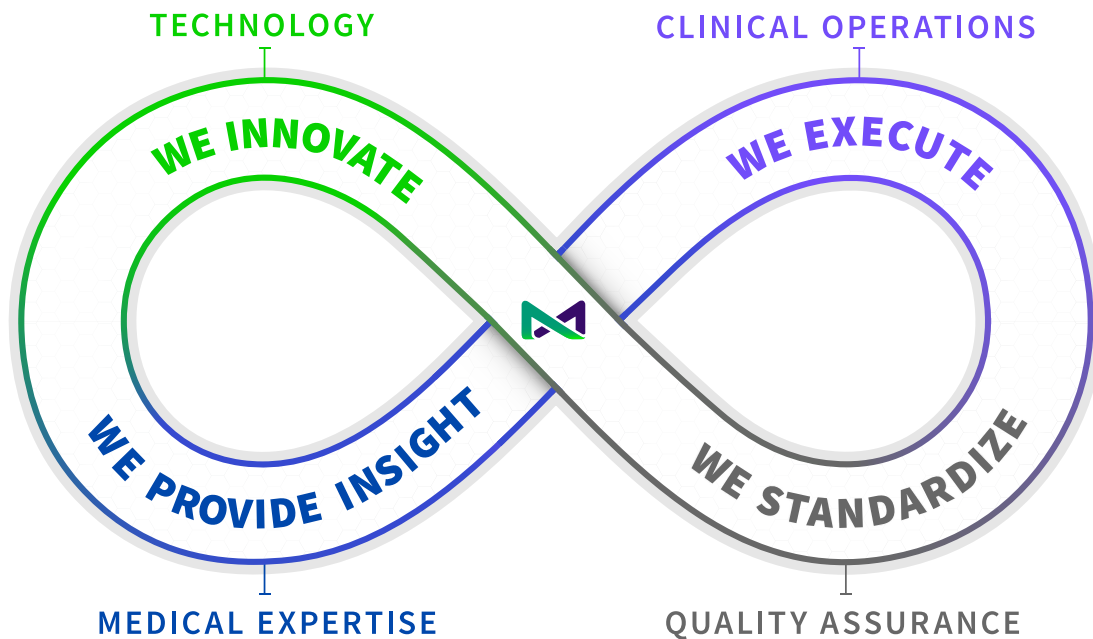


# MERIT Reading Center Services Solutions Guide



MERIT provides consistent, high-quality independent reading center services to our CRO, pharmaceutical, and biotech partners. Together our work advances and accelerates the improvement of therapeutic options for patients worldwide.



## MERIT offers comprehensive reading center services including:



### Technology

- Comprehensive Cloud-based Software Platform
- Image upload, evaluation and QC



### Clinical Operations

- Development of Study-Specific Documents
- Site Technician and Equipment Certification
- Project Management and Site Support
- Global Reach



### Medical Expertise

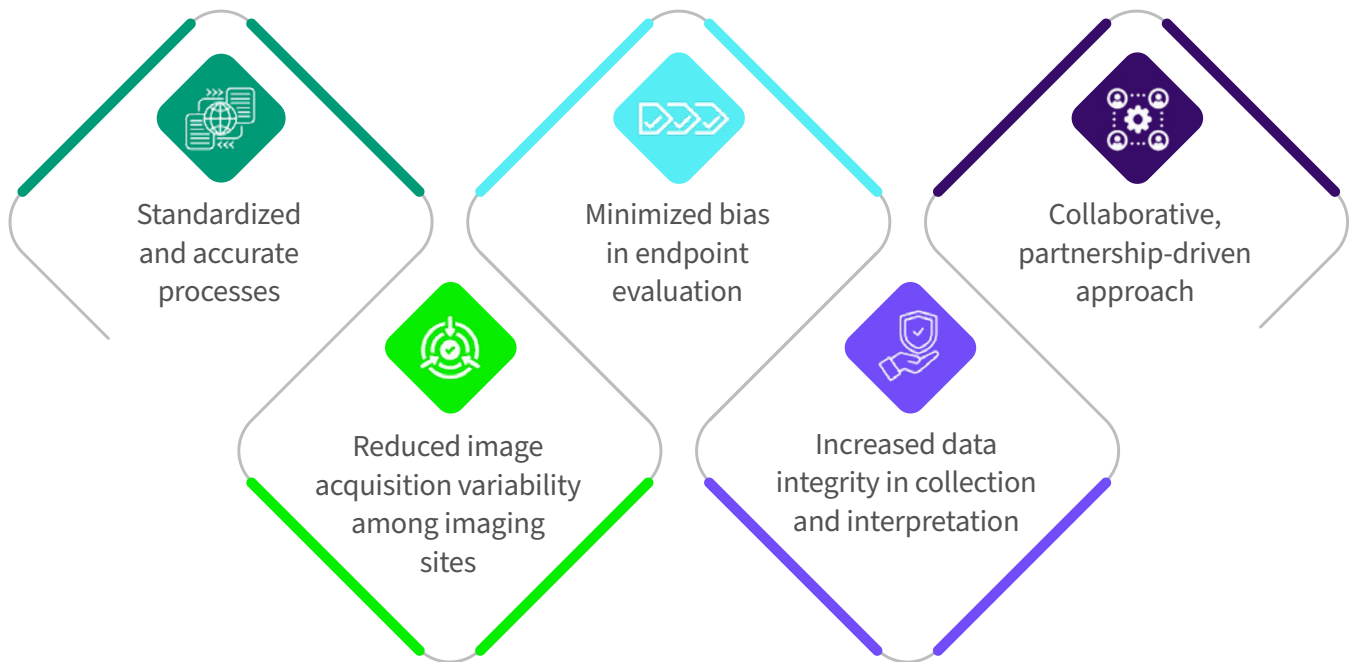
- Study Design Insights
- Masked Image Read & Adjudication



