MEDIDATA

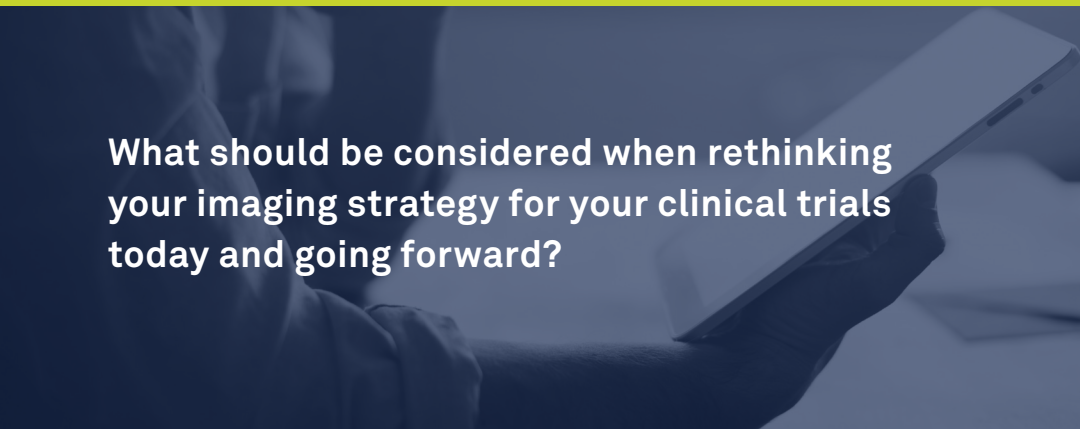
Rethinking Your Imaging Strategy

A guide to avoid pitfalls in a disrupted landscape,
regain control, and leap ahead in the transformation of imaging for your trials.

Most people involved in medical imaging are aware of the recent upheavals in the industry. Sponsors know that changes to their key Imaging relationships may be imminent. Anticipating these changes and properly handling them may well have an impact on your trial.

The current state of the clinical trial imaging industry can best be described as murky and unsettling and could put your timelines at risk. The wave of M&A activity across key imaging players has created confusion and a lack of transparency directly impacting sponsors and sites. The new mergers, acquisitions, and partnerships are causing disruptions across technology, process, and people.

This guide is designed to help you avoid the pitfalls in this disrupted landscape. Across eight parameters, learn how you can regain control of your Imaging strategy and leap ahead in the transformation of imaging for your trials.



What should be considered when rethinking your imaging strategy for your clinical trials today and going forward?

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1 INDUSTRY DISRUPTION

The mounting disruptions across medical imaging players pose a clear and present danger to all clinical trial stakeholders.

How up to date are you with the latest M&A activities in the imaging clinical trial industry?

Despite respective proven track records, newly merged entities must overcome a myriad of personnel shifts, technology integrations, security methodologies, process changes, and cultural differences that could adversely affect their clients and their studies. The impact of these integration challenges on trials and customers with imaging requirements can include:

- Transitioning your imaging trials from one company to another, forcing you to use an imaging platform or core lab you did not select
- Resulting integration challenges impacting operational performance, i.e., getting up and running plus ongoing support issues
- Staffing disruptions with continual changes in project leads and key personnel supporting your trials
- Inability to retain control of your imaging-related clinical trial data and activities
- Increased site-level burdens and disruptions with potential changes in imaging technologies and operations
- Incompatibility of technologies, compromising reconciliation and data security
- Contrasting company cultures within newly merged organizations, impacting quality and service

M&A momentum has magnified the need to select and deploy a secure, stable, scalable medical imaging solution that is under your control.

2 EASE OF USE

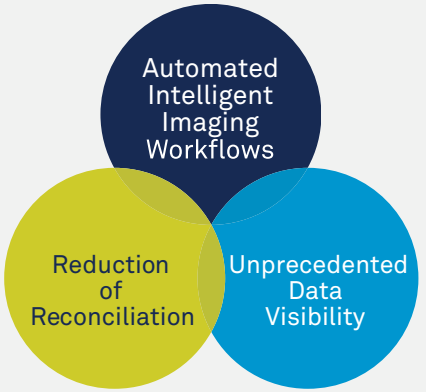
Clinical trials with imaging endpoints have increased over 500% in the last 10 years.[1] Sponsors and sites seek an imaging technology platform that enables all stakeholders to take control of their imaging data, offers flexibility, and is easy to use.

Does your current imaging technology offer a full end-to-end solution, from submission to image assessment to archive?

