

Inspection-Ready by Design:

Why Emerging Biotechs
Should Build a Compliant
Digital Foundation



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Executive Summary

Implementing a digital platform for Clinical Data Management is not a question of WHETHER but WHEN.

As emerging biotechs advance into clinical development, they are facing rapid data growth which becomes unmanageable when using self-developed data solutions and fragmented systems. This leads to increased financial and regulatory risk.

Regulators and investors expect more than strong science – they expect clear evidence of data integrity, documentation quality, and operational readiness.

However, many small companies struggle with manual processes and unclear ownership of data. This burdens teams with non-value-adding activities, exposes companies to inspection findings and delays, and reduces investor confidence.

Success in research and development relies on effective, compliant data management, built on a modern digital system that integrates essential functions such as documentation, quality management, and training into a single compliant platform.

A unified approach enables continuous inspection readiness, promotes transparency, and supports collaboration with external partners. Additionally, a modular, scalable platform grows with the company's needs without adding unnecessary complexity.

Crucially, early investment in a digital foundation reduces long-term costs and avoids reactive remediation efforts. It also serves as a strong signal of operational maturity, improving investor confidence, and positioning companies for growth.

► **Organizations that implement a compliant, cloud-based clinical data management platform from the start keep their teams focused on R&D instead of administrative tasks and stay ready for audits and due diligence at any time.**

1 | The Emerging Biotech: Context

Emerging biotechnology companies operate under distinct structural conditions compared with established pharmaceutical organizations. Typically founded around a specific scientific discovery, platform technology, or therapeutic hypothesis, these companies aim to translate promising biology into clinically and commercially viable development programs while working with lean teams and limited resources.

Strategic focus is a defining characteristic of early-stage biotech operations. With long development timelines and funding tied to value-inflection milestones, leadership teams must continuously prioritize which experiments to run, which indications to pursue, and how to allocate resources across scientific, operational, and organizational needs. Decisions regarding portfolio breadth, capability build-up, and external partnerships are often linked to the timing and objectives of future financing or partnering events.

Because internal infrastructures are intentionally lean, emerging biotechs rely heavily on external partners to execute critical activities across the development lifecycle. Contract Research Organizations (CROs), manufacturing partners, specialized consultants, and academic collaborators frequently act as extensions of the company. Managing this distributed operating model requires coordination across multiple stakeholders and regulatory expectations while maintaining strategic ownership of programs and development decisions.

In parallel, financing dynamics strongly influence how emerging biotechs design and advance their development strategies. Investors and potential partners evaluate not only the novelty of the underlying science but also the credibility of the path toward clinical validation and eventual commercialization. Companies must therefore generate decision-relevant evidence at each stage of development to support valuation progression, partnership discussions, and long-term strategic positioning.

As emerging biotechs advance their programs, managing and making sense of data becomes a key strategic task. Preclinical findings, clinical observations, and manufacturing insights form the basis for investment decisions, regulatory interactions, and partnering discussions. In a distributed and increasingly complex development environment, the ability to manage data effectively becomes critical to maintaining momentum and credibility.

► **Emerging biotechs are rarely constrained by a lack of scientific ideas; rather, they are constrained by their ability to translate those ideas into executable development strategies under uncertainty and limited resources. The early-stage model enables rapid decision-making and concentrated resource allocation, but it also introduces execution challenges that become more visible as companies scale, raise capital, or enter clinical development. At these inflection points, gaps in data governance, organizational maturity, and process clarity can quickly become strategic liabilities.**

2 | Emerging Biotech: Specific Pain Points

Emerging biotechs operate in an increasingly demanding environment where scientific excellence alone is no longer sufficient to secure investment or strategic partnerships. Funding for early-stage biotechnology companies has tightened, intensifying competition and investor scrutiny. Young companies are under pressure to move fast and deliver tangible results, often operating in a chaotic environment that can feel like the Wild West: fast-paced, resource-constrained, and not yet fully structured.

Key Challenges for Emerging Biotechs

1. Limited Organizational Maturity

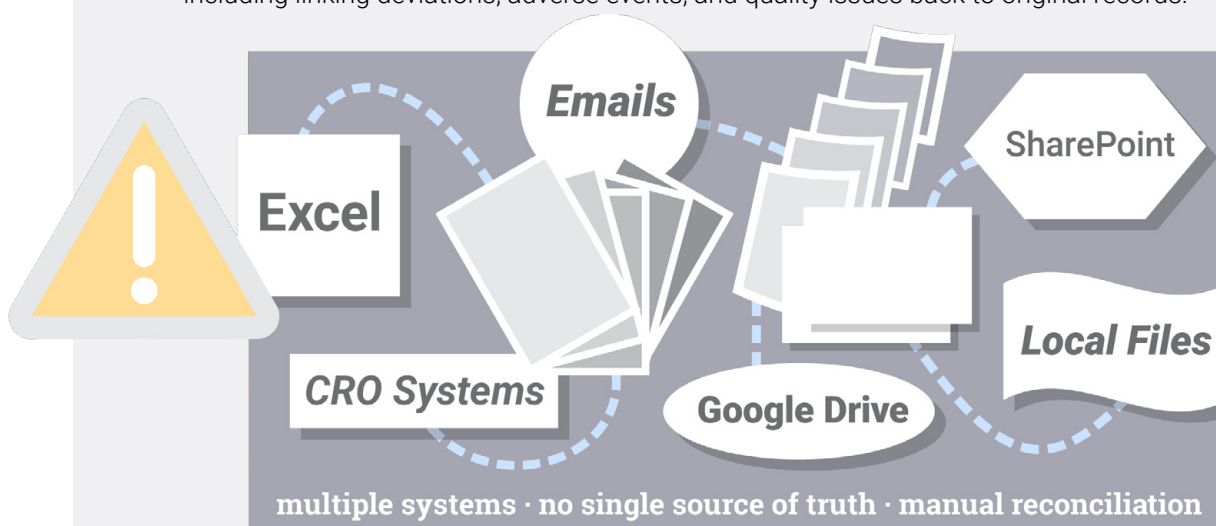
- Small teams, mostly scientific experts.
- Minimal regulatory, operational, or contractual experience.
- Lean structures and restricted budgets.

