

## CASE STUDY

# Designing and Monitoring Anti-NGF Imaging Endpoints

## SCENARIO

Anti-nerve growth factor (NGF) therapeutics are a new class of powerful analgesics in clinical development. But the FDA put their clinical development on hold in 2012 because joint destruction was observed in a small subset of patients.

## 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.



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## THE CHALLENGE


Pfizer, the leading developer of NGF compounds, needed a way to evaluate all major joints in subjects entering the new Phase III program.

## THE STRATEGY

Members of the Bracken team have substantial experience in imaging in osteoarthritis, and NGF-targeting therapies affected joints in a similar manner, so Pfizer specifically sought out our expertise.

In turn, our solution was to:

- Engage a team of radiologists to develop a new radiographic technique to evaluate the joints in the defined patient population.
- Build and participate in a strong academic team that published a landmark [Imaging Atlas](#) in 2015. The book described the technique and now serves as a key clinical reference.
- Further develop specific inter-reader training and validation techniques to reduce variability in this new arena. The first reproducibility paper from this study has already been published.

  
**THE RESULT?**  
**Reproducible,  
Effective Reads**

Pfizer conducted a very successful anti-NGF program with all the radiological and MRI reads done in a reproducible and effective manner