Merigold Case Study:
30-Day Imaging Study Start-up

Background

Merigold supported a biopharmaceutical Sponsor whose focus is on theranostic radiopharmaceuticals. The Sponsor was preparing for a U.S. FDA NDA submission for a new kit that can be used to prepare a prostate cancer imaging agent. The two-part trial required the initial execution of a rapid imaging review across two countries, with aggressive study timelines driven by the regulatory submission deadline. The study design involved screening, intervention, and imaging assessments across a condensed 22-day patient schedule. Imaging documents, read infrastructure, and training had to be fully implemented within weeks to avoid delaying the NDA package.

The Challenge

The sponsor required all imaging documentation, site training, reader materials, and central read infrastructure to be finalized within one month—an effort that would typically require a total of four to six months when executed sequentially. Furthermore, the imaging design and workflows were still being finalized as the clock ran. Document development, protocol interpretation, and system configuration had to be performed in parallel across multiple stakeholder teams: the sponsor's medical and operational teams, the imaging CRO's operation, data and scientific leads, and Merigold's imaging strategy experts.

The Solution

Merigold took the lead in organizing, drafting, and delivering all major imaging deliverables—including the Imaging Review Charter, Site Imaging Manual, Quality Monitoring Plan, reader training materials, and eCRF specifications—within a single 30-day window. Protocol training was delivered live to the internal imaging CRO team, while multiple collaborative sessions were held to finalize central read design. Merigold facilitated direct working meetings between operational, medical and scientific, and technical stakeholders to implement changes in real time, adjusting documentation and tools in parallel to keep the trial on track.

The Results

Within a single month, all imaging systems and documents were finalized, enabling the sponsor to complete cohort enrollment and database lock ahead of schedule. Eleven patients were successfully imaged and read, and the sponsor's NDA submission was accepted by the FDA, approving the preparation kit. The rapid documentation turnaround, and delivering in one month what typically takes several months, was a key enabler of this regulatory milestone.

Key Takeaways

Merigold's ability to coordinate imaging strategy, document development, and system implementation under extreme time pressure was pivotal in supporting this fast-paced, high-stakes trial. Our flexible engagement model, deep understanding of regulatory expectations, and hands-on execution ensured that the imaging component of the trial was not a bottleneck—but a competitive advantage.