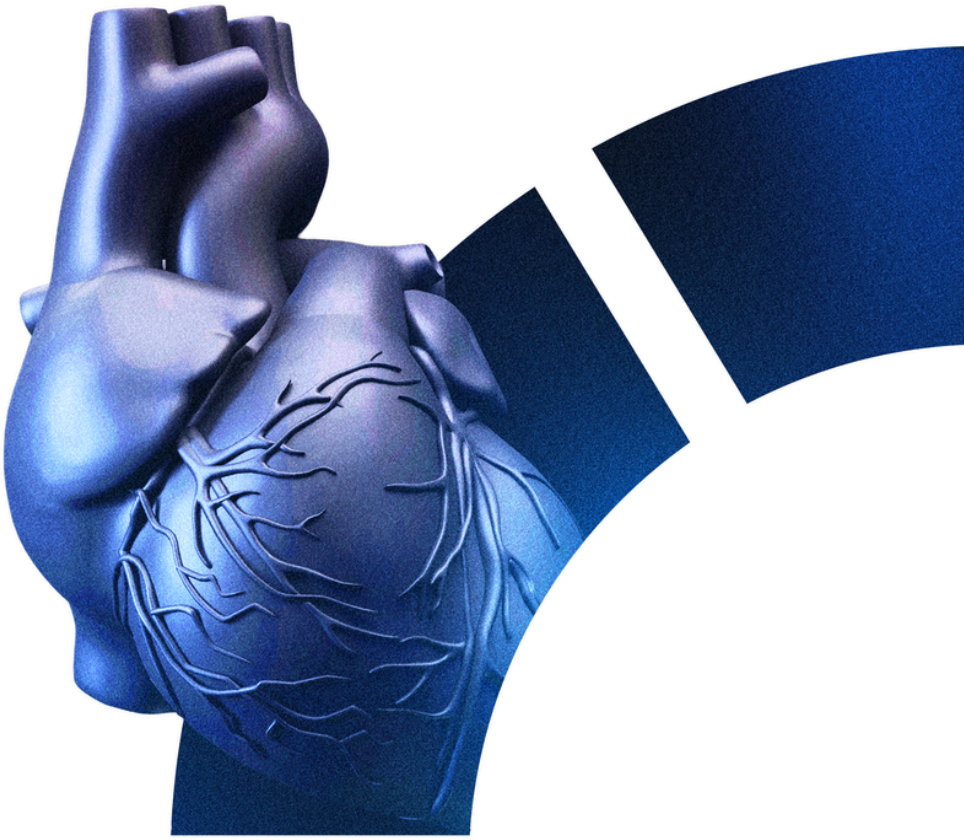
Perspectum



WHITEPAPER

Streamlining Cardiovascular Clinical Trials:

The Case for a Single Imaging Vendor

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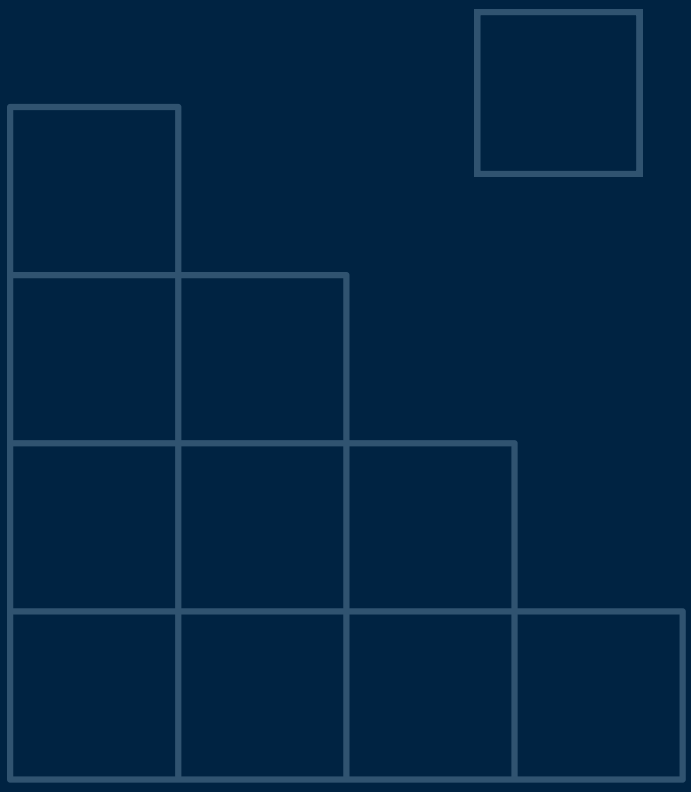

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Randomized trials are the gold standard method for evaluating new therapies and improving patient care. However, the cost and complexity of trials are becoming prohibitive and the current model is unsustainable...

— Franz Weidinger et al.

Executive Summary

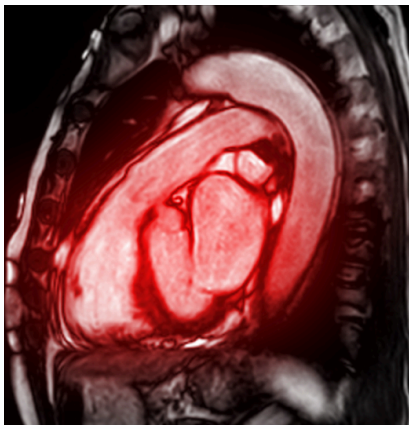
Imaging endpoints are central to cardiovascular clinical trials, providing quantitative, regulator relevant measures of cardiac structure and function.