2. Regulatory and Compliance Complexity

- Navigating frameworks like Good Clinical Practice (GCP) or Good Manufacturing Practice (GMP).
- Risk of over-implementing regulations due to uncertainty, wasting resources.
- Heavy reliance on external consultants, sometimes leading to unnecessary services.

3. Data Management Challenges

- Overwhelm from rapid data growth, particularly in early clinical phases and across outsourced partners (e.g., clinical trials generate exponentially more data points than before).
- Fragmentation of documents and data across tools like Google Drive, Box, SharePoint, personal folders, CDs, or FTPs.
- High dependency on CROs, yet the biotech company remains legally accountable for data.
- Version confusion and a missing “single source of truth” lead to difficulty contextualizing data, including linking deviations, adverse events, and quality issues back to original records.



4. Investor Expectations

- Strong data quality and traceability are essential to reducing perceived risk.
- Poor documentation or incomplete control over data lowers investor confidence and company valuation.
- Investors favor teams that demonstrate readiness to scale and operational rigor alongside scientific promise.

► **Left unaddressed, these challenges can erode compliance confidence and reduce control over clinical data, creating risks that may complicate inspections or undermine investor trust. For emerging biotechs, building structured data governance and operational readiness is therefore a prerequisite for sustainable growth and successful clinical advancement.**

3 | Business Challenges in Clinical Data & Document Management

Core Systems Under Pressure

Foundational systems such as eTMF, QMS and LMS are essential for regulated clinical development. However, emerging biotechs often operate with fragmented setups, bridging functional gaps through spreadsheets, shared drives, or manual trackers. This creates version-control issues, breaks in traceability, and increases operational risk as study activity intensifies.

When Inspection Requests Expose Structural Gaps

Routine inspection questions – such as demonstrating that a specific team member was trained on a procedure at a defined point in time – can quickly reveal weaknesses. Non-validated tools, missing audit trails, and inconsistent document versions make it difficult to provide reliable evidence. What appears manageable during daily operations can escalate into formal findings under regulatory scrutiny.

Operational Distraction in Lean Teams

Small organizations rely on highly specialized staff who are expected to move programs forward efficiently. Yet fragmented data environments often require scientists and clinical operations teams to spend disproportionate time reconciling lists, copy-pasting information between systems, or tracking document status manually. This administrative burden diverts focus from core scientific and development activities.

Data Integrity Risks During Transfers

Clinical data and documentation frequently move between sponsors, CROs, and vendors throughout a study lifecycle. Without structured validation and controlled repositories, transferred data can be incomplete, mismatched, or difficult to verify.

Complexity Scales Faster Than Headcount

As pipelines progress and teams expand, operational complexity often grows faster than organizational capacity. Processes that function informally in early phases can become bottlenecks when multiple studies, vendors, and regulatory interactions occur simultaneously. Without scalable digital foundations, this complexity translates into inefficiencies, rework, and increased compliance exposure.

► Administrative Overload Reduces Development Momentum.

When data and document management become chaotic, a growing portion of team capacity is consumed by non-value-adding tasks. Time spent searching, reconciling, and correcting information is time not spent advancing research and development. Over time, this hidden operational drag can weaken a company's competitive position.

4 | Regulatory Challenges & Inspection-Readiness

TMF Completeness and Availability are Central Inspection Criteria

TMF (Trial Master File) completeness and availability remain central inspection criteria. EMA (European Medicines Agency) guidance states that the Trial Master File is the core basis for inspection and must be complete, identifiable and immediately accessible, including documentation held across multiple systems or partners.¹ In practice, EMA-coordinated inspections continue to show that gaps in essential documents, source documentation and TMF/ISF (Investigator Site File) maintenance are among the most frequent critical and major findings.²

¹ EMA. Guidance for applicants/MAHs involved in GMP, GCP and GVP inspections coordinated by EMA, EMA/274221/2021, 2022.

² Annual Report of the Good Clinical Practice Inspectors Working Group 2024.

Documentation: A Leading Source of Inspection Findings

Documentation deficiencies remain one of the most common root causes of regulatory findings. In 2024, EMA-coordinated inspections raised 335 major and critical GCP deficiencies across 67 inspections, with 137 in 'General' (e.g. essential documents, source documentation, SOPs) and 86 in 'Trial Management' (Sponsor data management, monitoring, document control, CSR issues).

