



CASE STUDY

Responsive, hands-on support resolves site readiness issues quickly

Scenario

In their work on a viral vector cancer vaccine, our client was working with a sponsor to open a study involving approximately 50 sites in the United States.

Challenge

The complexity of this study, which involved a personalized vaccine, created several challenges: such as finding sites with the appropriate facilities to support the study and its complex IP.

Sabai and this client have a positive ongoing relationship, and while the sponsor had not worked with Sabai before, they were willing to trust the client's judgment and were drawn to Sabai's extensive cell and gene therapy experience.

Ultimately, the IBC's initial need led to working with Sabai's IRB services and to additional IBC consulting work as well, which included site submission support.

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Sabai has a kickoff call at the beginning of the project—that was significantly helpful in answering the multitude of questions that are essential to discuss early on in order to set appropriate expectations; I don't know any other IRB or IBC who does this. With Sabai, we weren't finding ourselves having to go back and correct things later on, or having to ask for corrections after something was already wrong.”

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It was that sort of expedience early on that showed their commitment to the trial. And so I think that really impressed the sponsor, and made it easy for us.”

Site Activation Manager
CRO CLIENT



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our IBC Services**

Strategy

Drawing on their extensive network and working history, Sabai provided speedy and effective guidance on sites provided by the client. For sites not already registered with Sabai, the Sabai team went above and beyond by reaching out—not only to the coordinator contacts, but directly to the institutions to get them registered, both IRBs and IBCs.

Sabai helped the client strengthen and improve their own site list by offering strategic information regarding sites with whom Sabai enjoyed a working relationship. This information was especially helpful regarding sites who were unsure if they could manage the complex IP. In those instances, Sabai met with the site pharmacies to review their processes and on multiple occasions were able to confirm that a site was in fact capable of supporting the study. This knowledge allowed the sponsor to bring this study to more community-based sites, reaching further patient populations than is typically possible in cell and gene therapy studies.

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Sabai's dedication and ability to turn things around very quickly spoke volumes. It really impressed the client...”

Site Activation Manager
CRO CLIENT

Results

The support Sabai provided greatly benefited the timelines of the study. In one instance, a site utilizing their local IBC and Sabai's consulting services sent a multi-page list of questions and asked for same-day turnaround—otherwise it would be another month before they could submit again. Sabai had everything answered and back to the site in less than two hours. Ultimately it was Sabai's reliability, engaged communication and flexibility of access that swiftly put the sponsor at ease during this stressful and fast-paced time for the project. In the end, approximately half of the sites in the study (many of which were academic institutions) were working with Sabai.

Reflection

Upon reflection, this very satisfied client stated they consider Sabai their go-to company for IRB as well as IBC needs, citing genuine partnership and collaboration as key factors along with accessibility: always being able to reach the Sabai team quickly. The client also noted Sabai's extensive relationship with sites has been quite valuable in ensuring the correct sites are proposed to sponsors—offering a key advantage to study success.

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They were a partner the whole way through—from beginning to end.”

Site Activation Manager
CRO CLIENT



 **sabai**

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Experience Sabai.