



THE HIDDEN COST OF DIY CLINICAL TRIAL SYSTEMS

**A Practical Business Case for
Implementing Validated eClinical Systems**

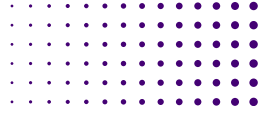
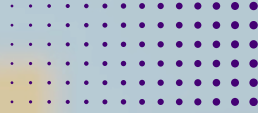


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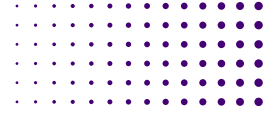
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Clinical trials depend on reliable, auditable, and compliant data systems. However, many emerging sponsors begin studies using general-purpose tools like Excel, survey platforms, and internal databases. While these tools may appear inexpensive, they introduce operational inefficiencies, compliance risks, and hidden costs that can ultimately delay studies and compromise data integrity.

This paper explains:

- **Why many early-stage studies rely on DIY systems**
- **The hidden operational costs they introduce**
- **Regulatory risks associated with non-validated tools**
- **How modern eClinical platforms eliminate these challenges**



EXECUTIVE SUMMARY

Many emerging biotech companies, academic research groups, and early-stage sponsors begin clinical studies using general-purpose tools such as:

- Excel spreadsheets for clinical datasets
- Survey tools for patient-reported outcomes
- Non-compliant cloud storage for document management
- Internal applications for subject tracking

These tools are often chosen because they are familiar, inexpensive, and easy to deploy. However, they were not designed to support clinical research.

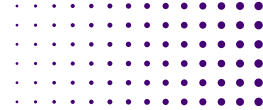
As studies expand, these improvised systems introduce significant challenges including:

- Data integrity risks
- Compliance gaps
- Operational inefficiencies
- Increased monitoring and data cleaning costs

Purpose-built eClinical platforms address these challenges by providing validated systems specifically designed for clinical trials.

Modern platforms integrate multiple trial functions into a single environment, allowing research teams to manage data collection, monitoring, reporting, and compliance from one system.

For many organizations, implementing a validated platform early in the clinical development process reduces both operational risk and overall study cost.



THE RISE OF DIY CLINICAL DATA SYSTEMS

WHY MANY STUDIES BEGIN WITH DIY SYSTEMS

Most organizations that rely on Excel or survey tools are not intentionally avoiding validated systems.

Instead, these decisions are usually driven by practical constraints common in early-stage research organizations.

LIMITED BUDGETS

Early-stage companies often prioritize scientific development over infrastructure investment.

SMALL CLINICAL TEAMS

Many startups launch studies with minimal clinical operations staff.

INTERNAL DEVELOPMENT OPTIMISM

Engineering teams may believe internal systems can be built quickly and inexpensively.

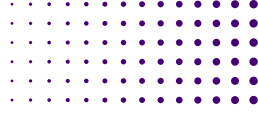
LACK OF REGULATORY FAMILIARITY

Executives outside clinical operations may not fully understand regulatory requirements for clinical data systems.

Because of these factors, many studies begin using combinations of general software tools.

Trial Function	Common DIY Tool
Data capture	Excel
Patient surveys	Mailchimp, SurveyMonkey
Study documents	Google Drive
Trial master file	SharePoint
Subject tracking	Internal applications

While this approach may appear workable at the beginning of a study, significant limitations quickly emerge as research progresses.



REGULATORY RISK: THE HIDDEN COST OF DIY CLINICAL DATA SYSTEMS

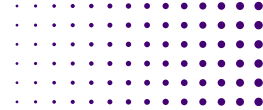
One of the most significant risks of using improvised clinical data systems is regulatory non-compliance.

Clinical trials that support regulatory submissions must follow strict requirements governing data integrity, traceability, and system validation. These standards are enforced by regulatory authorities worldwide, including:

- U.S. Food and Drug Administration (FDA)
- Health Canada
- European Medicines Agency (EMA)
- PMDA (Japan)
- MHRA (United Kingdom)

General-purpose tools such as Excel spreadsheets, survey platforms, and cloud file storage systems were not designed to meet these regulatory standards.