Drilling into the EMA's 2024 breakdown by subcategory, we see four themes:

- ▶ **Essential documents & TMF/ISF:** incomplete files, poor maintenance, missing version control, lack of TMF quality control, lack of inspection readiness at sites.
- ▶ **Source documentation:** incomplete, inaccurate or non-contemporaneous entries; discrepancies between source and CRF; inadequate documentation of key processes and sample handling.
- ▶ **SOPs:** missing or delayed SOPs for critical trial processes, lack of version control and change management, and SOPs not aligned with regulatory expectations.
- ▶ **Data management:** lack of data management plans, inadequate data migration and validation, use of Excel for sensitive data collection, poor traceability, weak data security.

For emerging biotechs, these are precisely the areas most exposed when documentation is scattered across email, shared drives, and unvalidated tools.

The challenge for emerging sponsors is intensified by the scale and diversity of modern clinical data. Studies now generate vast volumes of structured data, images, patient-reported outcomes and decentralized trial artefacts, making retrospective review or clean-up at study close-out increasingly unrealistic.

Earlier Expectations, Faster Timelines

Regulatory expectations increasingly arise earlier in the development lifecycle, accompanied by accelerated submission and response timelines. Sponsors are expected to demonstrate inspection-readiness well before pivotal milestones.

At the same time, signals of weak data control can quickly escalate risk, including:

- Disorganized document retrieval
- Broken traceability across systems
- Reliance on ad hoc or spreadsheet-based controls

Such signals may turn a manageable inspection into a critical event. They can also undermine an investor's confidence in a company's ability to scale.

Sponsor Accountability cannot be Outsourced

A common misconception among start-ups is that outsourcing operational execution also transfers regulatory responsibility. In reality, documentation completeness, data integrity, and oversight evidence remain the sponsor's obligation.

Guidance from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH E6(R3)) explicitly states that sponsors retain ultimate responsibility for trial quality and outsourced activities.³

Inspection data also make clear that sponsors remain the primary focus of regulatory scrutiny. Across all EMA inspected sites in 2024, sponsors were responsible for approximately 53% of major and critical findings, with a further 25% attributed to multiple parties.

Oversight must be documented within sponsor-controlled, validated systems and not solely within CRO platforms.

Between Under-interpretation and Over-compliance

Emerging biotech teams – often composed primarily of scientific experts – face a dual regulatory risk:

- **Under-interpretation:** assuming small size or outsourcing reduces compliance obligations

- **Over-compliance:** implementing excessive controls due to limited regulatory experience

Both extremes create inefficiency and exposure. A pragmatic, risk-based compliance approach is therefore critical and also required by GCP.

Data Governance as a Strategic Capability

Outsourcing is operationally necessary, but delegating core data storage or documentation control creates structural risk.

Sponsors remain accountable for the data during inspections, submissions, and due diligence. Early requests for oversight evidence and quality metrics are becoming standard.

Rising trial complexity and growing data intensity place additional pressure on oversight models.

► **According to the EMA GCP Inspectors Working Group's 2024 report, 335 major and critical findings were issued. These deficiencies map directly to weaknesses in foundational systems such as TMF, QMS and data-management platforms, particularly when sponsors rely on spreadsheets and unvalidated collaboration tools.**⁴

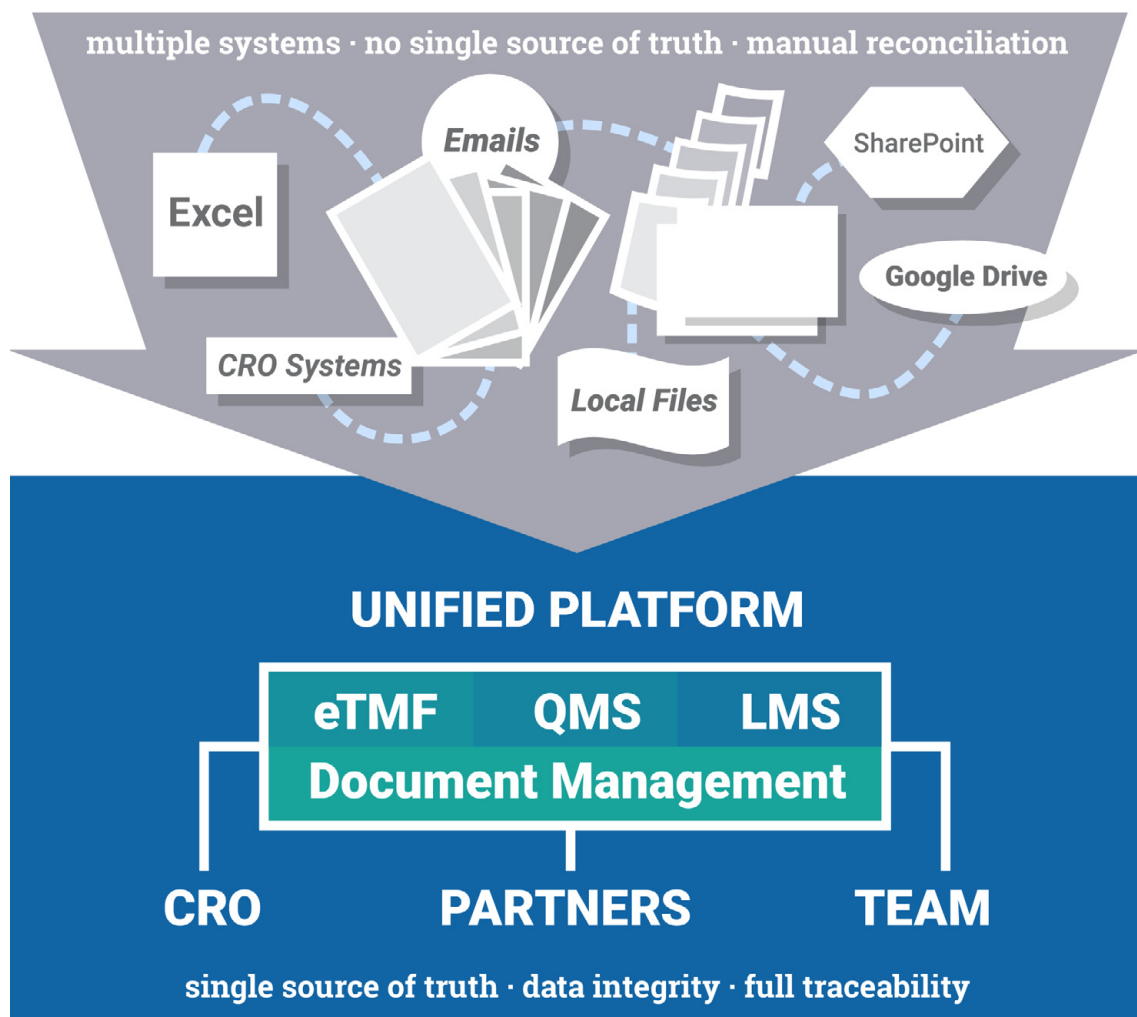
If fragmented systems and reactive processes increase regulatory exposure, the next question is clear: what kind of digital foundation ensures compliance by design?