In multicentre settings, however, the traditional model of decentralised imaging acquisition, local reads and central image processing can introduce variability and operational risk at a time when regulators increasingly expect standardised, auditable, and scalable imaging processes. A single, specialised imaging-vendor model offers a pragmatic evolution of current practice, enabling harmonised workflows, consistent quality management, and more reliable delivery of regulatory-grade imaging endpoints in late-phase programmes.

- **Imaging endpoints are critical:** MRI biomarkers directly inform efficacy, safety, and regulatory decision-making in cardiovascular trials.
- **Fragmentation increases risk:** Variability in protocols, reading standards, and regulatory readiness across multiple providers can compromise consistency, auditability, and scalability.
- **A single vendor mitigates this risk:** Centralising imaging with one qualified partner enables standardisation, embedded compliance, streamlined collaboration, supporting timely and reliable endpoint delivery.

Introduction

Cardiovascular clinical trials represent a large and growing market which was valued globally at approximately $5.6 billion in 2024 (Research and Markets 2026).



This reflects the sustained investment in therapies for cardiovascular diseases associated with high morbidity and mortality. Within this landscape, demand for imaging-based services to both identify patients eligible for studies and monitor treatment response is expanding rapidly, with this market segment, alongside device monitoring, growing at an estimated 7.8-8.4% CAGR (S&S Insider Strategy and Stats 2025) as trials become larger and more complex. This growth underscores both the strategic importance of imaging in cardiovascular development programmes and the need for scalable, standardised solutions to support regulatory-grade evidence generation.

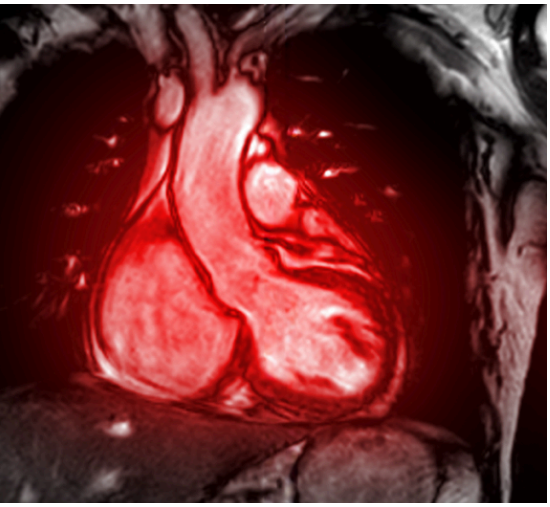
Cardiovascular clinical trials increasingly rely on imaging endpoints to assess both safety and efficacy.

Magnetic resonance imaging (MRI) provides quantitative biomarkers such as:

- *Ventricular volumes*
- *Ejection fraction*
- *Wall thickness*
- *Perfusion*

Each of these are essential for determining therapeutic impact. Yet despite the centrality of imaging to decision-making, the methods used to acquire, process, and interpret these data often **lack standardization.**

Traditionally, many cardiovascular trials have distributed imaging responsibilities across multiple academic laboratories or regional vendors, a model that has contributed substantially to methodological innovation and clinical insight. However, a lack of standardization in acquisition protocols, reading processes, data standards, and regulatory preparedness across local readers and academic core labs can increase variability in imaging endpoints and make it harder to achieve the level of consistency, auditability, and scalability required for regulatory-grade evidence.



In the current regulatory landscape, increasing emphasis is placed on imaging endpoints that are standardised, prospectively defined, and fully auditable throughout the clinical trial lifecycle. Regulatory guidance, including the FDA's Clinical Trial Imaging Endpoint Process Standards (U.S. Department of Health and Human Services Food and Drug Administration 2018), underscores the need for controlled acquisition, validated analysis methodologies, and traceable data handling to support the use of imaging endpoints in regulatory decision-making. Consistent with this guidance, prior studies have demonstrated that harmonised imaging workflows and centralised core laboratory oversight improve reproducibility, reduce variability, and enhance the interpretability of cardiovascular imaging data in multicentre trials. Collectively, these requirements heighten the importance of rigorously standardised imaging processes in global cardiovascular studies (Oh 2002, Jae K. Oh 2012, Amil M Shah 2015).

Against this backdrop, a single, specialised imaging-vendor model for cardiovascular clinical trials is proposed as an evolution of current practice. Centralisation of imaging operations by a qualified provider facilitates harmonisation of image acquisition and analysis across sites, supports the implementation of consistent quality management systems and regulatory compliance frameworks, and improves coordination between sponsors and contract research organisations (CROs). Collectively, this enhances the efficiency, reliability, and timeliness of imaging endpoint delivery in late-phase cardiovascular development programmes.

Perspectum is a specialised imaging partner capable of supporting large, multicentre, cardiac programmes. Our cloud-based infrastructure and standardised imaging workflows are designed to scale across geographically distributed trial sites, enabling consistent image acquisition, centralised analysis, and regulatory-grade data management. These capabilities align with current regulatory expectations for imaging endpoints, including those outlined in the FDA Clinical Trial Imaging Endpoint Process Standards, and support the generation of reproducible, auditable cardiac imaging data in complex clinical development programmes.

1. Imaging Endpoints in Cardiovascular Trials

1.1 CMR and Echocardiography Efficacy and Safety Measures

In cardiovascular medicine, imaging biomarkers are integral to nearly every phase of modern drug development from first-in-human safety assessments to pivotal Phase III efficacy trials.

