Toolbox Medical Relies on WCG IRB's Prompt, Personalized Expertise in an Unsettled Environment

The Background

Toolbox Medical Innovations is an ISO 13485 organization specializing in diagnostics development. During the last year, the company has been exceptionally busy, helping clients develop COVID-19-related products. In fact, they launched at least six studies in January 2021 alone. As Toolbox's client base and workload grows, it relies heavily on its long-time IRB partner, WCG IRB.

Why has the relationship with WCG IRB lasted since 2014? "It has the feel of a small company with the resources of a larger one," explains Jenn Zeis, CCRP, CCRA, VP of Clinical Operations. Conversations occur throughout anytime of the day, and those personalized one-on-one encounters are the bedrock of the relationship. Through these conversations, the two teams address challenges, prevent problems and get desperately needed products to market sooner.

The Unmatched Client Experience With WCG IRB

Tight deadlines, nimble partner: Even before the pandemic, deadlines for studies were tight. Toolbox typically has four to eight weeks for study startup, and sometimes as little as two weeks. "It's usually a mad dash to meet our goals, and many of the studies will have from three to 20 sites," Zeis

explains. Because it meets every day, WCG IRB's Board can process submissions thoroughly and at the speed required by Toolbox to meet its initiatives.

Urgent questions answered immediately: The close relationship means Toolbox can tap into WCG IRB's expertise any time via phone, email or through the WCG IRB Connexus submission platform. "I had a quick question, and everybody knows everybody's busy," recounts Colleen Monaco, CCRA, Director of Clinical Programs at Toolbox. Due to the time pressures, she decided to use the chat function in Connexus. "Within two minutes, someone responded with an answer, allowing me to move on with my day."

Reliable knowledge and guidance: This ability to ask for--and receive--expert guidance is one of the most important aspects of the Toolbox/WCG IRB partnership. A recent example involves the informed consent process--specifically, assent. Toolbox handles many pediatric studies and has been working to improve the assent process. WCG IRB and the Toolbox team created a signature block for all its pediatric studies. On the surface this may seem simple, but this process improvement has improved consistency and streamlined the process for onsite monitors reviewing ICFs.

Insurance against unexpected events: Toolbox has had only one serious adverse event in its lifetime of running studies;

> *Within two minutes, someone responded with an answer, allowing me to move on with my day."*
>
> — Colleen Monaco, CCRA, Director of Clinical Programs, Toolbox

---

> *"WCG IRB has just been amazing throughout our partnership, guiding us every step of the way with whatever issues we might have,"*
>
> —Jenn Zeis, CCRP, CCRA, VP of Clinical Operations, Toolbox

it occurred because of the way the protocol was written, and WCG IRB helped Toolbox work through it. It doesn't expect another SAE, but with WCG IRB's support, Toolbox is prepared.

Agile and personalized: "WCG IRB has just been amazing throughout our partnership, guiding us every step of the way with whatever issues we might have," says Zeis. "We pick up the phone all the time and say, 'What is the status on this?' When we email questions, I get a call: 'Hey, I got your email. Let's hash it out together.'"

Every conversation ends with WCG IRB asking this question: "How can we improve our service to you?" This approach means nothing is overlooked. That's yet another reason Toolbox continues its long collaboration with WCG IRB, along with unmatched access to IRB expertise and exceptionally personalized service.

Challenges and Solutions Addressed by WCG IRB

COVID-driven adjustments: With the looming pandemic, Toolbox needed to adapt quickly with evolving FDA regulations and new client demands. With WCG IRB's help, it succeeded.

The need to stand up COVID studies quickly: Rapid response times became critical during the pandemic. Toolbox needed to get sites up and running quickly. With WCG IRB's help, they did. Case in point, Ellume, a Toolbox client. The Toolbox client recently received Emergency Use Authorization from the U.S. FDA for its rapid, at-home COVID-19 antigen test. With WCG IRB's quick response, regulatory expertise and rapid turnaround, Toolbox played a critical role in planning, developing and executing successful studies and usability testing.

Adjusting to regulatory changes: The FDA has made significant changes in response to the pandemic, and WCG IRB ensured Toolbox stayed up to date with the latest guidance helping them navigate the changes. One important change was in device classifications--specifically, the difference between "exempt" and "non-significant risk." Toolbox worked closely with the IRB Board members, who carefully explained the nuances and ensured Toolbox was adhering to the most current guidelines.

WCG IRB also continues to support Toolbox with its non-COVID related initiatives.

The Grass Isn't Always Greener

"A few years ago, we were wooed away by another IRB for about six or eight months." Zeis had been more than satisfied with WCG IRB, so why the switch? The competitor appeared to be cheaper, which was a consideration for Toolbox's smaller clients. The move to another IRB didn't last. The Toolbox team missed the exceptional customer service and the prompt answer to questions. Moreover, after all the hidden costs and fees, Toolbox saw no meaningful cost savings.

Now, Zeis has no plans to find another IRB and they're back working with WCG IRB.

The Conclusion

> *WCG IRB has done such a great job, keeping the relationship going. One of our core values is to serve, and I think our two companies serve each other well,"*
>
> — Jenn Zeis, CCRP, CCRA,
> VP of Clinical Operations, Toolbox