### Quality Assurance

- Regulatory Compliance
- Data Privacy & Security

## With MERIT's Reading Center Services, you benefit from the following:



# MEDICAL EXPERTISE



### Study Design Insights

- Protocol design and consultation
- Reading criteria expertise
- Integration of published reading criteria with protocol and study needs
- Early involvement for protocol/imaging design/clinical data collection
- Advice on clinical endpoints and surrogate endpoints

### Masked Image Read & Adjudication

- Uniform image evaluations across clinical sites by masked, independent readers
- Minimize inter/intra-reader variability through rigorous reader training, monitoring and oversight.
- All readers are trained for study-specific reading techniques according to the configuration of the protocol and the expectation of the sponsor.

# CLINICAL OPERATIONS



## Development of Study-Specific Documents

- Imaging charters
  - Protocol and response-criterion driven, guide all imaging-related activities
- Site imaging manuals
  - Provide instructions for sites on imaging schedule, image acquisition & upload, answering queries, site support contact info
- Reading criteria
  - Modified and integrated based on protocol need
- Data management documents
  - Edit checks, Data Transfer Specification, CDISC standardization

## Project and Site Management

- Risk management through anticipating study challenges
- Data quality checks to ensure compliance
- Support ticketing system with <24hr resolution TAT
- Performance reporting
- Regular sponsor/site communications

## Site Technician and Equipment Certification

- Detailed user manuals and image acquisition procedures per the protocol
- Investigator Meeting, in-person or remote
- Web 1-1 training and instructions to site technicians
- Site (technician and equipment) certification to ensure readiness for FPI
- Supplemental performance information of a potential site based on prior experience

## Global Reach

- Images are collected from different sites around the world, standardized, and stored centrally
- EXCELSIOR delivers seamless image data sharing and evaluation
- Management of sites with different language requirements
- Global regulatory and data privacy compliance

# TECHNOLOGY PLATFORM



## Comprehensive Cloud-based Software Platform EXCELSIOR™

- ✓ One validated, secured system that contains all study data: images, tasks, queries, site materials, analysis, and read data
- ✓ Cloud-based platform bypasses site IT challenges and effectively manages access rights for sites, sponsors, and readers (zero footprint implementation)
- ✓ Eliminates the question: “Where is our data?” and reduces risk of data delays
- ✓ EXCELSIOR is a 510(k) cleared medical device for ophthalmic and radiological indications that is HIPAA compliant and meets all 21 CFR Part 11 requirements for electronic records and signatures

## QUALITY ASSURANCE

- ✓ MERIT’s Quality Management System (QMS) is ISO 13485 certified
- ✓ We prioritize data privacy; MERIT is GDPR compliant in both our processes and with our proprietary EXCELSIOR™ software
- ✓ EXCELSIOR is a 510(k) cleared medical device for ophthalmic and radiological indications that is HIPAA compliant and meets all 21 CFR Part 11 requirements for electronic records and signatures
- ✓ MERIT’s Information Security Management System (ISMS) is ISO 27001 certified



Connect with us to learn more about how our expertise and approach can support bringing your product to market on-time and on-budget. Your success is our priority.

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