Parameters including left ventricular ejection fraction, myocardial strain, and infarct size, are used not only to demonstrate therapeutic benefit but also to monitor adverse events such as cardiotoxicity (Alexandre Destere 2024), as summarized in Table 1. Importantly, advanced imaging markers such as global longitudinal strain GLS (shown to outperform LVEF in mortality prediction) and novel CMR-derived endpoints (e.g. left atrioventricular coupling index (LACI) and parametric T1 mapping) can detect subtle, subclinical changes well before conventional clinical or serum biomarkers (Abubakar Nazir 2025, Evelyne Meekers 2024, Vidhi Piyush kumar Prajapati 2025), allowing changes to be quantified earlier in the disease trajectory. This allows sponsors to make faster, data-driven decisions about compound efficacy or dose optimization. However, the power of imaging endpoints is highly dependent on reproducible acquisition, standardised analysis, and rigorous quality control (Dominik C Benz 2023).

In multicentre trials, key sources of variability include inconsistent protocol adherence across sites, operator dependent acquisition variability particularly in echocardiography, inter-reader and intra-reader differences in image interpretation, and heterogeneous post processing methodologies. Fragmented or academically led core lab models can further exacerbate these challenges by introducing variability related to scanner vendor and field strength differences, inconsistent protocol implementation, and inter-reader variability, thereby amplifying noise, obscuring true biological signal, and limiting the ability to effectively address these issues in large, multicentre clinical trials.

These risks directly impact decision-making across dose selection, efficacy assessment, and regulatory confidence, underscoring the need for harmonised, specialist imaging infrastructure to fully realise the value of advanced cardiovascular imaging endpoints. In particular, for imaging biomarkers to reduce sample size and strengthen efficacy assessment, trials depend on scalable, standardised imaging infrastructure that minimises technical and interpretative variability.

Table 1 High-Value Cardiac Imaging Metrics in Clinical Trials

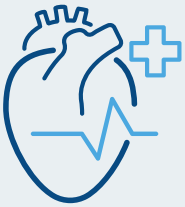
Metric	Modality	Clinical Relevance / Indications	Clinical Trial Value
Left Ventricular Ejection Fraction *(LVEF)*	CMR / Echo	HFrEF, HFpEF, cardiomyopathies, cardio-oncology, valvular disease	Established regulatory endpoint; global measure of systolic function; widely interpretable but relatively insensitive to early change
Global Longitudinal Strain *(GLS)*	CMR / Echo	HFpEF, early cardiomyopathy, cardio-oncology, aortic stenosis	Detects subclinical dysfunction; prognostic superiority to LVEF; sensitive to early treatment effects
Left Ventricular Volumes *(LVEDV/LVESV)*	CMR	HF, cardiomyopathy, post-MI remodelling	Gold-standard volumetric assessment; strong mechanistic and prognostic relevance
Myocardial Fibrosis *(LGE)*	CMR	Cardiomyopathies, aortic stenosis, myocarditis	Marker of irreversible myocardial injury; predictive of outcomes and response to therapy
Native T1 / Extracellular Volume *(ECV)*	CMR	HFpEF, amyloidosis, diffuse fibrosis, inflammatory disease	Quantifies diffuse myocardial disease not seen with LGE; early disease detection and monitoring
Left Atrial Volume / Function	CMR / Echo	HFpEF, atrial fibrillation, valvular disease	Reflects chronic diastolic burden; prognostic and responsive to intervention
Diastolic Function Parameters *(E/e', filling pressures)*	Echo	HFpEF, hypertensive heart disease	Key mechanistic endpoint in HFpEF; links symptoms with haemodynamics
Left Atrioventricular Coupling Index *(LACI)*	CMR	HFpEF, hypertensive heart disease	Quantitative measure of diastolic function and chamber interaction
Right Ventricular Function *(RVEF, RV strain)*	CMR / Echo	Pulmonary hypertension, HF, congenital heart disease	Strong predictor of outcomes; often under-captured by clinical endpoints
Myocardial Perfusion / Ischaemic Burden	CMR	CAD, microvascular disease, HFpEF	Quantifies reversible ischaemia; sensitive to therapeutic effects
Infarct Size / Area at Risk	CMR	Acute MI, cardioprotection trials	Mechanistically precise endpoint; correlates with long-term outcomes

1.2 Regulatory Requirements for Imaging Data

Regulatory authorities including the U.S. Food and Drug Administration (FDA), Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) increasingly demand imaging data that are standardized, auditable, and reproducible. With the FDA providing guidance on standards for imaging endpoints which emphasizes end-to-end control of imaging acquisition, management, and interpretation processes to reduce variability and support regulatory decision-making (U.S. Department of Health and Human Services Food and Drug Administration 2018).

Sponsors and CROs are also expected to demonstrate that imaging endpoints are delivered under validated procedures, within systems compliant with Good Clinical Practice (GCP), 21 CFR Part 11, and, where applicable, ISO 13485 quality standards. Meeting these regulatory expectations requires more than scientific expertise alone. It demands industry-specific operational discipline, validated systems, and end-to-end data governance from study initiation through regulatory submission. While academic core labs excel in methodological innovation and disease insight, they are often not equipped to provide the prospectively defined workflows, scalable quality management systems, validated software environments, and continuous audit trails outlined in FDA imaging endpoint guidance. In contrast, experienced CROs, such as Perspectum, embed these requirements contractually and operationally from study start-up, ensuring controlled image acquisition, standardised central reading, documented quality oversight, and traceable data lineage through to submission, reducing regulatory risk while preserving the scientific value of advanced imaging endpoints.

