

Improving the clinical trial process

How Biorasi reduced costs, overhead and time





Building a clinical trial is an extensive and often time consuming undertaking that involves a laborious data entry process. Inefficiencies in the process can cause serious delays, and the cost of each delay in getting a drug to market can be incredibly substantial, depending on the price of the therapy and the market for it.

Most importantly, the inefficiencies can cause serious delays in getting potentially life-saving medicines to patients. The team at Biorasi, LLC was experiencing just these issues and was in search of a data science partner that could potentially shorten the development lifecycle of the drugs it was helping to get to market—and do so at a reasonable cost.

Biorasi is an award-winning organization that focuses on combining the personal care and attention of a customer-focused contract research organization (CRO) with the global capabilities of market-leading, full-service organizations. So, when looking for a data science partner, Biorasi wanted to not only find a partner that could help it get drugs to market faster, but also one that could provide the customer support it needed throughout the process.

According to Biorasi, the standard for an electronic data capture build is

73 days

Zelta clinical trials platform builds an electronic data capture in

<40 days

"The speed with which you can deploy in Zelta is crucial and has proven vital to clinical trials. And having technology that you can trust has been very, very important."

Roberto Silberwasser

Vice President, Data Sciences and Biometrics, Biorasi, LLC

Reducing costs, overhead and time

Intuitive design streamlines a lengthy process

After a comprehensive bidding process,
Biorasi selected Merative and its Zelta™ clinical
trials platform

"We found a lot of commonality with what Zelta offers, including common interests in the things we believe are important to clinical research," says Roberto Silberwasser, Vice President of Data Sciences and Biometrics at Biorasi.

Common interests included adapting to better processes and technology to get patients the drugs they need.

And immediately upon implementation of Zelta, the Biorasi team realized the convenience of the build process. "Zelta is very user friendly," says Sara Vaidya, Director of Data Management at Biorasi. "All of our users—from data management to the clinical teams to the

project management teams—are using the Zelta to its optimum potential because it is so easy to use."

Preparing the electronic data capture (EDC) includes entering trial data into several forms and data validations for all phases of the trial. The more intuitive a platform is, the more quickly clinical trial data can be entered and analyzed. However, many solutions are not intuitive and disjointed in the build phase and may require special programming skills, and the standard for these captures is **73 days to build and release a study**, according to Biorasi. Reporting in some databases using other EDC applications can potentially take even longer, sometimes nearly 80 days.

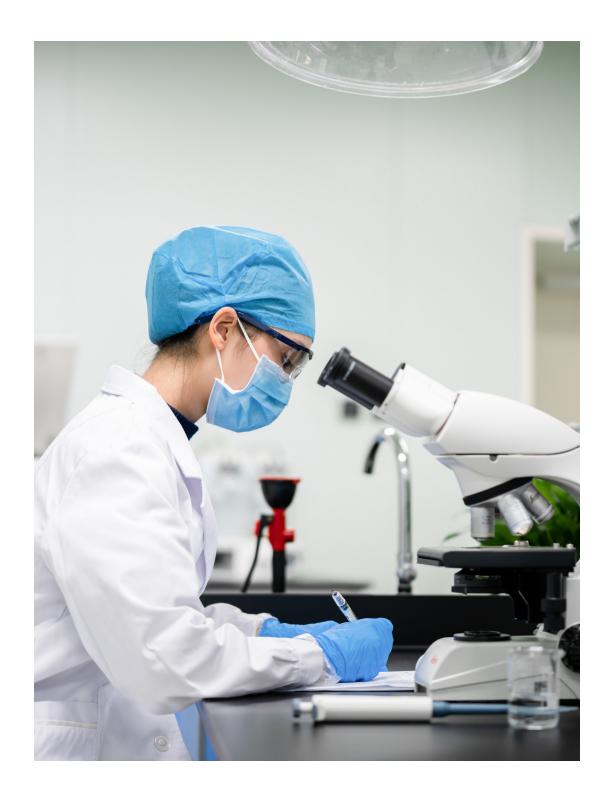


But with the Zelta platform, Biorasi's team was able to complete its study build faster, which ultimately **reduced its average EDC deployment to a 4- to 6-week timeframe**.

Additionally, Vaidya credits the design workflows of the solution because it is designed to help the team address their specific needs and requirements.

"When someone asks me why we use Zelta, I always tell them there are several reasons," says Vaidya. "It's a completely adaptable, customizable and scalable platform that provides us the ability to support all kinds of trials."

"The interface doesn't require manual programming for additional features," she adds. Zelta has, according to them, helped the Biorasi team "work faster and smarter," which is critical when building study databases because it can help lead to bigger savings of both time and money.



Reduced costs and a shorter lifecycle

In addition to shortening the study build time, Biorasi also realized significant cost savings.

Not only did the organization manage to trim a month off its database build—contributing to an **overall reduction of 25% off the build time**—but because the solution required fewer working hours, the team was able to also **cut more than 50% off the full life cycle cost.**

Additionally, the Biorasi team has completed several builds on timelines using Zelta that were previously deemed impossible, including:

- 15-day go live with EDC/Interactive Response Technology (IRT)
- 15-day extension study go live with data migration
- 25-day go live with EDC/IRT/data migration
- 33-day go live with EDC/IRT/data migration
- 38-day go live with EDC/IRT/cohorts/Digital Imaging and Communications in Medicine (DICOM) imaging



Cost and time savings are critical, as they ultimately can affect patients who are awaiting new drugs.

"Whenever we can save time, it's a huge advantage to us, because it not only means cost savings for our sponsors, but also allows us to get potential life-saving drugs to market faster, and that's exactly what Zelta has helped us to do," says Raul Lopez, Manager of Data Management and Lead Clinical Database Developer at Biorasi.

"We are so confident that we can independently perform all the data management activities needed to conduct a clinical trial through the Zelta platform."

Roberto Silberwasser Vice President, Data Sciences and Biometrics, Biorasi. LLC





About Biorasi, LLC

Biorasi is an award-winning CRO accelerating drug and device clinical development for life sciences companies around the world. Since 2002, Biorasi has achieved success in bringing innovative therapies to market by forming true partnerships with sponsors and focusing on processes, methodologies and technologies that move the industry forward. Biorasi is headquartered in Miami, Florida and has regional offices around the globe.

About Merative

Merative is a data, analytics and technology partner for the health industry, including providers, payers, life sciences companies and governments. With trusted technology and human expertise, Merative works with clients to drive real progress. Merative helps clients reassemble information and insights around the people they serve to improve healthcare delivery, decision making and performance. Merative, formerly IBM Watson Health, became a new standalone company as part of Francisco Partners in 2022.

Learn more at www.merative.com.

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