medrio

Case Study

Medical Device Sponsor Deploys Medrio EDC and Yields a Multitude of Immediate Benefits

Israel-based Medi-Tate implemented Medrio as its first foray into EDC. They immediately benefitted from rapid study build, remote monitoring, and excellent training and support.

Looking for a Better Process

- Struggled with inefficiencies of paper CRFs
- Pursued large, multi-national device study
- Needed solution conducive to remote monitoring

Why Medrio?

- Outstanding customer support
- Ability to monitor sites and results remotely and access near-real-time data
- One-week build time for initial study, with one-day duplication

Medi-Tate's Success

- Benefits from flexible pricing model
- Rapid, easy staff training in Medrio EDC
- Planning 5 more studies in Medrio

Background

Medi-Tate Ltd., a medical device company based in Israel, was regularly using a paper-based process for collecting and managing data in clinical studies of its flagship product, the iTind system for treatment of BPH. By choosing Medrio as their introduction to EDC, they were able to take advantage of rapid study build functionality, remote monitoring capabilities, and top-tier training and support. Medrio proved an ideal system for the transition away from paper, providing speed and ease and helping the organization realize the benefits of the changeover immediately.

Looking for a Better Process

Lihi Liviatan, Vice President of Clinical and Regulatory for Medi-Tate, says the company decided to switch to an EDC because paper CRFs and other forms her company was using are simply too inefficient. "And the query process is just too cumbersome—we send the physician queries and wait for them to sign," she says. "When they reply, they may forget one of ten queries. And we have to send it back again, and then they need the original. It's a mess."

A key motivator for Medi-Tate to move to an EDC was the prospect of a large study with sites in the U.S., geographically far removed from the company's base in Israel. Medi-Tate's previous studies were in Italy and Israel, locations that made personal visits for monitoring much easier. Those studies also had only one site, and Medi-Tate staff could talk with investigators weekly and stay informed about progress. "But our current Phase III study has 15 sites in the U.S. and 170 patients," says Liviatan, "and we have to find a way to stay in close touch despite the 10-hour time difference and travel distance. We have monitors there, but we want to know as much as possible as quickly as possible."

Copyright ©2018 Medrio, Inc.
www.medrio.com

1-800-498-6830 345 California St. Ste 325
info@medrio.com San Francisco, CA 94104

Case Study: Medi-Tate

Why Medrio?

Medi-Tate chose Medrio's EDC solution to help manage and monitor the study in near-real time. With Medrio's cloud-based architecture, information from the U.S. sites is uploaded to the cloud, making it immediately available to Medi-Tate staffers in Israel for viewing, analyzing and reporting. "Morning for me in Israel is night for people at our U.S. sites, so if we needed to do this by phone, we'd have to wait probably 24 hours to find out if everything is okay," says Liviatan. "But with Medrio, I can log in first thing in the morning and make sure patient information is randomized and the testing is going well."

Approximately 60 members of Medi-Tate's clinical staff are using Medrio EDC, and Liviatan says the training process was easy, in part because the software is so "intuitive and easy to understand and use." According to Liviatan, using Medrio to build study forms has been a big time-saver. "For our second study, I just duplicated forms from our first study and made a few changes. It took me just a week to build the CRFs the first time, and only a day for the second." The quality of the data that Medrio EDC collects is critical to Medi-Tate because it's the data the company will send to the FDA to gain approval for its device in the U.S. "There are fewer queries, and the answers are more complete," says Liviatan.

Just as much as the product functionality, a major differentiator for Liviatan has been Medrio's customer support offerings, available 24/7 to all Medrio customers. She notes that the support team is consistent in immediately identifying solutions to hurdles that arise. "They're extremely prompt in responding to requests," she says. "And always check back in later to make sure the problem has been solved."

Medi-Tate's Success

Compared to the more intricate studies in pharma Phase III, device trials like Medi-Tate's have a simpler design and a greater focus on real-world patient experiences. Their eClinical needs are also more straightforward, and don't require extended EDC functionality. This makes Medrio, which offers the flexibility to meet the specific needs of studies ranging from simple to complex, a perfect fit. Unlike other eClinical packages that charge for expensive products that simple studies may not need, Medrio enables users to pay only for the tools and modules necessary for a given study, making it much more affordable, especially for smaller device companies like Medi-Tate. In addition, Medrio is flexible in offering additional, easy-to-integrate modules if necessary, and a patient-centric ePRO tool that facilitates easier receipt of patient-reported data.

For Medi-Tate, the transition to Medrio EDC has been well received by staff members, who find the system easy to learn and use, and appreciate that it streamlines the entire process of collecting and validating clinical trial data. Medi-Tate management sees the benefits of time and cost savings, as well as rapid access to trial results for analysis and reporting. In light of these benefits, the company is planning five more studies in Medrio. Summing up Medi-Tate's experience with Medrio and the move to EDC, Liviatan says, "The whole process with Medrio is so much simpler. Monitoring is easy and the data is always visible—if there's something like a trend or event you need to know about, you know it immediately. We still have one study using paper CRF, but we're closing it. There's no way we'll ever go back to paper."

Copyright ©2018 Medrio, Inc.
www.medrio.com

1-800-498-6830 345 California St. Ste 325
info@medrio.com San Francisco, CA 94104

Case Study: Medi-Tate

About Medrio

Founded in 2005, Medrio is a leading healthcare technology company providing eClinical solutions including EDC, eSource, and ePRO for clinical research. The company's cloud-based software platform and mobile suite of products deliver fast, flexible, and easy-to-use tools for the collection and management of clinical data and patient reported outcome responses. Study sponsors and contract research organizations have used Medrio extensively across drug, device, diagnostic, and animal health trials. Medrio has extensive experience in all study phases and leads the market in early-phase trials. The company serves over 500 customers globally, with headquarters in San Francisco and offices in numerous domestic and international locations.

For more information, please visit **www.medrio.com**.

About Medi-Tate

Founded in 2007, Medi-Tate is a privately held medical device company headquartered in Or Akiva, Israel, that deals in the R&D, manufacture and sale of innovative solutions for the treatment of BPH. The company's vision is to improve men's care and quality of life by commercializing an effective, non-surgical solution for BPH. Medi-Tate's flagship product, the iTind system for treatment of BPH, is CE Marked and available for sale in the European Union, Canada and Israel.

For more information, please visit **http://www.medi-tate.com/**

Copyright ©2018 Medrio, Inc.
www.medrio.com

1-800-498-6830 345 California St. Ste 325
info@medrio.com San Francisco, CA 94104