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WHITE PAPER

Modernizing Clinical Research Technology through Policy

By Anthony Corso and Jackie Ward, Veeva Public Policy

Clinical trial modernization and patient access are heavily hindered by a critical "digital disconnect" within clinical research, where research sites continue to rely on paper binders, manual spreadsheets, and fragmented, non-interoperable systems. While the broader healthcare industry has successfully transitioned to certified electronic health records (EHRs), in part due to legislation and federal incentives, clinical research remains a generation behind. This lack of digital adoption results in frequent data transcription errors, severe administrative burdens, and slow, highly expensive manual source data verification (SDV), which alone accounts for an estimated 25% to 40% of overall clinical trial spend. Furthermore, the lack of remote digital tools and reliance on physical site visits restrict trial participation, disproportionately excluding rural, working-class, and mobility-challenged patients, which ultimately narrows the participant pool and limits how broadly trial results can be applied.

To address these systemic barriers, the Veeva Public Policy team proposes the development of a voluntary, federal certification program for clinical research technology. Modeled after the federal Health IT Certification Program, this vendor-neutral framework would establish common standards for core trial data management, data security, and seamless interoperability. Implementing certified technology would enable health data to flow automatically from existing EHRs into trial databases, eliminating redundant manual entry, reducing regulatory audit friction, and building the structured, digital foundation required for safe, large-scale AI utility.

Ultimately, this policy-driven approach would reduce study costs and timelines for sponsors, alleviate administrative site burnout, and significantly expand trial representation and access for patients.

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Clinical trials lag behind in digital adoption

One of the most significant – and underappreciated – barriers in clinical trials is the "digital disconnect" that occurs as clinical research sites rely on paper binders, manual spreadsheets, and isolated systems to conduct day-to-day data collection. The impact of this, discussed more below, is a significant drag on the time and cost that is required to execute clinical trials. This same problem used to plague routine healthcare as well, but there have been significant strides in the last 20 years, as the nation's healthcare providers and health systems have almost entirely transitioned from paper binders to electronic health records (EHRs) to track and manage patient care. Today roughly **99% of non-federal acute care hospitals** and nearly **90% of office-based physicians** use certified EHRs.

Despite real growing pains in usability and clinician workload, this transition has fundamentally changed how patients and providers access, share, and act on health information, making care more coordinated, more accurate, and safer. This shift was accelerated by federal legislation (the **HITECH Act** and **21st Century Cures Act**) that incentivized the adoption and use of health information technology. However, not all parts of healthcare have been included in this transition. Clinical research, the industry that generates the evidence underpinning modern medicine, remains a generation behind. **This digital disconnect drives up costs, introduces avoidable errors, and slows the clinical trials that bring innovative treatments to patients.**

The "Digital Disconnect": Core Structural Problems that Slow Progress, Raise Cost, and Increase Burden on Patients

PROBLEM 1

Research still runs on paper

Current state: Today, highly trained research staff often act as manual data scribes. Critical trial records such as source data, informed consent documentation, and other study records are **frequently collected on paper**.

Impact: This increases the risk of transcription errors, delays data availability until paper records are later keyed into digital systems, and pulls skilled staff away from participants and the research itself to do clerical data entry. Additionally, dependence on physical records carries significant regulatory liability - critical documents like informed consent forms can and do get lost, ultimately jeopardizing the integrity of the entire trial.

PROBLEM 2

Technology systems don't talk to each other

Current state: Research sites operate in a fragmented technology environment. A single trial can span 100+ sites across a dozen countries, and each site must maintain its own source documentation while, for each study, working in a separate set of systems to capture and report trial data. These systems were built independently, for different purposes, and use inconsistent data formats. The technology to connect them increasingly exists; modern EHRs, for example, are standardized and can already share data. What is missing is the industry-wide willingness or investment to put that capability to use. As a result, systems that could exchange information seldom do, and a site working across several studies ends up juggling a patchwork of disconnected tools, a leading driver of the multiple logins and repeated, study-by-study training that sites rank among their top operational burdens. A site's own records, including its EHR when it has one, rarely flow into the other systems a trial runs on. Information that could move directly from where it is collected to where it must be reported instead stays trapped.

