Cook Research: A Global MedTech's Journey of Digital Transformation to Speed Clinical Research

Any company thriving after more than a half-century has had to transform in some way to meet the changing needs of patients and the industry. This is evident in medtech where clinical research is now global, data volume has exploded, and audit and regulatory requirements are more complex.

Cook Research Incorporated, a wholly-owned subsidiary of Cook Medical Incorporated (Bloomington, Indiana) has tackled these challenges through digital transformation.

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>
> *– **Jennifer Kerr,** President, Cook Research*

From modest beginnings to a global operation

What began in the spare bedroom of its founders, Bill and Gayle Cook, in 1963 in Bloomington, Indiana, is today a global organization, Cook Medical, which makes more than 16,000 medical devices that span more than 40 specialties delivered to 135 countries.

In the beginning, when the Cooks were manufacturing the first percutaneous wire guides and catheters from their home under the auspices of Cook Incorporated, there were no governing regulations for the development, approval, or oversight of medical devices.

To say that times have changed is putting it mildly. In 1976, the first U.S. regulations governing the development of such devices came into place. And in 1983, Cook Research was founded. Located in West Lafayette, Indiana, Cook Research initially focused on product development. However, that focus quickly expanded to include clinical research, non-clinical and pre-clinical testing, medical and scientific writing, and regulatory strategy.

Keeping pace with the growing complexity of clinical research

In the intervening years, clinical research has evolved from a largely siloed practice focused on the needs of a particular region to a highly regulated global operation. Along the way, it's gained a whole new layer of complexity.

"Suddenly, clinical research and product development become a much more complicated process," explains Jennifer Kerr, President of Cook Research. "You need to understand the regulations you're bound to in whatever country you're operating in. And you need to be able to adapt to rapid changes in all those regulatory markets."

Add increased global regulatory requirements, data privacy, a complex audit landscape, an explosion of data, and the need for real-time analysis, and you begin to see the enormity of the challenge.

"We wanted to start doing simultaneous clinical studies in multiple countries, but truly understanding and accounting for regional differences in regulatory requirements and varying expectations around data and patient privacy proved extremely difficult," explains Kerr.

A single source of truth for data

By 2013, Kerr and the team realized that to remain responsive , Cook Research needed a system that could capture and harmonize data from simultaneous studies in multiple countries to provide a single source of truth, and address the unique requirements for medical devices. The company decided to develop its own clinical trial management system (CTMS).

"When the new European Union Medical Device Regulation [EU MDR] was published in 2017, we knew we had a tremendous amount of work in front of us if we wanted to continue to manufacture the products we've had on the market in Europe—not to mention bring forward new technology and products," says Kerr.

The Cook Research team knew that it would have to revamp its current CTMS to handle these challenges and understood that maintaining and scaling such a system would be difficult and time-consuming. So they began looking for an external partner to provide a CTMS and electronic trial master file (eTMF).

The right solution would allow the company to easily (and automatically) keep pace with changing regulations in the global market, streamline global clinical processes, and enable collaboration in one place so teams can focus on research and clinical tasks.

Cook Research found that partner in Veeva MedTech. "We chose to go with Veeva because we knew that they would be able to respond to changes in the global market," explains Kerr. "We also appreciated Veeva's expertise and focus on medical devices. We knew that they would understand our language, our pressure points, and our global needs."

Aiming for constant transformation

Today, Cook Research has a cloud-based, unified solution that provides global collaboration and 24/7 availability, which is critical for global management.

Purpose-built with medtech requirements and processes in mind, Veeva Vault CTMS and eTMF help Cook Research:

- Create a single source of truth
- Facilitate global collaboration
- Accelerate clinical trials execution
- Ensure compliance in multiple countries
- Meet real-time data needs
- Always audit ready

As a result, Cook Research has harmonized clinical research and operations, improved visibility across the organization, and provided a unified system for global efficiency. With modern systems in place, Cook Research strives to be audit and inspection ready and has the scale and operational efficiency to support innovation and speed to market.

“The Veeva platform has allowed us to live in the ‘we are audit-ready’ mindset,” remarks Kerr. “So if a regulatory agency comes in, we are prepared to undergo an audit on their schedule.”

Today, Cook Research has more than 200 projects covering over 300 clinical sites in its Veeva Vault CTMS and eTMF systems, but its digital transformation is far from over.

“Our journey is not done,” says Kerr. “Our goal is to continuously look for ways to transform because the medical device ecosystem is never going to stop changing. If we can continue to be transparent in resource allocation and keep gaining in process efficiency, we will be able to achieve our goal of constant transformation.”

To learn more about Cook Research’s story, watch the webinar “Clinical Operations Excellence: How Cook Research is Taking Advantage of Digital.”

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