The use of disparate systems across trials requires multiple image submission, data reconciliation, and workflow processes, resulting in increased workload, extended timelines, and opportunities for error. By eliminating manual steps and increasing data visibility, you reduce query rates and ensure your imaging data is distributed to the right users at the right time, minimizing the risks and complexities of image management and gaining:

- Flexibility to select and integrate with any Core Lab, system, and vendor
- Autonomy from proprietary systems tied to specific core labs
- Standardized image submission processes, including acquisition, de-identification, edit checks, distribution, image assessment, and archiving across ALL trials and Core Labs
- Unified site experience with a single solution for ALL sites across ALL trials and Core Labs

Transform manually intensive, non-aligned workflows into intelligent, guided workflows that work with your evolving clinical development strategies.



Provides a single source of truth for all imaging data

50% of trials use medical imaging today

95% of all oncolgoy trials use imaging

Clinical trials with imaging have increased over 500% in the last 10 years[1]

[1] https://brackendata.com/blog-posts/medical-imaging-clinical-trials-growth-ratem (2009 - 2019)

3 REAL-TIME DATA ACCESS

Roughly 50% of all clinical trials use medical imaging as an endpoint or for eligibility criteria in therapeutic areas like oncology.

Real-time access is critical to ensure accurate, timely decision making and completion of study goals.

Do you have real-time access to your images and imaging activities across all your trials and Core Labs?

When imaging activities are managed across multiple technologies, protocols and processes can cause delays in image access crucial to your trial pace and success.

Without the need for customization, gain the ability to:

- View and review image upload status and submission time
- Track image review status, CRF data, and image-specific queries
- Maintain real-time accessibility and audit-ready integrity of all your imaging data on one platform

Real-time access to data drives critical efficiencies for all your study stakeholders and dramatically impacts your trial performance.

6–8 weeks to build studies

20+ fewer hours spent reconciling per month

86% reduction in data query rate

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DATA SECURITY

Shedding light on the imaging industry over the last year highlights the pressing need for a transformative approach with a focus on control, security, and stability.

How confident are you that your imaging data is being securely and compliantly managed?

Increasing complexity and volume of clinical data introduces compliance and quality risks. Having a data security strategy in place provides protection for a trial's patients and prepares for compliance audits.

Imaging data should be maintained by a robust and inspection-ready Quality Management System inclusive of policies and procedures to ensure that software products and services are developed, implemented, and maintained in a manner that meets your needs and expectations and ensures compliance with applicable regulatory requirements. Software should be 21 CRF Part 11 compliant, with access to robust audit trails and an electronic signature that meets regulatory requirements. In addition, the most robust solutions are built using the principles of "Security by Design" control that is built in at the design phase. By using the most advanced technologies and techniques, your data should be protected against the newest threats in a world of increasing risk.

Additionally, Rave Imaging Archive is a cloud-based solution that provides regulatory compliant digital storage of completed trial data in read only mode. With real-time, long-term access to view data and images within the environment in which they were captured, the need to store imaging files on removable media is eliminated, keeping your data unexposed to external drive transfer errors and potential security breaches.

- Immediate access to clinical trial data in case of a regulatory audit
- Instant retrieval of data for safety review or secondary use
- Secure DICOM communications performed locally, within the network

IMAGING TECHNOLOGY

Intensifying the urgency to clarify your medical imaging strategy is the advancement of new technologies, including cloud-based end-to-end clinical trial solution platforms.

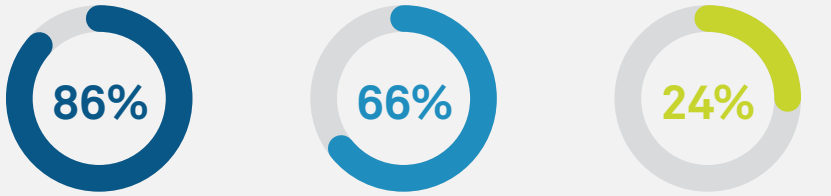
How well are your imaging processes, data, and system implementations standardized across all trials and Core Labs?

Automation will improve virtually every stage of your imaging workflow:

- Configurable, intelligent workflow management including blinded reviews and adjudication to support on-time completion of all steps in the clinical trial
- Configurable, automated de-identification during image upload to ensure images are de-identified prior to leaving the site
- Structured image submission process complements user work process to minimize data entry and workflow steps and reduces the chance of error during image selection
- Configurable edit checks of all data prior to submission to reduce query rates
- The proliferation of AI to improve quality and efficiency

LEVERAGE THE POWER OF AN INTEGRATED DATA PLATFORM WHEN INTEGRATING IMAGING + EDC:

Integration leads to streamlined processes, accelerated timelines, and greater visibility



faster startup time from charter to "go live"

reduction in image prep time

additional reduction of image queries

6

TRANSPARENT PRICING

Utilizing the technology platform provided by your Core Labs typically results in sponsors having to use multiple technologies across their trials with little to no visibility into the actual cost of that technology.