Impact: Because these systems stay disconnected, staff absorb the gap through manual transcription, duplicate data entry, and reconciliation, all while context-switching between tools that each carry their own login and training. This reduces the time and attention that can be dedicated to participant recruitment and interaction, and compounds an already high rate of staff turnover. Ultimately, this raises costs, delays timelines, increases errors, and burdens both research staff and patients.

PROBLEM 3

Verifying data is slow and expensive

Current state: Because source data – the original record of findings and observations about a trial participant – often lives on paper or in tools sponsors cannot audit remotely, sponsors have no easy way to trust that the information reaching their database matches what was originally recorded. Source data verification (SDV) is still largely manual, and it consumes a considerable share of trial resources. This typically means sending monitors to the site to check paper documents or to look over research staff's shoulders at their screens, in combination with some remote review if digital technology is available.

Impact: Accurate source data is essential for ensuring that the FDA has complete and correct information when weighing whether a new therapy is safe and effective for patients. The sponsor is ultimately accountable to regulators for trial data integrity. When data is not recorded in auditable systems, the sponsor cannot easily verify its accuracy. This verification is a major cost, estimated to account for **25-40%** of clinical trial costs. Even after the FDA moved to a risk-based model that no longer expects 100% verification, many sponsors continue extensive verification, both in person and remotely as trials are still rejected on the basis of data incompleteness. Sponsors treat thorough verification as insurance against that uncertainty. In addition to the financial cost, this constant scrutiny often strains the relationship between sponsors and sites, creating unnecessary friction for research staff who are already stretched thin. Consistent, auditable technology could provide the same assurance with far less effort.

PROBLEM 4

Systemic barriers to trial access and generalizability

Current state: Today, participating in a clinical trial often requires flexible work hours, reliable transportation, and proximity to a major research center. Participants may travel several hours to sign a paper informed consent form. Instead of taking their own blood pressure or glucose levels at home and submitting them digitally, they have to take time off of work to have those measurements done at a research site.

Technology tools like electronic informed consent and digital data capture are straightforward and available on the market today; they can help close the remote access gap. Yet operational hurdles like adherence to antiquated workflows and inconsistent sponsor requirements prevent sites from leveraging them effectively.

Impact: Disconnected digital systems and lack of remote-access capabilities compound participant challenges, and ultimately exclude suitable patients. Participation remains out of reach for many patients in rural areas, working families, and people with mobility limitations. This narrows the participant pool to those who live near and can travel to research hubs, which limits how broadly trial results apply to the full range of patients who will ultimately use a treatment. It also denies many patients access to potentially valuable care options.

These challenges share a common root cause. Sites and sponsors each have distinct requirements for managing clinical trial data, and the technology and processes in use today were built to serve those separate needs, not the flow of trial data across the research process as a whole. The result is the fragmented, disconnected landscape described above: a research enterprise that is slower, costlier, and less accessible than it needs to be, with the cost measured not only in dollars and delays but also in treatments reaching patients later than they should. No single fix is enough.

Solving any one of these problems in isolation is not sufficient. What's missing is a common foundation that lets data move securely and seamlessly across the entire research ecosystem.

A Path Forward: Certified Clinical Research Technology

These problems can be overcome. Most clinical research technology today is built for a single actor: either the trial participant, research site, sponsor, or regulator. Rarely do these tools connect to one another. Each tool is designed to close a specific gap, not meet a common standard that would apply across the ecosystem. Yet secure, interoperable technology can make clinical trials faster, more efficient, and safer.

Healthcare faced the same fragmentation a generation ago and solved it: the Office of the National Coordinator for Health Information Technology's certification program set common standards that technology had to meet, and interoperable EHRs scaled from there.

