



Enabling High-Speed, High-Integrity Biospecimen Collection for Biomarker Discovery

The Challenge

Boca Bio's client is a next-generation drug discovery company focused on discovering biomarkers associated with specific disease states. The company's work depends on its ability to collect and analyze high-quality biospecimens that can reveal subtle biological differences between patient populations. The speed of data generation directly impacts research progress and fundraising efforts, requiring the startup to operate with urgency.

To better understand chronic migraines, the company, hereafter referred to as the Sponsor, designed a study comparing individuals suffering from chronic migraines with a matched cohort of healthy control participants. This study aimed to identify biological differences that could explain why migraines occur, reveal potential treatment targets, and support future biomarker discovery efforts. The study required the Sponsor to identify participants who met highly specific criteria, including:

- Age range
- Body Mass Index (BMI) threshold
- Restrictions on medication use
- Absence of additional health conditions

This criterion created a narrow, difficult-to-recruit population, especially since the study required individuals with chronic migraines who were otherwise healthy. The Sponsor also needed to recruit participants from multiple geographic locations to ensure a sufficiently large pool of eligible participants. A diverse and representative dataset would reduce the risk of bias in the study's outcomes.

Furthermore, the biomarkers under study were highly sensitive to pre-analytical variables, including sample handling, storage, and processing speed. Even minor deviations in temperature or timing could degrade the biomarkers, making the samples unusable for analysis.

Finally, the Sponsor needed to complete its study within only two months of initiation. This aggressive timeline was driven by the Sponsor's operating model, where rapid data generation is essential for advancing internal research. There was also a strong need to keep pace with the high-speed expectations of being a venture-backed startup.

"We're venture-backed, so we were interested in collecting samples quickly, which is usually how our studies go. In addition, we had a list of strict sample inclusion criteria, precise handling instructions, and we needed a broad enough sample to ensure generalizable results."

- Platform Director at the Sponsor

The strict criteria, urgency, participant diversity, and sample sensitivity created complex operational challenges. The Sponsor needed a partner capable of executing with precision while maintaining speed and flexibility.



Solution

Boca Bio delivered precise, end-to-end execution with speed, communication, and reach

To execute the study, the Sponsor partnered with Boca Bio, a provider of biospecimen procurement and clinical research services. Boca Bio was selected for its ability to deliver high-quality samples with speed, precision, and transparency.

Boca Bio assumed responsibility for the study's full execution, which included:

- Identifying and activating clinical sites
- Recruiting eligible patients
- Collecting biospecimens
- Processing, storing, and shipping samples
- Delivering associated clinical metadata

The partnership enabled the outsourcing of the study's operational complexity while maintaining control over scientific requirements. Here's how Boca Bio's end-to-end ownership reduced the burden on the Sponsor's internal team and maintained consistency across all stages of the study.

Boca Bio delivered value across four key areas, enabling the Sponsor to meet its most demanding scientific and operational requirements.

1. Quality assurance and scientific rigor

Under the Platform Director's leadership, the Sponsor established strict scientific and operational requirements to ensure biospecimen integrity. These requirements included tight control over immediate sample processing, temperature stability, standardized handling procedures, and other pre-analytical variables. Boca Bio met these requirements with a high degree of precision, guaranteeing that samples were collected, handled, and transported in ways that preserved biomarker stability.

The Sponsor also defined specific operational needs to support downstream analysis, including a customized sample organization format. By adapting to these requirements, Boca Bio reduced manual steps, streamlined sample retrieval, and lowered the risk of handling errors.

Boca Bio also demonstrated proactive scientific oversight by identifying potential risks early. For example, the team recognized that recruitment at a specific site could lead to a demographic imbalance in the cohort. Boca Bio adjusted site selection to ensure a more balanced and representative population.

"Quality is critical for us because the markers we measure are highly sensitive to how samples are handled. Boca was very diligent in executing everything exactly as needed and even adapted their processes to make things easier for us. They were also proactive in catching issues like cohort imbalances early, helping us avoid bias in the study."

2. Speed and operational efficiency

Boca Bio met the Sponsor's aggressive timeline while maintaining the required level of quality and scientific rigor.

During the study, recruitment at one site began to lag behind expectations. Boca Bio quickly identified the issue, analyzed recruitment patterns, and found that certain inclusion criteria were limiting participant eligibility more than expected. Boca Bio and the Sponsor then collaborated to refine these criteria and improve enrollment without compromising scientific validity. Boca Bio also reallocated resources by increasing supply availability at higher-performing sites, thereby maintaining momentum, accelerating enrollment, and keeping the study on track.

“Speed is critical for us. We operate on an ‘as soon as possible’ basis, so timelines really matter. When recruitment started to slow at one site, Boca quickly identified the issue, worked with us to adjust the criteria, and shifted resources to higher-performing sites. Because of that, we were able to stay on track and complete the study within our expected timeline.”

3. Communication and collaboration

Boca Bio provided regular updates on study progress, ensuring the Sponsor always had visibility into recruitment status, operational challenges, and next steps. Instead of waiting for issues to escalate, Boca Bio proactively identified potential risks and communicated them early. Boca Bio also proposed solutions to enable rapid decision-making and minimize delays.

This continuous and transparent communication reduced the Sponsor's need to follow up or closely manage the process. It also represented a significant improvement over previous vendor experiences, where a lack of visibility often led to delays.

“Communication was a huge factor for us. We always knew how the project was progressing and were quickly informed of any issues. Boca was very proactive, not only flagging problems early but also working with us to solve them in real time. I never had to chase anyone for updates. In fact, they were usually the ones reaching out to keep things moving.”

4. Geographic reach and recruitment diversity

Boca Bio leveraged its network of clinical sites across multiple regions to support recruitment. This multi-site approach enabled the Sponsor to access a larger pool of eligible participants, thereby ensuring geographic diversity and limiting recruitment bottlenecks.

“Geographic reach was really important for us because we didn’t want to bias our study by recruiting from just one location. Boca’s ability to work across multiple sites meant we could access a broader and more diverse patient population, which helped ensure we didn’t run into recruitment limits and could build a more representative cohort.”

Results

The study was completed on time with high-quality samples and improved efficiency

The collaboration with Boca Bio resulted in both scientific and operational improvements for the Sponsor, including:

- **On-time study completion:** The study was completed within the targeted two-month timeframe, keeping research and milestone timelines on track.
- **High-quality sample delivery:** Boca Bio delivered biospecimens in accordance with all requirements, reducing rework and enabling faster analysis.
- **Improved operational efficiency:** Process improvements streamlined and reduced the manual work required of the Sponsor's team, such as sorting samples, managing inventory, and preparing for analysis.
- **Enhanced study integrity:** Proactive adjustments reduced bias, maintained cohort balance, and enabled reliable comparisons between groups.

Ongoing partnership: The Sponsor continues to work with Boca Bio on additional studies across different indications.

"Overall, the project was delivered exactly as we needed: on time, with high-quality samples, and in a way that made things much easier for our team operationally. Boca kept everything on track and ensured we had a well-balanced, usable dataset. It's been a very smooth, end-to-end experience and reinforced our confidence in continuing to work with them."