^{3 + 4} ICH: Guideline for Good Clinical Practice E6(R3), January 6, 2025.

5 | The Role of Integrated Digital Solutions

From Fragmentation to a Single Source of Truth

An effective digital foundation brings critical functions such as TMF, QMS, LMS, and core documentation into one controlled environment. Centralization reduces system switching, breaks in traceability, and reliance on spreadsheets or locally stored files. A validated, unified platform increases transparency and simplifies audit preparation by making documentation complete, consistent, and accessible.



Design for Simplicity, Not Complexity

For small and growing organizations, simplicity is achieved through fit-for-purpose integration. Platforms that overload users with unnecessary features or force rigid, one-size-fits-all processes often create workarounds and inefficiencies. Flexible configuration allows companies to align systems with their real workflows and regulatory needs while maintaining compliance.

Inspection-Readiness as a Built-In Capability

When quality processes, training records, and study documentation are integrated, control becomes demonstrable at any time - not only during inspection preparation. By reducing manual reconciliation and system-hopping, integrated platforms help lean teams maintain oversight even as data volumes and study complexity increase.

What does “Inspection-Readiness by Design” Mean?

It means embedding compliance, traceability, and control into the operating mode from the start. So that the organization can produce evidence for inspectors at any time.

Key enablers:

- Audit trails
- Controlled workflows
- Role-based access
- Standardized processes
- Data flow overview
- Real-time oversight
- Always-available documentation

Scaling in Step with Business Growth

Digital foundations should evolve alongside the organization they support. Rather than introducing large, disruptive systems upfront, companies benefit from modular platforms that enable a gradual build-up of capabilities.

Tailored system environments allow workflows, user roles, and functionality to align with the company's stage of development, avoiding the constraints of one-size-fits-all solutions. As operational needs grow, additional capabilities - such as CAPA management or advanced reporting - can be introduced when they become relevant, supporting efficient adoption without unnecessary complexity.

► Governance as an Investment Signal

Operational control over data and documentation is increasingly viewed as a marker of organizational maturity. Investors favor companies that combine scientific potential with structured governance and reliable data environments. Demonstrating inspection-readiness and data integrity signals reduced execution risk and stronger scalability.

6 | IT Architecture & Process Integration

Digital platforms only deliver lasting value when their architecture supports scalability, governance, and cost control. The critical question is not just which system to choose, but whether its design will simplify operations or introduce new complexity.

Consolidation Instead of Version Chaos

Relying on a patchwork of shared drives, spreadsheets, and generic collaboration tools often results in fragmented document landscapes and inconsistent version control. Such environments typically lack validated audit trails and controlled access, increasing exposure during inspections or due diligence. A consolidated platform reduces these risks by creating a single, governed environment for critical data and documentation.

Controlled Collaboration with External Stakeholders

Secure exchange environments enable structured collaboration with CROs, statisticians, auditors, and investors. External partners can contribute data, review documentation, or conduct due diligence within a controlled system context, minimizing uncontrolled downloads and reducing the risk of fragmented data transfers.

Process-Driven Integration Without “Oil Tanker” Complexity

Effective integration should enable seamless data exchange without creating heavy system dependencies that require extensive administrative resources.

Sustainable digital architecture starts with mapping organizational responsibilities, data flows, and contractual interfaces before selecting technology. Platforms designed around real processes remain easier to steer as organizations grow, avoiding the “oil tanker” effect of systems that are difficult to adapt once implemented.

Beyond Technology: Platform and Advisory as a Combined Capability

Technology alone does not guarantee successful adoption. Combining an integrated platform with experienced life science advisory support helps organizations configure systems appropriately, manage validation and administration tasks, and avoid costly missteps.

It also reduces the burden of in-house IT and system maintenance, allowing biotech teams to focus fully on advancing research and development.

► Predictable Costs and Scalable Operations

When architecture and process integration are aligned, digital platforms can be implemented quickly and operated without dedicated internal IT teams. Guided onboarding and modular scalability keep cost structures transparent while enabling organizations to maintain efficient, compliant control over their data and documentation.

