panelists agree it's been an awakening moment for the industry and shared how they are working to establish better infrastructure to prepare for the future.

Read on to learn how these companies are leveraging technology to streamline processes to get products to patients faster.

## **Transforming Clinical Systems**

With the significant M&A activity in medtech, many companies are faced with the challenge of dealing with as many as 40-50 disparate systems that need to be connected in order to create a global clinical infrastructure. In these situations, teams cannot rely on the way things have always been done, instead they need to dig deeper into why certain processes are in place and determine if they're integral to the business. Those integral processes should then be evaluated with a critical eye for efficiency and improvement.

John Acampado, Sr. Manager Clinical Affairs at BD, challenged the status quo and is now constantly looking for ways to make things more efficient across the clinical organization. "We wanted to have everything under one roof and partner with a forward-thinking organization to help us streamline. Veeva provided the most value," he said.



#### **Rethinking Site Monitoring**

The pandemic forced Marla Kuleszynski, Sr. Clinical Study Manager at Exact Sciences, to implement remote monitoring as an option for her studies. "I used to pull that out of our contracts, but once the pandemic hit, I was on the phone trying to add it back in," she said. Now, it's expected for sites to have a plan in place for remote monitoring.

By leveraging Site Connect and Site Vault, BD tries to make things more efficient and effective for sites. "There have been high levels of attrition at sites," commented Acampado, so they focus on finding ways to make the information transfer from sites to sponsors as seamlessly as possible. "Automation will be our friend," he said.

Exact Sciences examined their site-management and data review strategies. "Veeva tracks metrics and issues and allows us to spend our extra effort with sites that need the attention," said Kuleszynski. "It allows us to be smarter about the way we handle our site monitoring."

Standardizing remote monitoring to help eliminate concerns from sites is a focus across medtech. Some sites believe remote monitoring takes longer than traditional approaches, but it can be more efficient with proper tools and expectations in place. Remote monitoring also allows sponsors to flush out errors with data analysis.

### **Delivering Patient Value**

"The way we're going to deliver value to our patients is to be forward-thinking. We can't continue to do trials the same way, and the momentum from the COVID pandemic has pushed us to learn how to do things better and smarter," said Acampado.

"How can we take advantage of the resources and infrastructure that we've already created to find efficiencies," asks Kuleszynski from Exact Sciences. They have started using the same forms and edit checks to save on time and resources.

Some medtech companies are also adopting patient profiling instead of traditional models of risk-based study management. With the data available, they can identify which data points are essential. By reducing the administrational overview of standard data, you can transform the way to conduct studies.

"How can we leverage the data to streamline the process and find a more effective way to do clinical trials," asked Acampado. By looking at past data, BD focuses on identifying critical points in the study to put resources like additional edit checks.

#### **Maintaining Forward Momentum**

The focus of our panelists is to maintain that collaboration by finding better and more efficient ways to conduct studies and transfer data, including embracing technology and having a single source of data. One of the ways BD and Exact Sciences are unifying clinical operations is through the Vault Clinical Operations Suite.

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