2. Limitations of Multi-Vendor & Academic Core Lab Models

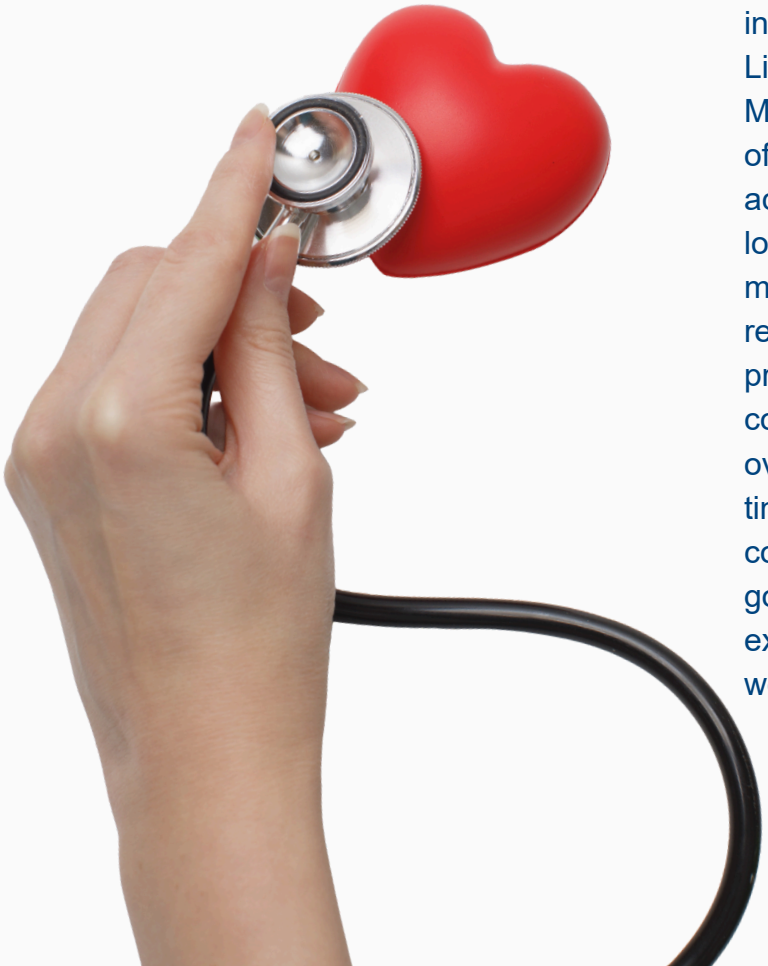


Despite their historical contributions to cardiovascular imaging, academic core labs present several drawbacks when used in the context of large, multicentre clinical trials. These challenges can be grouped into four main categories:

- *Lack of Standardization*
- *Operational Inefficiencies*
- *Regulatory Limitations*
- *Scalability Challenges*

2.1 Site-level Acquisition Complexity & Global Operations

In practice, much of the variability in imaging endpoints arises at the site level rather than from the analytical methodology itself. Large, multinational trials require consistent site training, standardised scanner setup, including across scanner manufacturer and field strengths, and continuous monitoring of acquisition quality to ensure protocol adherence.



Recent late-phase heart failure programs incorporating CMR sub-studies, such as Eli Lilly's SUMMIT CMR sub-study, (Christopher M Kramer and Group 2025) illustrate the scale of coordination required, with imaging delivered across geographically dispersed networks and longitudinal follow-up extending over many months. Even where imaging components represent only a sub-study within a broader program, they introduce substantial operational complexity, including centralized quality oversight, sustained site engagement, and real-time performance monitoring. Delivering this consistently at scale requires infrastructure and governance models designed for industrial-level execution rather than investigator-led workflows.

Academic core labs, while scientifically expert, are often not resourced to deliver continuous global site enablement, real-time image quality feedback, or proactive performance monitoring at scale. Particularly as CMR is technically complex, and many participating centres have variable experience with advanced CMR protocols.

Common operational challenges include:

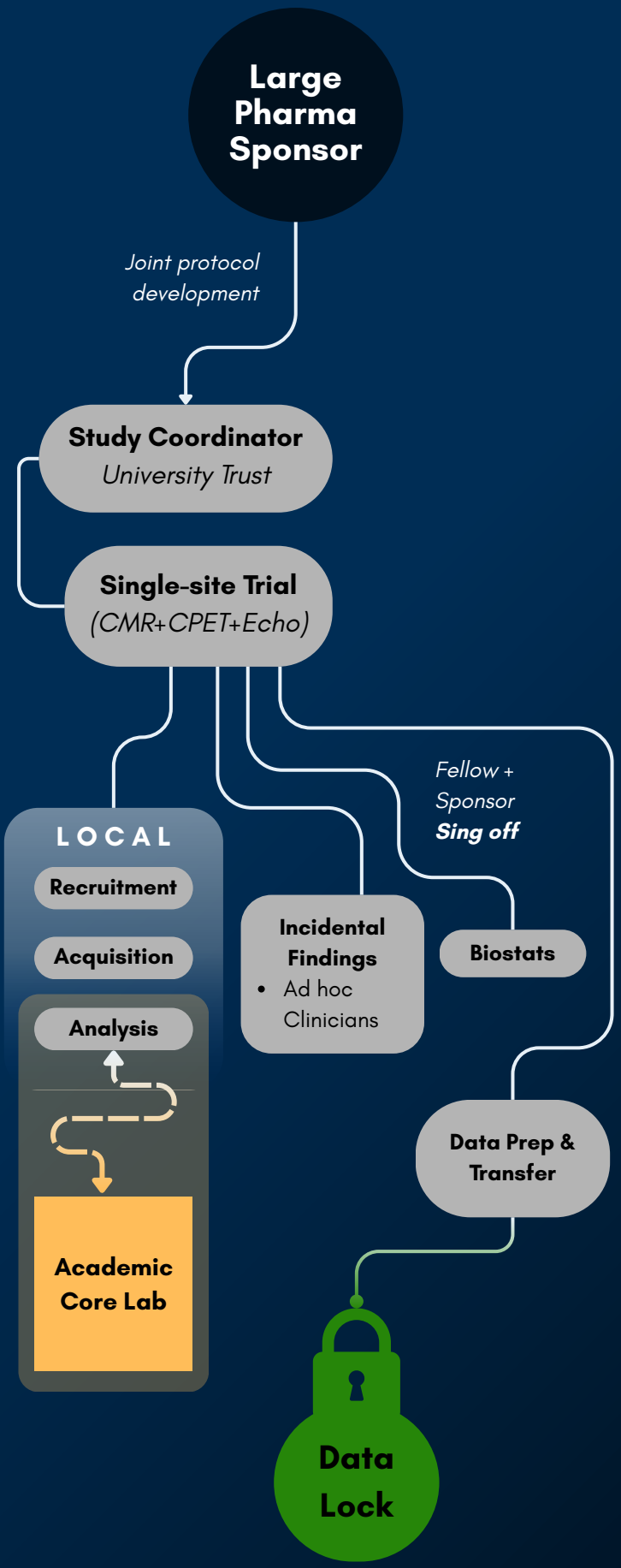
- Manual or email-based image transfer instead of centralized upload portals.
- Lack of integrated data management tools for tracking site compliance or image quality.
- Delays in query resolution due to resource constraints.
- Missing or inconsistent manuals for image acquisition and analysis.
- Lack of documented reader qualification and re-training programs.
- Incomplete data retention or traceability.
- Key study oversight factors: audit trials, version histories, corrective and preventive action (CAPA) processes