How clear is your understanding of your imaging technology costs within your core lab contracts?

Medical imaging technology costs are often bundled together with other services, making it difficult to determine what you're actually paying for and whether you're getting the best value for your Imaging technology. Imaging technology costs within Core Lab contracts can sometimes be buried within many different descriptions, categories, and fees including imaging processing fees, image upload fees, image handling fees, and more.

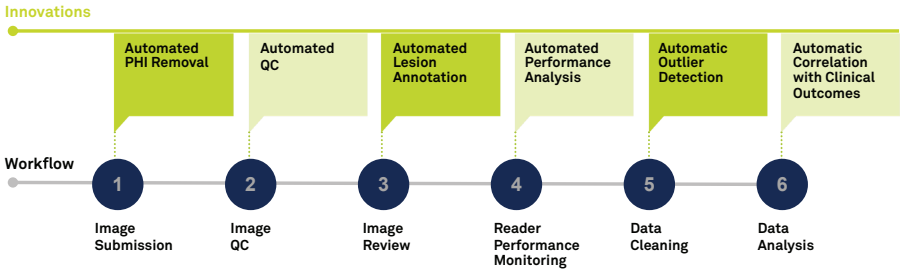
Pricing transparency for your imaging technology that is detailed and understandable, consistent across all trials and core labs, and associated with tasks and timelines avoids hidden and unexpected costs, giving you control over your costs and keeping your trial within budget.

AI SCIENCE

Automation is changing virtually every stage of the imaging workflow, from improved compliance with privacy regulations to stronger data quality controls, more accurate and efficient imaging reads, and advanced data analysis for improved decision making.

Do you have the opportunity, presently or in the future, to leverage AI to improve your imaging quality, review processes, and overall assessment timelines?

For the first 125 years of medical imaging, technological advances focused primarily on new modes of imaging as we progressed from the discovery of the X-ray in 1895 to ultrasounds, MRIs, PET, and CT scans in the late 20th century. Currently, the most notable advances are being made in how images from those technologies are securely shared, managed, stored, and assessed.



Advancements are largely due to the application of Artificial Intelligence (AI) and Machine Learning (ML) to imaging systems and data platforms, new capabilities that enable you to:

- Automatically detect and remove PHI from Digital Imaging and Communications
- Remove a level of subjectivity in quality control and any opportunity for human error in the review step
- Perform automated measurements according to the relevant assessment criteria (for example, RECIST, Lugano, RANO, etc. for oncology assessments)
- Extract radiomic data and operationalize it for use in clinical trials
- Ensure compliance with all data privacy regulations

8 PROFESSIONAL SERVICES

A winning strategy will ideally include access to specialized service teams to accelerate and assure successful implementation of your imaging technology and trial.

How often do you receive guidance from your partners on best practices for implementing your trials, according to your protocol and specifications?

Partnering with imaging technology specialists to design, deploy, or outsource your Imaging strategy not only helps accelerate the adoption of industry leading capabilities, but also guarantees a strategy that will meet compliance and help you leap ahead in the transformation of imaging for your trials.

Our experts are dedicated to supporting you with leading technology, training and skill building, operational and technical support, and market awareness, all focused on growth.

Collaborating with your team, our experts work closely through discovery and identify critical initiatives to respond in a timely, effective, and sustainable way.

- **Study-by-Study Support:** Plan, Deploy, Operate, and Close
- **Operational Excellence:** Accreditation/Enablement, Product Optimization, Implementation Guidance, Knowledge Maintenance
- **Implementation:** Startup, Implement, Live, Conclude
- **Account Oversight:** Governance, Value Attainment, Channel to Product, Dedicated Team

MEDIDATA PERFORMANCE METRICS

870K+
Imaging Exams Uploaded

1000+
Imaging Trials

75+
Core Labs and Imaging CROs Connected

400+
Unique Sponsors

21K+
Global Sites

228K+
Patients

RETHINK YOUR IMAGING STRATEGY CHECKLIST

- ☐ Industry Disruption
- ☐ Imaging Technology
- ☐ Ease of Use
- ☐ Transparent Pricing
- ☐ Real-Time Data Access
- ☐ AI Science
- ☐ Data Security
- ☐ Professional Services

A GUIDE TO RETHINKING YOUR IMAGING STRATEGY

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,700 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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