Case Study: Curadel Surgical Innovations

Onboarding a combined CTMS and eTMF at a medtech company in 5 weeks.

The digital maturity of clinical trials and operations has been at the forefront of pharmaceutical and medtech strategies over the last decade. Many companies have yet to digitize their clinical operations for various reasons: antiquated habits, fear of adopting an electronic solution, deadline delays, or concerns about country, city, and municipality compliances. Listening to these concerns and finding the right solutions to address them is now the most important next step.

The Challenge

Curadel Surgical Innovations, Inc. (CSI; Boston, MA, USA), a mid-sized medtech manufacturer, needed a clinical trial management system (CTMS) with an integrated eTMF that could be rapidly adopted to conduct a new series of global clinical trials spanning two continents.

The CTMS had to fulfill these criteria:

- Fully compliant with both US FDA and EU regulations
- Easy onboarding and use for trial managers and CRAs, both internal and external
- A "one-stop" platform for clinical studies, incorporating an eTMF and eMVR (electronic monitor visit reporting system)
- Highly customizable to existing processes
- A responsive and easily accessible support team
- Smart integration with their current EDC
- Easily validated by the company's QMS (quality management system)
- A solution that provides a rapid ROI

The Result

CSI partnered with BSI Life Sciences to adopt an ICH GCP- and 21 CFR Part 11-compliant CTMS with an integrated eTMF and eMVR. CSI came into the onboarding process motivated to rapidly implement BSI's CTMS, with a small dedicated team and QMS in place.

The onboarding process was completed in five weeks, from an initial go-live and the adoption of BSI's proven standards, configurations, and built-in study templates for a high immediate ROI. CSI received two fully validated CTMS environments, validation and production, and completed an integrated three-day virtual training. BSI's API integration also enabledCSI to integrate with their current EDC solution.

Additionally, BSI provided a 4-week Hypercare program to assist CSI for ongoing maintenance after Go-Live. The partnership with BSI also opens CSI up to joining a network of like-minded organizations looking to run clinical trials safely and efficiently.

To learn more about BSI's client success stories, visit bsi-lifesciences.com/clients.html.

The Takeaway

- Fully validated software saves time and effort, so you can focus on what you do best.
  - Choose a fully validated CTMS or eTMF solution with proven standard configurations and templates, or a pre-existing eClinical solution.

- Gather information on software customizability to ensure an eClinical solution fits your needs.
  - Which use cases can be accomplished using BSI's standard configuration?
  - When is manufacturer programming required?
  - BSI's CTMS allows internal solution administrators to configure almost every setting by themselves–no IT background required!

- Choose to work with a CTMS provider that:
  - Has a record of successful software rollouts at pharma/medtech companies.
  - Travels with you throughout your trial.

About Curadel Surgical Innovations, Inc.

Curadel Surgical Innovations, Inc. is a clinical-stage pharmaceutical company developing near-infrared fluorescent theranostics for image-guided surgery. Its FLARE® brand of theranostics "light up" tumors, blood vessels, nerves, sentinel lymph nodes, ureters, and other anatomical structures that surgeons need to see in real-time. curadelsurgicalinnovations.com

About BSI Life Sciences

Offering smart eClinical software for CTMS, eTMF and more, BSI has been making life science software for real people for 25+ years. Our innovative, user-friendly software solutions are made in Switzerland, Germany, and the United States, and available anywhere a client may require.

By focusing resources on delivering functional, compliant, and affordable eClinical software, BSI helps its customers continuously optimize and accelerate the clinical development process, and that's what they love! bsi-lifesciences.com

BSI is a software house headquartered in Switzerland with global offices. **What can we do for you?**
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