These operational constraints increase downstream monitoring burden, prolong database lock, and ultimately drive higher trial costs and delivery risk for sponsors, which could be mitigated through structured site qualification, hands-on training, and ongoing technical support to ensure consistent acquisition quality, which commercial imaging CROs are well-equipped to provide at scale.

2.2 Downstream analysis at the core lab level

In many academic environments, image analysis is frequently performed by rotating research staff, including PhD students or fellows, whose availability, experience, and long-term continuity may vary over the lifecycle of a multi-year trial. While scientifically capable, this model can introduce inconsistency in contouring practices, reader calibration, and adherence to standard operating procedures, particularly in the absence of formalised reader certification, performance monitoring, and re-training programmes. Variability introduced through personnel turnover and informal calibration processes can compound methodological heterogeneity, further challenging reproducibility in large, global studies.

For example, multi-centre studies show that differences in contouring conventions (especially basal slice selection) and post-processing software can introduce clinically meaningful inter-reader/inter-site and inter-vendor variation in LV volumes and ejection fraction often in the high single digits and, in some settings, around or above ~10% for key derived parameters materially impacting statistical power and comparability across trial sites (Avan Suinesiaputra 2015, Doyin S. Mansell 2020).

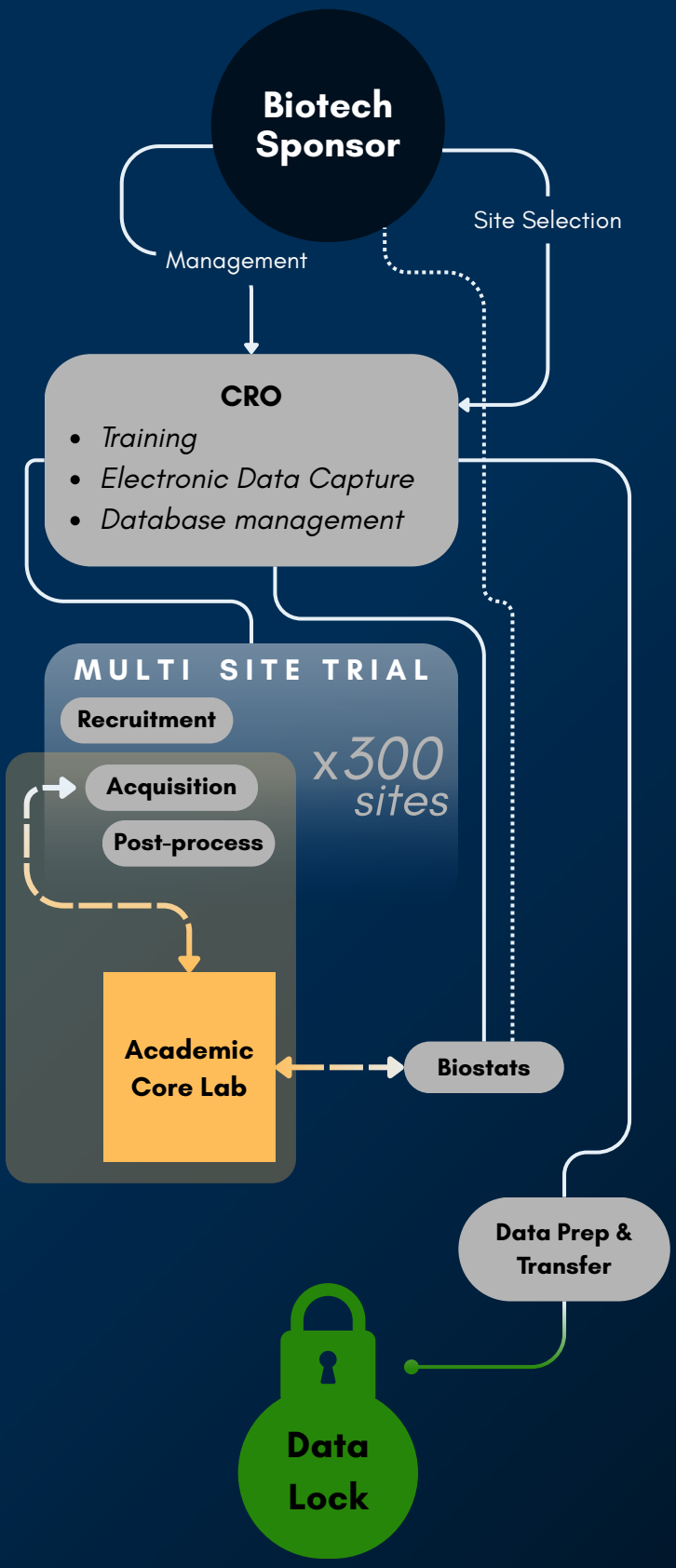


2.3 Case Example:

Cardiac Trial Using 1 Academic Core Lab

The trial faced significant operational complexity driven by structural misalignment and limited infrastructure (left). Academic-led protocols were not designed for scalable, regulatory-grade delivery, while a single site performed multiple roles, investigator site, imaging core lab, and data manager, creating conflicts in accountability and priorities.

The lack of cloud-based, distributed systems led to data loss and exposed a single point of failure, compounded by limited staffing redundancy and no dedicated Clinical Project Manager. Fragmented responsibilities and high reliance on individual availability further constrained delivery, resulting in low patient recruitment, slow issue resolution, and increased operational risk at critical milestones.



2.4 Case Example:

Large-scale Cardiac Trial Using 1 Academic Corelab

This large-scale trial, spanning ~300 sites, faced substantial operational strain driven by variability in site experience, workflow maturity, and imaging quality, placing a heavy coordination burden on the CRO (left). A point-in-time certification model, without continuous quality oversight, left gaps in managing technique drift, staff turnover, and inter-operator variability. Site personnel often juggled multiple responsibilities alongside clinical duties, increasing the risk of protocol deviations and inconsistent execution. Fragmented modality management across different vendors further complicated integration, while gaps in data capture and late identification of missing data reduced statistical power and limited opportunities for remediation.

Turnaround times for imaging reads are a critical determinant of clinical trial timelines, particularly in studies with interim analyses, adaptive designs, or predefined safety review checkpoints. Delays in image acquisition review or central reads can postpone go/no-go decisions, dose-escalation steps, or safety signal assessments triggered by imaging findings, introducing downstream protocol deviations or operational pauses.