Clinical research needs an equivalent effort to spur adoption of certified, interoperable technology.

To accomplish this, the most effective path forward is for the federal government to develop a voluntary certification program for clinical research technology products that supports:

1. **Core functionality for managing regulated trial data**
2. **Interoperability through standardized data exchange**
3. **Security controls appropriate for regulated health research**

By establishing a common standard and encouraging adoption, certification would let sites and sponsors choose from technologies built to talk to each other, meet regulatory requirements, and connect the research ecosystem. Experts will need to define the certification criteria, much as they did for certified EHRs. Done well, certification would help the clinical trial enterprise move off paper, exchange information across disparate systems, maintain audit trails that reduce manual data verification, and, critically, connect to the technology participants use so that taking part in research is less burdensome. Importantly, this will modernize research infrastructure without prescribing specific vendors or platforms – it will benefit the industry as a whole. This is a practical way to bridge the digital disconnect and speed life-saving innovations to patients.

LOOKING AHEAD

The foundation AI needs

This foundation also prepares clinical research for what comes next.

Today, because so much clinical research data is still captured on paper or trapped in siloed tools, AI cannot reliably use it.

The promise of AI in medical product development is substantial. The life sciences industry already uses it to **design safer, more precise drugs**, and **patients** and **providers** use AI tools to review medical literature and their own records. In clinical trials, AI is beginning to **accelerate individual steps**, but its full potential will not be realized until trial data is completely digital and structured. Certified, interoperable technology would build the structured foundation AI needs to be applied safely, consistently, and at scale.

Benefits for Every Stakeholder

A certification program would address the problems outlined above, with distinct advantages for each:

Stakeholder Group	Core Operational Benefit	Key Metrics & Systemic Impact
Sponsors & Clinical Research Organizations (CROs)	**Cost & Timeline Efficiency**	Reduces the need for time-intensive and expensive source data verification. Secure, traceable digital source data minimizes the need to send personnel to sites to confirm records, cutting monitoring and source data verification costs which amount to 25-40% of trial spend. Real-time access to clean data shortens study startup and reduces the costly delays that average **$40,000 per day**, speeding the path to submission.
Research Sites	**Less Burden, Fewer Errors**	Reduces burden by connecting systems. EHR data is already standardized and shareable, but most research tools have not been built to use it. Certified research technology would connect to existing EHR standards so routine health data flows into trial databases automatically, eliminating manual transcription, duplicate data entry, and physical document scanning, with no new regulatory reporting mandates. By removing manual transcription, it also cuts the data-entry errors that carry real clinical risk.
Regulators & Research Agencies	**Data Integrity & AI Readiness**	Establishes clear digital audit trails that meet **industry data standards** for critical steps like patient consent, data entry, and key trial events. Standardizing this data makes it easy to automatically catch missing or out-of-order records, giving regulators high-quality, trustworthy data. It also builds the structured foundation needed for AI-ready regulatory review.
Patients & Families	**Expanded Access & Representation**	Accelerates the delivery of innovative treatments. By incentivizing remote technology, rural patients, working families, people with rare diseases, and any willing participant can more easily take part in trials from home.

Conclusion: A Shared Vision to Modernize Clinical Research

Clinical research is long overdue for the same modernization that has transformed the rest of healthcare. Faster, less expensive, and less burdensome trials mean treatments reach patients sooner. A connected research ecosystem serves everyone who depends on the evidence it produces.

Advancing that future is core to Veeva's mission as a **Public Benefit Corporation**: to help the life sciences industry improve health and extend life. That is why our public policy team developed this blueprint to close the digital disconnect in clinical research, and why we are working to build industry-wide support for it. We invite policymakers, research institutions, sponsors, and sites to join us. Whether you agree, disagree, or simply want to talk through what a more connected clinical trial ecosystem could look like, we would like to hear from you. Please reach out to **PublicPolicy@veeva.com**.

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