As a result, organizations that rely on these tools may unknowingly expose their studies to significant regulatory risk.



21 CFR PART 11 COMPLIANCE RISKS

In the United States, electronic records used in FDA-regulated clinical trials must comply with **21 CFR Part 11**.

This regulation requires systems to maintain:

- Secure user authentication
- Electronic signatures
- Complete audit trails
- Controlled access to records
- Protection against unauthorized data changes
- Validated system performance

Most general-purpose software tools do not provide these capabilities.

For example:

DIY Tool	Compliance Gap
Excel spreadsheets	No reliable audit trail
Email survey tools	No validated electronic signatures
Cloud file storage	No validated system controls
Internal databases	Typically not validated for regulatory use

Without these protections, regulators cannot verify who entered data, when changes were made, or whether records were altered.

This directly undermines the regulatory concept of data integrity.

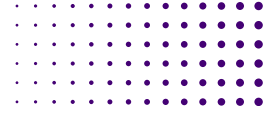
DATA PRIVACY RISKS (GDPR AND HIPAA)

Clinical trials frequently involve sensitive personal information, including:

- Protected Health Information (PHI)
- Personally Identifiable Information (PII)
- Genetic and biomarker data

Improvised systems may fail to meet requirements under:

- HIPAA (United States) for PHI protection
- GDPR (European Union) for personal data privacy
- national data protection laws in many jurisdictions



Improper handling of clinical data can lead to:

- Regulatory investigations
- Financial penalties
- Mandatory breach notifications
- Reputational damage

For multinational trials, compliance must often be demonstrated simultaneously across multiple regulatory frameworks.

REAL-WORLD CONSEQUENCE: STUDY DATA REJECTION

In some cases, sponsors discover these compliance gaps only after significant data has already been collected.

When regulators determine that electronic records cannot be trusted due to missing audit trails or system validation, the data may be considered unreliable for regulatory submission.

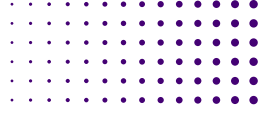
Sponsors may then be required to:

- Repeat data collection
- Reconstruct missing audit trails
- Migrate data into validated systems
- Conduct additional monitoring and verification

In extreme cases, entire studies may need to be repeated.

The financial impact of repeating a clinical study can exceed millions of dollars, far surpassing the cost of implementing validated systems at the beginning of the trial.





WHY VALIDATED SYSTEMS EXIST

Purpose-built eClinical platforms are designed specifically to meet regulatory expectations.

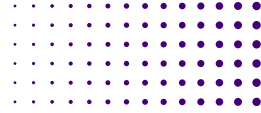
Validated systems provide:

- ▶ Immutable audit trails
- ▶ Electronic signatures compliant with 21 CFR Part 11
- ▶ Controlled user access and permissions
- ▶ System validation documentation
- ▶ Secure data storage and encryption

These capabilities ensure that clinical data remains traceable, auditable, and defensible during regulatory inspections.

For organizations conducting regulated clinical research, validated eClinical systems are not simply a convenience.

They are a fundamental requirement for regulatory acceptance of study data.



DATA INTEGRITY CHALLENGES

DATA QUALITY AND DATA INTEGRITY RISKS

Clinical trial data must be accurate, traceable, and auditable. General-purpose software tools lack built-in mechanisms that ensure data integrity.

Common issues include:

- Inconsistent data formatting
- Manual transcription errors
- Missing fields or incomplete records
- Difficulty tracking changes to data

These issues often lead to extended data cleaning cycles and delayed database lock.

Modern electronic data capture systems address these challenges through structured data entry and configurable validation rules.

These validation rules automatically identify potential errors during data entry, significantly reducing downstream data cleaning requirements.