At the back end of a programme, unpredictable read timelines can delay database lock and cascade into missed submission windows, extended trial duration, and increased cost, transforming what's initially an operational issue into a material risk to development timelines and regulatory strategy.

In contrast, single vendor, specialised imaging CROs provide trial derisking through dedicated quality assurance frameworks, secure cloud-based data ingestion and storage, and robust cybersecurity controls aligned with clinical and regulatory requirements. Stable, low-turnover teams of full-time, experienced image analysts enable consistent application of standards across studies, supported by defined staffing ratios and protected delivery capacity.

3. The Single, Specialized Imaging Vendor Model

For global cardiac programmes, Sponsors are increasingly favouring a single, specialised imaging vendor as a means of reducing operational risk, preserving endpoint integrity, and ensuring regulatory grade data across all trial phases. While academic core labs are highly effective in single centre or regionally limited studies, they are often not structured to deliver global site enablement, real time quality surveillance, or ongoing monitoring of inter-reader and inter-site variability at scale.

Without these capabilities, differences in site performance. scanner configuration, and acquisition protocol adherence can introduce variability that propagates into downstream measurements, reinforcing the rationale for a specialised imaging partner in global programmes.

3.1 End-to-end Operational Ownership

A single cardiac imaging vendor enables harmonised site qualification, modality-specific training, and standardised acquisition protocols across all centres. Centralised oversight allows continuous monitoring of image quality, rapid feedback to sites, and proactive management of protocol deviations. These capabilities are critical for CMR- and echo-based endpoints and difficult to sustain in fragmented or academic-led models.

Defined governance structures underpin this accountability. Formalized governance models with documented roles and responsibilities, steering committees, structured project management and communication plans, and systematic tracking of site and reader performance enable transparent oversight of imaging performance across all centres.

Clear quality escalation pathways are equally critical. Established escalation frameworks and CAPA processes, aligned with regulatory expectations for data integrity ((U.S. Department of Health and Human Services Food and Drug Administration 2018) and inspection readiness, ensure that issues are documented, investigated, and remediated in a controlled and auditable manner. This structured approach protects endpoint robustness and reduces regulatory risk for CMR- and echocardiography-based programmes.

3.2 Site-level Execution at Scale

In multicentre trials, the primary source of imaging variability arises at the point of acquisition. A specialised imaging vendor mitigates this risk through structured site training and management models designed specifically for consistent execution across diverse geographical regions and scanner environments. This includes:

- Formal site qualification and technical feasibility assessment
- Vendor-neutral scanner harmonisation across field-strengths and manufacturers
- Modality-specific training and certification of technologists
- Standardized acquisition manuals and protocols
- Test case submission prior to first patient enrolment

Beyond site initiation, centralised real-time image quality review enables early identification of protocol deviations, suboptimal acquisitions, or performance drift. Structured feedback loops allow for rapid corrective actions to be taken, reducing the need for repeat scans, minimising data loss, and protecting statistical power. This industrialised oversight model contrasts with the more-investigator led workflows seen when using academic core labs.

