Merigold Case Study:
Imaging Master Charter Framework

Background

A global imaging CRO engaged Merigold to standardize BICR imaging documentation for a top-tier pharmaceutical sponsor managing multiple oncology portfolios. With dozens of ongoing and planned studies requiring varied review criteria and custom read workflows, the sponsor needed a scalable solution to ensure consistency, efficiency, and regulatory compliance. Goals included reducing rework, accelerating study startup, minimizing errors, and improving data quality across portfolios of trials.

The Challenge

Traditional Imaging Charters were being developed from generic templates that lacked content and required teams to make significant edits for each study. This approach introduced variability, slowed timelines, and increased the risk of inconsistencies and errors. Further complexity arose from the need to support multiple review criteria (e.g., RECIST 1.1, Lugano, limited RECIST) and custom workflows (eligibility and progression confirmation), making it difficult to maintain complete yet manageable templates.

The Solution

Merigold introduced an Imaging Master Charter Framework with two components:

- BICR Methodology Template: Used to create a BICR Methodology document for each study to capture protocol-specific details and reference the relevant appendices.
- Modular Appendices: Pre-approved, version-controlled modules containing re-usable content including content such as review criteria, read workflows, and lesion location lists. Content within modules is fixed; any study-specific modifications are noted in the study specific BICR Methodology document with rationale.

Merigold also provided training and review guidance, to ensure smooth adoption by both the imaging CRO and sponsor teams.

The Results

The Imaging Master Charter Framework standardized core content while preserving flexibility for protocol-specific needs. Fixed content, version-controlled appendices- governed by senior approvers- ensure clarity and a defined escalation path. Study teams save time by reusing the fixed content appendices and only need to develop and review a BICR Methodology document for each study, rather than a full charter.

Once finalized, document comparisons are streamlined, as any study-specific appendix modifications are explicitly captured. This transparency improves understanding of the root causes of variations in imaging data sets across a drug portfolio.

The framework is now in use across multiple oncology portfolios, significantly reducing document development time, minimizing draft cycles, and improving consistency and data quality. Merigold continues to exercise governance oversight, ensuring the framework evolves with regulatory changes, emerging response criteria, and the sponsor's advancing pipeline.

Key Takeaways

Merigold's combination of imaging expertise and process innovation produced a scalable documentation framework that benefits both sponsors and imaging CROs. By pioneering a modular Master Charter architecture, Merigold delivered faster study startups, improved imaging data reliability, and created operational efficiencies across a high-volume clinical program.

References

Fotinos-Hoyer, K. (2020). Master trial documents for increased efficiency and scientific integrity. EMWA Regulatory Matters, 29(2), 88–89