

CASE STUDY

Supporting Biotech and Pharma Companies Using Imaging Endpoints in Clinical Trials

OVERVIEW

Inadequate knowledge of imaging in clinical trials and ICLs can lead to problems for sponsors. They can be avoided when sponsors work with the imaging experts at Bracken to advise them and serve as a knowledgeable intermediary with their ICLs.

Quality Advisement

Let's face it: In the life science industry, there's challenges at every turn.

Thankfully, Bracken's team is comprised of talent from the biggest names in pharma, digital health, medical imaging, and software to back our clients with industry knowledge and subject matter expertise.

We'll support you and your team with quality advisement to ensure you have the knowledge needed to make only the best, evidence-based decisions.

The life science markets are tough to navigate---don't go it alone.

KEY SERVICES & DELIVERABLES

There are numerous services that Bracken might provide on the subject of imaging. The earlier that sponsors engage with us, the more we can do and the greater impact we can have. Subjects and areas that can benefit from our attention include:

- Protocol development, including optimizing endpoints
- Imaging charters
- Imaging guidance documents
- Reader training

THE CHALLENGE

FACILITATING ICL KNOWLEDGE

While the typical sponsor's team is not an expert in imaging, the typical ICL team is not an expert in biopharmaceutical development, either. With expertise in both imaging and biopharmaceutical development, Bracken bridges the gap in knowledge between sponsors and ICLs, allowing the two to communicate effectively and work together efficiently.

In one recent case, a sponsor had a study underway with an ICL when an interim analysis revealed that the quality of the ICL's work was inadequate. The sponsor pulled the study from that ICL and engaged with a second. Unfortunately, concerns developed surrounding the second ICL as well. At this point, the sponsor sought our input.

Acting as an intermediary between the sponsor and the second ICL, we were able to identify the fundamental problem as one of communication. In our initial conversation, we provided the critical guidance that corrected the situation and put the sponsor on the path for success with its ICL.

Our guidance touched on challenges including the imaging charter, the number of readers to employ, how readers should be trained, various considerations for read design, and more.



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THE BRACKEN SOLUTION

ICLs have a preferred system and approach that may not ideally align with the sponsor's needs and endpoints.

Bracken can objectively evaluate the ICL's recommendations and procedures and advise sponsors when and where changes should be made.

When sponsors work with Bracken, they secure an ally and an advocate, one that brings world-class expertise in imaging to the table, and one that ICLs can respect.



THE RESULT EXPERT REGULATORY GUIDANCE

The clients were supported by an "embedded consultant" who understood their imaging endpoint. Without having to employ staff, the clients enjoyed the benefits of having an imaging expert on their side.

Bracken consultants saved the client time and money and simplified the read design, helping to ensure results were available on time for the NDA.

THE TAKEAWAY

Clients who engage with the Bracken team can be confident that they will receive the expert guidance required to successfully work with an ICL and leverage imaging in their clinical trials, avoiding setbacks, delays, unnecessary expense, and frustration.