3.3 Standardized Analysis & Reader

A single specialised imaging vendor can apply consistent reader training frameworks, contouring conventions, and validated analysis algorithms across all study participants. Structured reader training programmes and certification processes, periodic recalibration exercises, and formal inter- and intra-reader variability monitoring are embedded within this framework to maintain analytical consistency over the lifecycle of the trial. This systematic governance model supports the regulatory expectations for standardisation, reproducibility, and documented control of endpoint derivation.

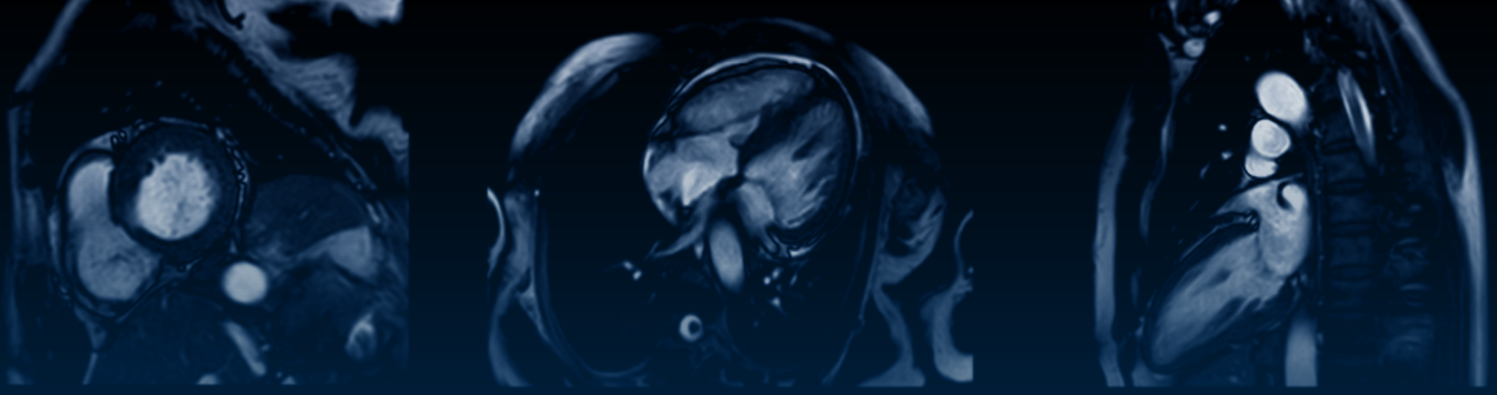
Equally important is the use of purpose-built data platforms compliant with GCP, 21 CFR Part 11, GDPR, and HIPAA, proving controlled environments for secure image management and central analysis. Version-controlled software, locked algorithms, full audit trails, and formal change control processes align with regulatory guidance on computerised systems used in clinical investigations. Together, these controls ensure that analytical methods remain stable, traceable, and defensible at the time of submission, with complete data lineage from acquisition through database lock.

3.4 Cross Trial Data Strategy

Beyond operation execution within a single study, the strategic advantage of a single, specialised imaging vendor becomes more pronounced across programmes.

Standardisation in acquisition protocols, analysis conventions, and reporting formats across trials enable harmonised cardiac imaging datasets over time. This continuity reduces the need for re-validation between phases, supports integrated safety and efficacy assessments, and allows Sponsors to build cumulative evidence around cardiac biomarkers across indications. Such alignment is particularly valuable in cardiovascular and cardiometabolic development, where overlapping imaging biomarkers, such as ventricular function, myocardial structure, and tissue characterisation, are used across multiple indications

In contrast, fragmented imaging oversight across different vendors or academic core labs can lead to methodological drift, data re-analysis, and inconsistencies that complicate cross-study interpretation. A single, specialized imaging partner therefore not only provides operational control within individual trials, but also strategic data continuity across the lifecycle of a development programme.



4. Perspectum Capabilities

4.1 An overview of our operational delivery

In cardiovascular imaging, small variations in quantification can have large implications for statistical outcomes. Standardization across acquisition protocols, reconstruction algorithms, and reader interpretations is therefore essential.

Perspectum's specialist services can handle complex and large-scale operational delivery. As an imaging vendor we implement harmonized analysis pipelines, validated algorithms, fixed contouring conventions, and centralized calibration. This reduces inter-reader and inter-site variability and enhances the statistical power of efficacy analyses. Consistency begins upstream through formal site qualification, structured technical training for technologists, detailed acquisition manuals, and protocol-specific certification prior to site activation.

Quality control is embedded throughout the workflow, including real time image quality review, predefined acceptance criteria, automated data checks, continuous reader performance monitoring, and formalized inter and intra reader variability assessments. Continuous feedback loops allow early identification of protocol drift and immediate corrective action.

Perspectum's dedicated cloud-based portal provide sponsors and CROs with real-time visibility into site performance, image quality, and read status, while enabling seamless integration with CRO Electronic Data Capture (EDC) systems.

Defined governance frameworks, performance dashboards, and structured escalation pathways with documented CAPA processes, ensure that issues are investigated, resolved, and auditable in alignment with regulatory expectations.

Throughout the study, data collection is supported by dedicated Clinical Project Managers (CPJMs) who act as the single, consistent point of contact (POC). This project management structure ensures clear accountability, coordinated communication across sites and CRO partners, and proactive risk management across the trial lifecycle.

CPJMs draw on specialist technical teams and R&D expertise as needed to rapidly resolve imaging-related issues. This model is underpinned by established infrastructure for information security and quality assurance, ensuring reliable and compliant data delivery across the trial lifecycle.

