

GLOBAL CAPABILITIES

Case Study



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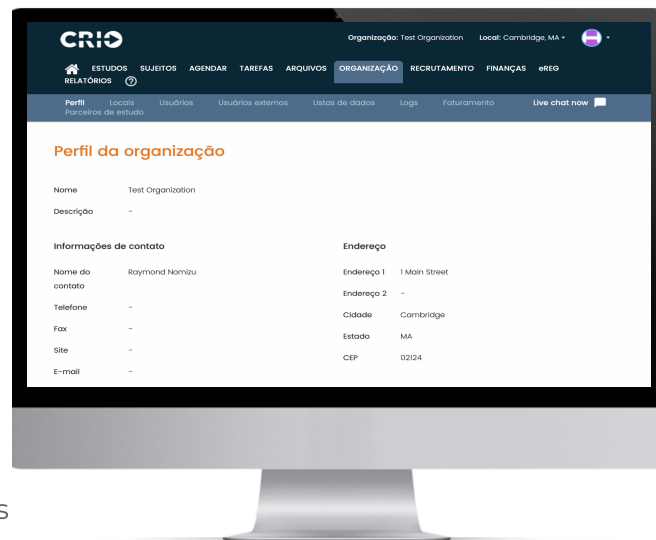
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BIOSEV SMO - GLOBAL RESEARCH POWERED BY CRIO



OVERVIEW

Keyla Deucher operates Bioserv SMO, a multi-site clinical research operator in Brazil. Bioserv partners with physician practices and uses CRIO to centralize all critical functions outside of recruiting and data collection. With its Portuguese language version, CRIO has been an instrumental part of Bioserv's success. Bioserv now serves as CRIO's re-seller and service provider in the region.



CHALLENGE

Keyla Deucher started Bioserv in 2008 as a clinical trial operator. Their first partner site was Hospital São Vicente de Paulo (HSVP), a community-based hospital in Passo Fundo. Keyla realized that the paper charts they were using were inefficient, and that her staff was spending far too much time correcting errors and chasing down signatures. She started looking for an electronic solution.



SOLUTION

Keyla discovered the CRIO system in 2017 at the DIA Summit in Chicago. She proposed a customized arrangement whereby CRIO would build a Portuguese language version of the software. BioServ would deploy the CRIO system and then expand to other practices and sites. After CRIO built the Portuguese version of its software, Bioserv implemented it at HSVP.



The staff loved it because it was so easy to use. We probably ended up saving 30% of our time not having to chase down signatures from doctors. - Keyla Deucher, Director, Bioserv



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OUTCOMES

Fueling Geographic Growth

With an electronic backbone to its operations, Bioserv quickly expanded to new locations. In 2020 Keyla partnered with Institut Mederi and Clinica Supera, two nearby health care clinics. By January 2021, she had contracts with two additional institutions, bringing her total network to five locations.

In Bioserv's partnership arrangements, the local institutions provide the investigators, patients and facilities, while Bioserv trains and deploys the coordinators. Bioserv centralizes all other critical functions, including business development, contract negotiation, study design, EDC entry, and regulatory.

Centralizing functions gives Bioserv significant efficiencies. For example, a single EDC specialist can perform data entry for multiple partner facilities, instead of dispersing that function across multiple locations, where each is subject to fluctuating workload. Similarly, a single coordinator can travel from one site to another while still doing work on the source at the first site.

CRIO also helps Bioserv train new coordinators. "Our facilities are located in smaller cities where it's very hard to find no pre-trained coordinators," said Keyla. "Therefore, it's easier to hire and train new coordinators with CRIO because CRIO has built in quality checks."

Sponsor Acceptance

Bioserv is the first and only research site implementing electronic source and regulatory in Brazil. As a result, Keyla encountered a lot of curiosity and sometimes skepticism from sponsors and CRO's when she first unveiled CRIO. However, after learning more about CRIO, the CRA's embraced the technology. "The monitors absolutely love it because they can work on it without having to travel," said Keyla. During the pandemic, about half the CRO's adopted virtual monitoring through CRIO. This was especially helpful since the main airport near HSPV closed down, resulting in much longer – sometime full-day – travel requirements to get to the site.

Even for CRO's that still do on-site monitoring, there is 100% acceptance of CRIO as the source of truth. "To be honest," says Keyla, "the main issue with virtual monitoring has been with sponsor SOP's, not with CRA willingness to use the system."



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CRIO's Global Capabilities

Bioserv writes all source templates in Portuguese. They also take advantage of CRIO's library feature to build and save commonly used procedure templates in Portuguese. While date formats in CRIO are currently being transformed to clinical date format (e.g., 05APR2020), all other settings, such as timezone, were localized from the outset.

For budgets, CRIO lets users specify the currency for revenue at the study level, while specifying a different currency for expenses at the vendor level. This multi-currency functionality supports BioServ's operations well: BioServ, depending on the study sponsor, gets paid in Brazilian Real, US Dollars, Euros or British Pounds, while all vendors are paid in Brazilian Real.

CRIO's compliance and security have also been critical. Recently, Brazil enacted a privacy law similar to EU's GDPR. The regulations are still being refined, but in the meantime, Keyla was able to get assurance that Bioserv's use of CRIO would fulfill these regulations because of CRIO's documented compliance with GDPR.

CRIO's Re-Seller in Brazil

As Bioserv mastered the technology, it realized it could effectively serve as a re-seller and service provider to other sites in the country. Thus, CRIO and BioServ reached a revenue-sharing arrangement whereby Bioserv sells, trains and supports the software to other sites. In all cases, the end user client has a direct license to use the software from CRIO, and owns all their data; however, Bioserv acts as the site's main point of contact.

"We really like this model," said Raymond Nomizu, CRIO CEO, "because it lets us expand into a large market with a different language while ensuring that our new clients get appropriate service." Raymond sees this model as a potential avenue for the company's growth in new markets.



With a technology enabled business model, we can add many more sites and bring research to so many more patients.

- Keyla Deucher





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Looking Forward

This business model has significant potential for growth. Brazil, with a population of 211 million, is roughly the same geographic size as the United States, and travel to and from locations can be long and cumbersome, even within the country.

Furthermore, while Brazil has universal healthcare, wait times for treatment can be very long, especially for treatments that are considered second lines of defense. So for many patients, clinical research is an attractive treatment alternative.

For these reasons, Keyla is optimistic about Bioserv's potential for growth. "With a technology enabled business model, we can add many more sites and therefore bring research to so many more patients," she said.

ABOUT THE PROFILE



Keyla Deucher is the director of Bioserv, a clinical research service company specializing in delivering improved products, data security and reliability to pharmaceutical and medical companies throughout Brazil. She has served in clinical research since 2004 as a Site Monitor and Site Manager in the multinational pharmaceutical industry, as well as the management of Bioserv SMO since 2008. Keyla holds a Master of Science from the Faculdade de Saúde Pública, Universidade de São Paulo.