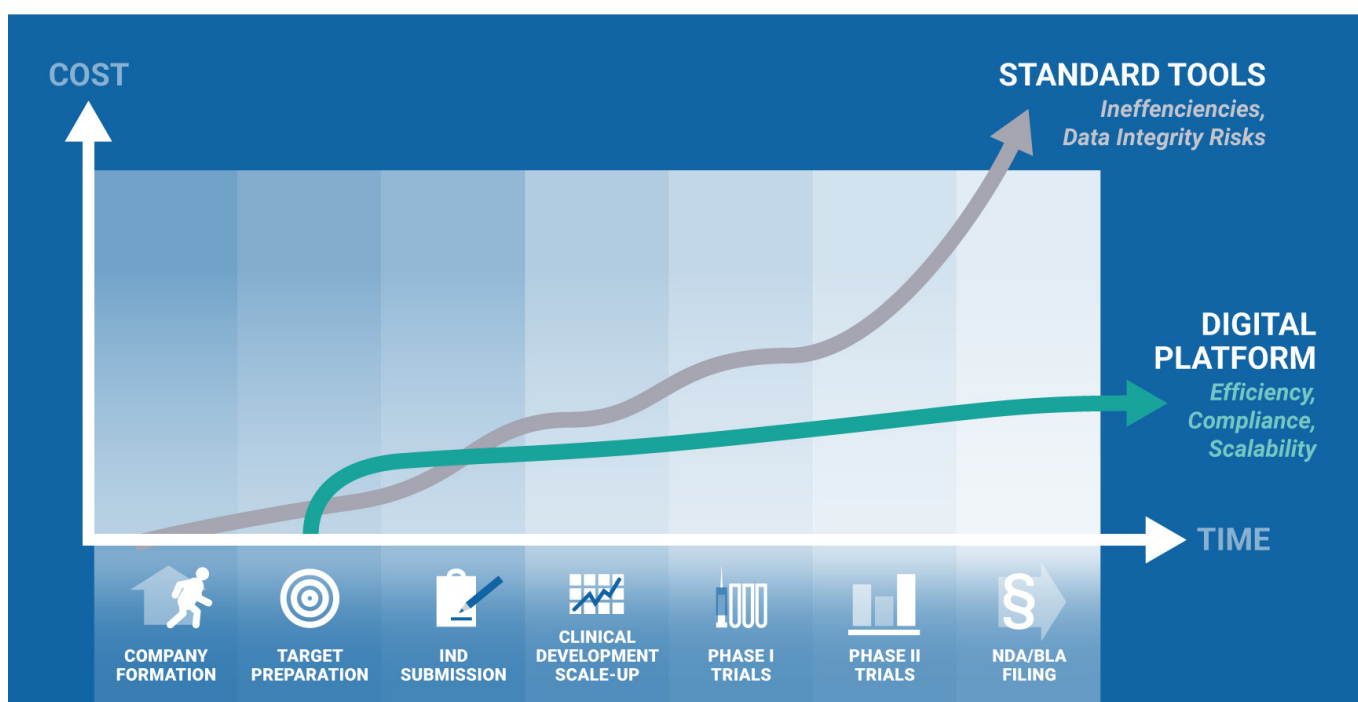
7 | The Strategic Value of Early Digital Foundations

Delaying Digital Foundations Increases Cost and Complexity

Establishing a validated, cloud-based digital foundation early allows inspection readiness to become a routine practice rather than a reactive effort. Just like preventative medicine helps avoid serious health issues by addressing them early, maintaining a continuous structure prevents the buildup of problems that would later require significant intervention.

Organizations that delay implementation often face fragmented systems, inconsistent data, and loss of control as operations grow. Widely used tools such as Excel, Dropbox, or SharePoint may appear sufficient in early phases, but they lack validation, audit trails, and controlled access. Over time, this results in disconnected data, unclear ownership, and increasing governance risks.

Costs of Managing Clinical, TMF & Scientific Research Document Data over Time



The result is a significantly higher total cost of ownership, driven not only by inefficiencies, but by:

■ Costly data migration and system replacement

When organizations outgrow Excel files or shared drives, they are forced to transition to validated systems, often under time pressure. This requires manual data structuring, reclassification of documents, and rebuilding metadata across large document volumes.

The result: additional external consulting costs and/or internal resource strain.

■ Remediation ahead of audits or due diligence

Prior to investor due diligence or regulatory inspections, companies frequently need to reconstruct missing documentation, correct version histories, or justify incomplete audit trails. These reactive efforts are time-critical and carry the risk that gaps cannot be fully resolved.

■ Delays in clinical timelines

Inconsistent or poorly controlled data can slow down key milestones such as study start or submissions. Teams may spend significant time locating, verifying, or reconciling data instead of progressing trials, directly impacting development timelines.

■ Increased internal workload to restore control

Without structured systems, teams rely on manual tracking, email follow-ups, and duplicate documentation efforts. As complexity grows, this creates a continuous operational burden, diverting skilled staff from strategic work to administrative firefighting.

Operational Maturity as a Measurable Financial Signal

Investors and strategic partners evaluate more than scientific potential. They assess whether a company demonstrates control over its data, documentation, and processes. Reliable, audit-ready systems reduce perceived risk and increase confidence in execution.