By integrating site enablement, continuous quality oversight, validated analysis environments, and formal governance into a single operational framework, we ensure consistency across centres, phases, and indications rather than relying on retrospective correction of variability.

4.2 Our Reading Frameworks

Perspectum's reading frameworks are designed to ensure reproducibility, consistency, and regulatory readiness across studies, phases, and indications (left). We use locked algorithms, documented verification and validation, full audit trails, and traceable data lineage to generate quantitative imaging biomarkers within validated, version controlled environments. Where novel or exploratory endpoints are required, methods are developed within a controlled framework and formally verified and validated prior to regulatory deployment.

Reader performance is governed through structured training, and protocol-specific certification, with ongoing calibration to standardised contouring conventions.

Inter- and intra-reader variability are routinely assessed, and performance is continuously monitored over the study duration to detect drift early. All analytical methods operate under documented change control and quality management processes, embedding validation, traceability, and inspection readiness directly into the workflow from early development through to late-phase programmes (M N Bossa 2025).

4.3 Platform & Infrastructure

Perspectum is designed to operate seamlessly within sponsor and CRO delivery models, with established integrations across most major global CROs. Our secure, validated cloud infrastructure supports compliant storage, processing, and transfer of imaging data within a single controlled environment, with full audit trails, role-based access controls, and documented data lineage from upload through final data export. This unified architecture reduces operational complexity while maintaining inspection readiness.

Through direct integration with CRO clinical data management and EDC systems, the platform enables secure, near real time exchange of endpoint data, minimizing manual reconciliation and accelerating downstream analyses. By synchronising imaging endpoints with the broader clinical database, transcription risk and reconciliation delays are materially reduced.

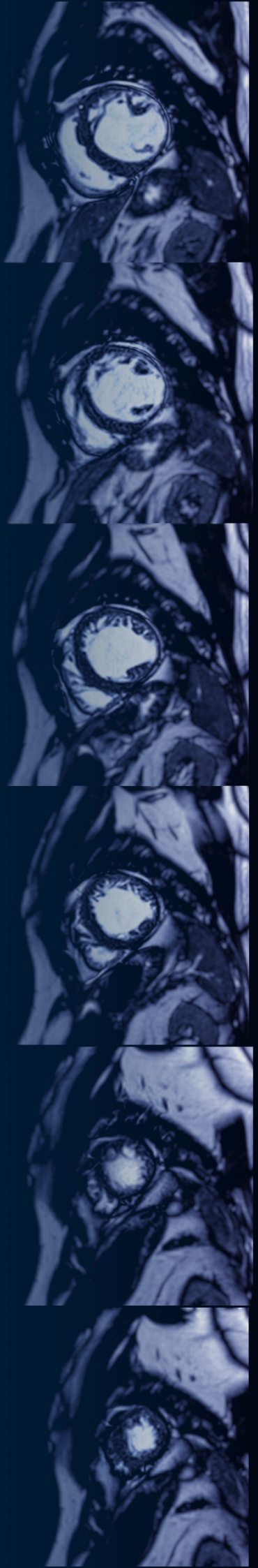
Both sponsors and CROs are provided with controlled access to Perspectum's portal, offering real-time monitoring through configurable dashboards displaying site performance, image quality metrics, protocol deviations, read status, and turnaround times. This shared operational interface consolidates oversight into a single source of truth, supporting efficient trial management, timely decision making at critical milestones, and ensuring imaging endpoints remain fully aligned with overall clinical programme execution.

Conclusion

The success of cardiovascular clinical trials depends increasingly on the precision and reproducibility of imaging-derived endpoints as therapeutic effects are often modest, disease trajectories are heterogeneous, and imaging endpoints frequently serve as primary or key secondary determinants of efficacy, safety, and regulatory decision-making. While academic core labs have historically driven methodological innovation, their operational variability, limited scalability, and regulatory constraints pose significant risks in large-scale commercial trials.

A failed trial in the CVRM space carries major financial and patient-level costs. Large, event-driven cardiovascular trials often represent a $50–200M+ direct investment, with cardiovascular pivotal trials among the most expensive therapeutic areas, averaging ~$157M per trial in FDA-era analyses (Olivier J. Wouters 2020). Ongoing execution also incurs substantial time costs, with Phase III trials costing approximately $55,700 per day, meaning delays or inconclusive outcomes rapidly compound losses (Zachary Smith n.d.).

From a patient perspective, trial failure means participants absorb significant burdens: time, travel, procedures, without yielding practice-changing evidence, while for the wider CVRM population, failed or delayed trials postpone access to effective therapies and definitive evidence on outcomes (Wouters et al., 2020; Tufts CSDD, 2024). In cardiovascular development, where imaging endpoints are often used to justify pivotal decisions or early intervention strategies, failure driven by avoidable endpoint variability represents a preventable and unacceptable risk.



Adopting a single imaging vendor model offers a clear path forward. It ensures standardized methodologies, validated software environments, robust quality management, and centralized data integrity, all of which align with the expectations of CROs, sponsors, and regulators alike.

The FDA has explicitly articulated expectations for independent, prospectively defined, and auditable central review of imaging endpoints, reinforcing the need for qualified vendors capable of maintaining end-to-end control, traceability, and reproducibility. Beyond operational efficiency, the model enhances scientific credibility and accelerates the translation of cardiovascular therapies from research to patient care.

In an era where imaging data often determines the fate of multi-million-dollar clinical programs, **the question is no longer whether centralization adds value**, but whether any sponsor can afford not to embrace it.

Get In Touch

Pharma.Business.Development@perspectum.com

www.perspectum.com

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