WHY INTERNAL IT TEAMS CANNOT BUILD A COMPLIANT EDC

THE “BUILD VS BUY” MISCONCEPTION IN CLINICAL SOFTWARE

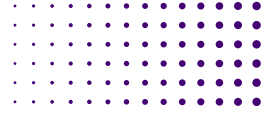
Many early-stage biotechnology companies consider building internal tools to manage clinical data.

At first glance, this approach may appear attractive. Internal development teams are already familiar with the company’s technology stack, and a custom solution may seem less expensive than purchasing commercial clinical software.

However, building a compliant clinical data system requires far more than basic software development.

Electronic Data Capture (EDC) systems used in regulated clinical trials must satisfy strict requirements related to validation, auditability, security, and regulatory compliance.

These requirements dramatically increase the complexity of building and maintaining an internal system.



REGULATORY VALIDATION REQUIREMENTS

One of the most significant challenges in developing clinical software internally is system validation.

Under regulatory frameworks such as:

- FDA 21 CFR Part 11
- EU Annex 11
- Good Clinical Practice (GCP)

Software used to collect clinical trial data must be formally validated to demonstrate that it consistently performs as intended.

Validation typically requires:

- Documented system requirements
- Risk assessments
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)
- Test scripts and validation reports
- Change control procedures

For commercial clinical platforms, this validation documentation often consists of hundreds or even thousands of pages of testing evidence.

Maintaining validation over time also requires re-testing whenever the system is modified.

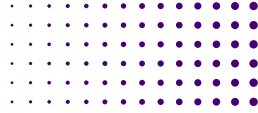
For most internal engineering teams, maintaining this level of validation infrastructure quickly becomes a significant operational burden.

AUDIT TRAIL AND DATA INTEGRITY REQUIREMENTS

Regulatory authorities require clinical data systems to maintain complete and immutable audit trails.

This means the system must record:

- Who entered or modified data
- When changes occurred
- What values were changed
- Why changes were made



Audit trails must be secure, tamper-evident, and easily accessible during regulatory inspections.

Designing and validating a compliant audit trail architecture is one of the most technically complex aspects of clinical software development.

Many internally developed systems lack sufficient audit controls, which can compromise the integrity of study data.

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SECURITY AND PRIVACY COMPLIANCE

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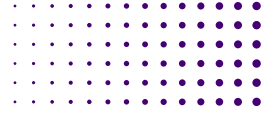
These systems must therefore comply with strict data protection standards such as:

- HIPAA (United States)
- GDPR (European Union)
- Regional privacy laws across multiple jurisdictions

Compliance requires secure infrastructure, encryption protocols, access controls, logging, and documented security procedures.

Commercial eClinical vendors maintain dedicated security programs to support these requirements.

Internal systems often lack the resources required to maintain this level of security and compliance oversight.



LONG-TERM MAINTENANCE BURDEN

Even if an internal system can be built successfully, maintaining it over time presents additional challenges.

Clinical trials frequently run for several years, during which systems must remain stable, secure, and validated.

This requires ongoing responsibilities including:

- Software maintenance and bug fixes
- Validation updates
- Infrastructure monitoring
- User support and training
- Security patching

If internal development priorities shift, maintaining the clinical system may become increasingly difficult.

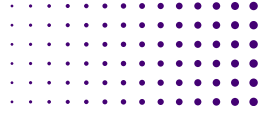
WHY SPONSORS CHOOSE COMMERCIAL ECLINICAL PLATFORMS

Commercial eClinical platforms are specifically designed to support the regulatory, operational, and security requirements of clinical trials.

These systems typically provide:

- pre-validated system infrastructure
- built-in audit trails and electronic signatures
- regulatory compliance documentation
- secure cloud infrastructure
- ongoing system maintenance and support

By adopting validated commercial platforms, sponsors can focus their internal resources on scientific and clinical development rather than software infrastructure.



THE STRATEGIC ADVANTAGE OF PURPOSE-BUILT PLATFORMS

For organizations conducting regulated clinical research, clinical data infrastructure is a critical component of study success.