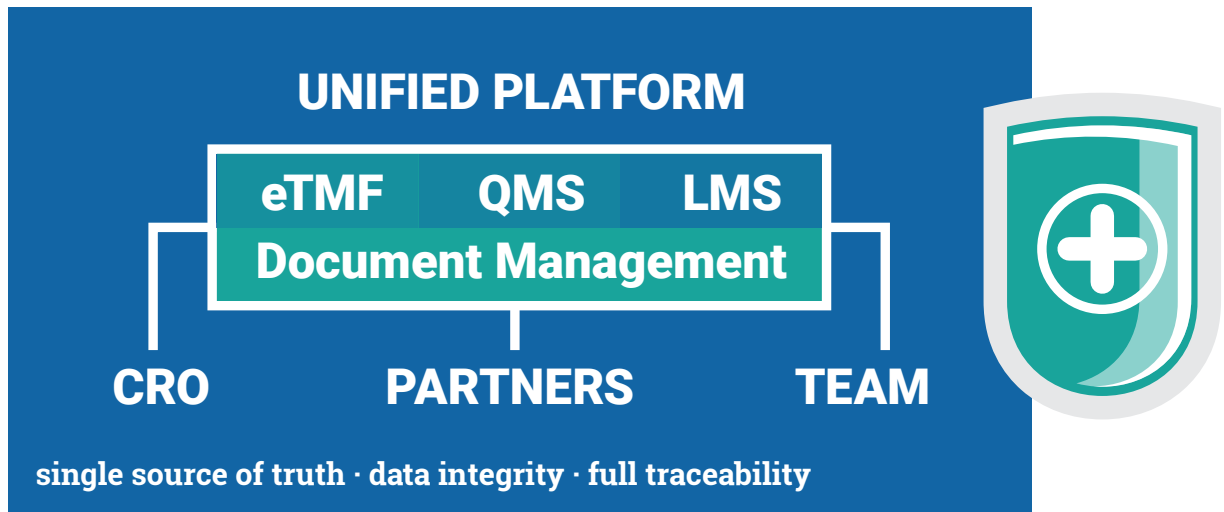
Conversely, fragmented or insecure data environments introduce uncertainty. Limited traceability, inconsistent documentation, or missing audit trails raise concerns about data integrity and regulatory exposure. These risks are often reflected in lower valuations, increased due diligence scrutiny, or delayed investment decisions.

A unified, cloud-based platform with well-governed data is not just a compliance tool, but a financial asset. It enables faster, more transparent due diligence and supports stronger negotiation positions in funding rounds or licensing discussions.

Simplifying Inspection Readiness

Inspection readiness is most effective when established from the start rather than addressed later. Retrospectively creating the necessary traceability and compliance takes significant time and effort, often requiring time-consuming remediation activities.

Embedding these practices into daily operations through a validated digital platform reduces rework and eases the burden of inspections.



► **It is not a question of WHETHER to implement a digital foundation, but WHEN.**

Establishing a validated, cloud-based, and unified platform from the outset avoids costly remediation, reduces operational and financial risk, and ensures continuous inspection readiness.

Organizations that start early transform compliance, data control, and investor confidence into scalable strategic and monetary advantages. Capabilities that will become increasingly important as regulatory expectations, data complexity, and competitive pressures continue to evolve.

8 | Future Outlook

Regulators will Maintain or Tighten Focus

Regulatory expectations will not necessarily become more demanding in absolute terms but will arrive earlier and move faster. Submission and response timelines continue to accelerate, leaving less room for reactive approaches.

Data Growth will Redefine Clinical Operations

The sheer scale of clinical data is not just increasing; it is transforming. Traditional alphanumeric records now sit alongside vast volumes of images, genomics, sensor streams, and rich media generated across decentralized and hybrid studies. At the same time, the rise of artificial intelligence and machine learning is adding new layers of derived data, annotations, and automatically generated documents.

This means clinical operations will soon need to manage not only more data, but different kinds of data: data that is complex, interconnected, and continuously evolving. Organizations are well advised to ensure that their infrastructure scales in step with an expanding information footprint.

Sponsor Oversight: From Obligation to Continuous Capability

As clinical development continues to shift toward outsourced models, sponsor oversight is evolving from a regulatory obligation into a defining strategic capability. Under ICH E6 on Good Clinical Practice (GCP), accountability remains with the sponsor, regardless of outsourcing. EMA's 2024 inspection data confirms that regulators expect sponsors to maintain continuous, evidence-based oversight, supported by real-time access to data, robust TMF and ISF control, and structured review of vendor performance.

Looking ahead, increasing complexity and distributed responsibilities across CRO networks will further reduce transparency unless actively managed. In alignment with the ICH E6(R3), oversight is already evolving into a proactive, continuous, data-driven and evidence-based process rather than a periodic and reactive one.

Sponsors will need real-time visibility into trial activities, sustained control over their data and documentation, and the ability to demonstrate proactive oversight at any point in time.

Market Consolidation and Competition

The competitive landscape in clinical development is shifting, driven by increased cross-regional competition, ongoing consolidation, and tighter funding conditions.

Declining third-party investment - particularly in the US - is intensifying competition and making it harder for early-stage biotechs to access capital.

Use of Artificial Intelligence in Clinical Data Management

Today, in clinical data management, Artificial Intelligence (AI) is expected to play a primarily supportive and cautiously implemented role in the near to mid-term. Current experience shows that AI delivers its most reliable value in automation, completeness checking, signal generation, and workflow support rather than in autonomous decision-making. Demand for AI-driven approaches also remains relatively limited in Quality Assurance discussions, reflecting ongoing uncertainty around validation expectations, explainability, and regulatory acceptance.

