Merigold Case Study:
Imaging Rescue Study

Background

A mid-sized immuno-oncology sponsor was conducting a multi-trial oncology program with imaging as a critical efficacy endpoint. Following regulatory review of blinded independent central read (BICR) data, serious gaps were identified in the imaging workflow, documentation, and oversight for their Phase II study. To protect trial integrity and prepare for future regulatory scrutiny, the sponsor made the urgent decision to transition imaging oversight from their original vendor to a new imaging CRO. Merigold was brought in as the imaging subject matter expert and documentation lead to resolve technical, procedural, and compliance issues.

The Challenge

Merigold entered a highly charged rescue scenario where:

- Documentation and imaging systems were non-compliant with FDA 2018 BICR guidance.
- Critical procedures—including reader training, reader monitoring, and QC—were undocumented.
- Timelines were critically compressed, with BICR halted and regulators expecting rapid remediation.

The Solution

Merigold executed a comprehensive remediation plan across technical, procedural, and operational dimensions:

- Charter and Technical Document Overhaul: Rewrote the Independent Review Charter and image analysis platform requirements specifications to comply with FDA expectations and needed platform functionality.
- Gap Analysis and Process Remediation: Conducted a full mapping analysis of imaging documents, identified undocumented procedures, and authored compliant SOP-aligned materials.
- Analysis System Testing: Designed and led user acceptance testing (UAT), including test script development, execution, and defect resolution, ensuring platform readiness.
- Reader Training & Implementation: Created training materials, onboarded readers, and delivered live platform demonstrations to ensure protocol-aligned reads.
- Cross-Functional Alignment: Facilitated working sessions with the sponsor and new imaging CRO's cross-functional teams to establish a compliant, harmonized BICR process.

The Results

- A fully compliant, FDA-aligned read system was implemented in record time.
- Imaging Review Charter and supporting documentation were rewritten, harmonized, and aligned with operational procedures.
- Regulatory risks were mitigated through process transparency and quality controls introduced by Merigold.
- The sponsor gained confidence in the imaging data, and all reads resumed on an expedited timeline.

Key Takeaways

- Expertise in Action: Merigold's deep imaging, regulatory, and operational expertise enabled swift, precise, and compliant remediation under pressure.
- Technical Fluency: Our dual expertise in documentation and imaging platforms accelerated UAT, defect resolution, and system readiness.
- Strategic Partnership: Merigold's ability to lead difficult conversations and build consensus was critical in a high-stakes environment.
- Proven Under Pressure: This case highlights Merigold's role as both a technical authority and a strategic partner for imaging-critical trials facing regulatory and operational crises.