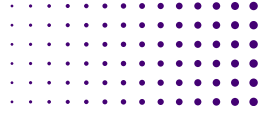
Purpose-built eClinical platforms allow research teams to:

- reduce regulatory risk
- improve data quality
- accelerate study startup
- streamline monitoring and analysis

Rather than building and maintaining complex software internally, many sponsors choose to implement validated systems that are designed specifically for clinical research.

This approach allows organizations to focus on advancing their therapies while ensuring that clinical data remains reliable, compliant, and ready for regulatory submission.





OPERATIONAL INEFFICIENCY

WORKFLOW FRAGMENTATION

DIY systems typically involve multiple disconnected tools.

This fragmentation creates inefficiencies throughout the study lifecycle.

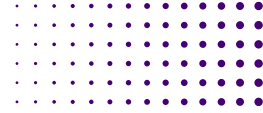
Clinical teams must manually:

- reconcile spreadsheets
- track document versions
- transfer survey data between systems
- merge datasets for statistical analysis

These manual processes slow down key milestones including:

- monitoring reviews
- database lock
- data cleaning
- statistical analysis

Integrated clinical platforms eliminate these inefficiencies by centralizing study data within a single system.



THE TRUE COST COMPARISON

THE TRUE COST OF CLINICAL DATA INFRASTRUCTURE

When evaluating clinical technology, many organizations focus only on software subscription costs.

However, the true cost of clinical data infrastructure includes:

DATA MANAGEMENT LABOR

Manual reconciliation and cleaning can significantly increase staff workload.

MONITORING COSTS

Fragmented systems increase monitoring complexity.

DATA CLEANING CYCLES

Studies using improvised systems often require additional query cycles.

DATABASE LOCK DELAYS

Manual processes frequently delay final data analysis.

When these operational costs are considered, validated clinical platforms are often more cost-effective than improvised systems.

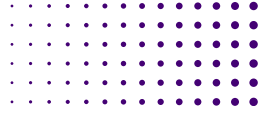
WHEN SPONSORS TRANSITION TO ECLINICAL PLATFORMS

WHEN ORGANIZATIONS TYPICALLY ADOPT VALIDATED SYSTEMS

Many organizations transition to validated clinical systems after encountering challenges with improvised infrastructure.

Common triggers include:

- launching a regulated clinical trial
- preparing for regulatory submission
- expanding to multiple study sites
- increasing monitoring requirements



Transitioning earlier in the clinical development process can prevent costly system migrations and data reconciliation later.

Modern eClinical platforms allow research teams to manage:

- data capture
- reporting and analytics
- patient-reported outcomes
- regulatory compliance
- randomization

within a unified system.

CLINICAL TECHNOLOGY READINESS CHECKLIST

IS YOUR STUDY INFRASTRUCTURE READY FOR REGULATORY OVERSIGHT?

Use the following checklist to evaluate whether your current systems are appropriate for clinical research.

DATA COLLECTION

Are clinical datasets collected in a validated electronic data capture system?

Yes No Needs Improvement

AUDIT TRAILS

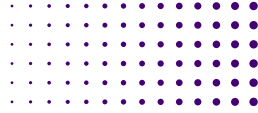
Can you track every change made to study data?

Yes No Needs Improvement

ELECTRONIC SIGNATURES

Does your system support regulatory-compliant signatures?

Yes No Needs Improvement



ACCESS CONTROL

Can you control and document user permissions?

Yes No Needs Improvement

REPORTING

Can you generate regulatory-ready datasets?

Yes No Needs Improvement

If your organization cannot confidently answer "yes" to these questions, it may be time to evaluate purpose-built clinical data systems.



LEARN MORE

Captivate provides a unified platform for modern clinical research, including:

- Electronic Data Capture (EDC)
- ePRO and eConsent
- Randomization systems
- Real-time reporting and analytics
- Regulatory compliance tools

To learn more about implementing validated clinical infrastructure, contact the ClinCapture team at

contact@clincapture.com

or visit

www.captivate.org