Importantly, AI is increasingly viewed not as a “black-box decision engine,” but as a process-orchestration layer that can optimize workflows designed by experienced data professionals. Human expertise will therefore continue to define clinical data processes, while AI enhances execution through better prioritization, coordination, and predictive insight.

Over time, however, the role of AI in clinical data management is expected to extend beyond supportive automation toward predictive and semi-autonomous operational optimization. As governance models mature and AI validation practices become more standardized, AI capabilities are likely to become increasingly integrated into Electronic Data Capture and Risk-Based Quality Management environments.

Potential future applications may include:

- AI-assisted generation of submission-ready data narratives
- Proactive risk mitigation based on cross-study learning
- Advanced search capabilities
- Study management with real time overview and risk prediction
- Pre-site monitoring
- Data quality estimation
- Cross data elements analysis of data integrity

► **In this longer-term perspective, AI will not replace clinical data expertise but will support faster scaling. Clinical data management may gradually evolve from a predominantly reactive data-cleaning function toward a proactive, intelligence-driven discipline focused on anticipating risk and strengthening decision support.**

9 | Conclusion: A Strategic Imperative

Emerging biotech companies must balance scientific goals, financial needs, and strict regulatory rules. Problems with data management and documentation can pose significant risks, especially when companies rely on inadequate tools such as spreadsheets and email.

For early-stage biotech firms, adopting an “inspection-ready by design” approach is not a luxury but a strategic imperative. It means integrating compliance into everyday operations. By investing in a robust digital system, companies can achieve:

- **Inspection-readiness at all times:** A pre-validated environment with structured workflows, audit trails, and controlled access reduces compliance risk and prevents audit findings.
- **Improved efficiency – more focus on science:** Reduced manual reconciliation and eliminated workarounds enable teams to concentrate on research instead of administrative tasks.
- **Full transparency and control across all critical data:** Seamless integration of eTMF, QMS, and training into a single source of truth eliminates fragmentation and ensures full traceability.
- **Scalable growth and stronger investor confidence:** Early adoption of a modular, cloud-based platform supports sustainable growth, maintains continuous inspection-readiness, and demonstrates effective data control to regulators, partners, and investors.

Together, these capabilities **reduce total cost of ownership** through less rework, fewer risks, and more efficient scaling.

► **As a result, early investment in digital infrastructure becomes a strategic lever for growth, not just a compliance decision.**

Using a modular, cloud-based platform from the outset enables emerging biotechs to scale with control, strengthen investor confidence, and ultimately turn innovative science into effective treatments for patients. Faster, more reliably, and with greater confidence.

10 | From Fragmentation to Control: The Path Forward

The transition from fragmentation to control involves a series of deliberate moves across the dimensions this paper has covered: clinical trial systems, data and documents, process and quality, vendor oversight, people and capability, and technology and infrastructure.

Each emerging biotech is positioned differently across these areas, highlighting the importance of identifying the most impactful next step rather than assessing overall maturity.

Identifying the right next step can be challenging, especially in small organizations where the dynamics often prioritize speed and quick solutions. Most teams have a general understanding of where their weaknesses lie, but few take a step back to assess overall capability, and even fewer understand how their situation compares to peers at a similar stage.

Without this comprehensive view, decisions tend to follow whoever is the most vocal about a specific issue, rather than focusing on the most critical areas that could lead to meaningful improvements.

Why Act Now

Three key forces compress the timeline for action:

- 1. Regulatory:** ICH E6(R3) has tightened expectations on sponsor oversight and risk-proportionate quality.
- 2. Commercial:** Partnering and diligence cycles increasingly assume that a clean data and document package is available on demand, impacting company valuation.
- 3. Structural:** Operational debt accumulates during critical moments like funding rounds and milestone readouts.

None of these forces are new; what is new is their visibility. In the past, the differences between companies that had prepared well and those that had not were often hidden. This is no longer the case. Experienced partners now focus on operational maturity from the very beginning and examine it closely.

The honest argument for acting now is not the potential for catastrophic consequences; many companies manage to struggle through challenging times and recover. Instead, the focus should be on how proactive measures establishing control are cheaper, simpler, and more sustainable when implemented before they become urgent.

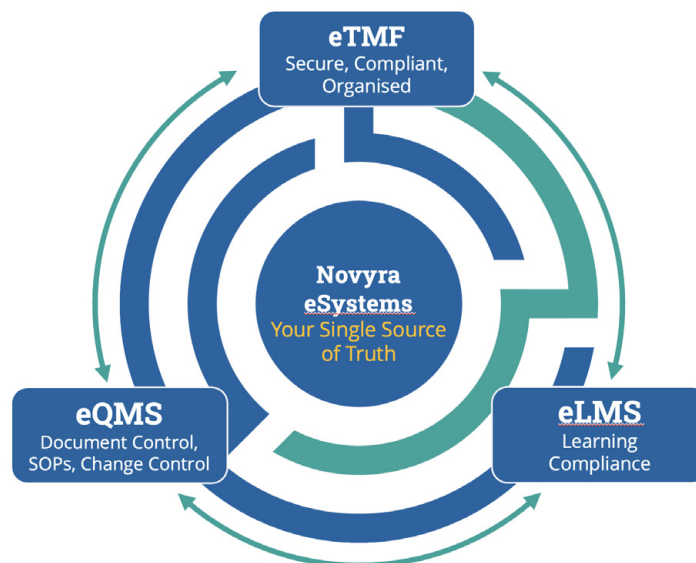
Your Next Steps

1. **Assess your current status and receive your indicative maturity level.**
2. **Build your digital foundation roadmap.**
3. **Partner with life science professionals: Let Novyra guide your journey with their compliant cloud-based platform eSystems and support you with setting up, operating, and maintaining a compliant system.**
4. **Start small, scale as you grow: Pay only for the functionality you need today and expand seamlessly as your needs evolve.**

Start with a free Novyra Maturity Check

Assess your current clinical, quality, and document management capabilities in around seven minutes. Eight guided questions provide an indicative maturity level, a snapshot across key dimensions, and three practical points for expert discussion.

