

# Centralized Image Review Supporting Breast Cancer Study



## CHALLENGE

The sponsor was a large biopharmaceutical company engaged in a Phase III breast cancer study. As the chosen outsourcing partner, BioTel Research (BTR) was requested to “collect and hold” subject data for the study. Review and analysis of subject images was not part of the initial agreement with the sponsor.

The study was successfully completed, and data from the study were prepared for submission to the FDA for review. Unforeseen to the sponsor, the **FDA concluded it would require centralized reads, and not the site reads** provided by the sponsor. To keep the study timeline from slipping, the sponsor would **need to complete the review, analysis, and submission of new data within 6 weeks. The volume of scans to be overread was significant, totaling approximately 10,000.**

## FDA REQUIRED

- **Central Overread**
- **Phase III Breast Cancer Study**
- **10,000 Image Reviews**

## SOLUTION

With its study now on the line, the sponsor turned to BTR for assistance. BTR accepted the challenge and proceeded to organize a **dedicated team to expedite imaging workflow, interpretation, analysis and quality assurance.**

Project managers were challenged with streamlining workflows that could process the high volume of scans. **Radiologists were assembled for around-the-clock interpretation and analysis.** Quality assurance controls were honed so as not to jeopardize data integrity under stressful timeline constraints.

## RESULT

BTR was **able to complete the 10,000 reads in just 5 weeks, one full week short of the sponsor deadline.** The trust and collaborative working relationship between the sponsor and BTR enabled a successful solution. The sponsor views BTR as more than just a partner, but as a true extension of their team. In their own words, *“No other imaging core lab would have accepted, not to mention successfully completed, this challenge.”*