To request your assessment, contact info@novyra.eu.



Novyra eSystems is built for emerging biotechs by life science professionals. Discover how Novyra eSystems empowers your organization with “inspection-readiness by design”, seamlessly integrating eTMF, QMS, and training into one single source of truth – eliminating fragmentation and ensuring full traceability. See how you can free teams from administrative burden to focus on science, not administration.

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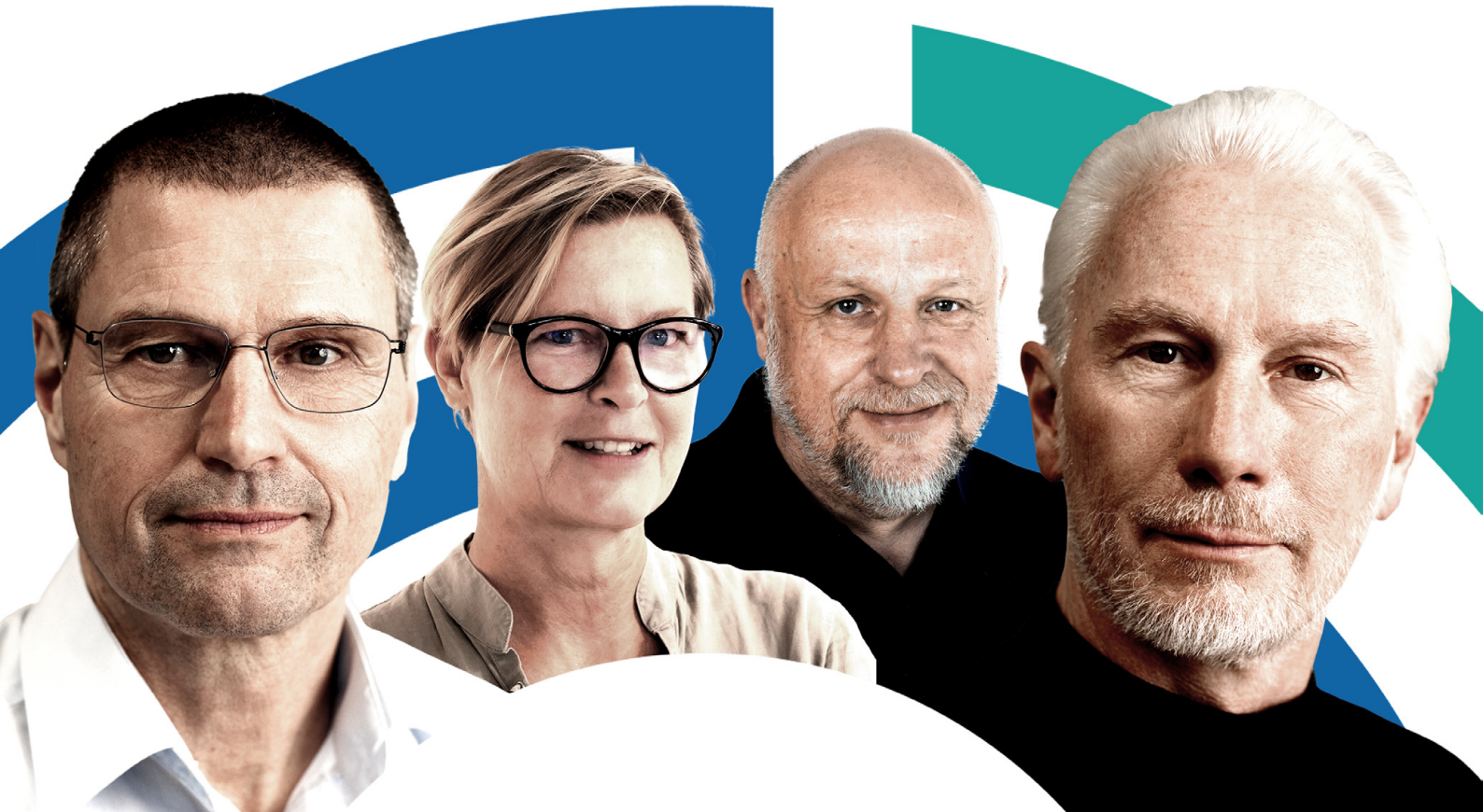
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Novyra Lifescience

About Novyra Lifescience

Novyra, headquartered in Switzerland, provides software and consultancy that enable life science companies to navigate the complex regulatory landscape from pre-clinical planning through to marketing authorization readiness.

Its cloud-based Novyra eSystems platform unifies eTMF, eQMS, and eLMS into a secure and audit-ready foundation that scales with growing organizations. It is built by life science professionals for life science professionals.

For more information, visit www.novyra.eu

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