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Clinical Trial Site Technology Burden: Sponsor Scorecard

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Executive Summary

Sponsor and contract research organization (CRO) buyers who ask whether a proposed study stack is practical for research sites have more evidence than they had in 2023, but none of it is a clean benchmark. The most cited source, WCG's 2023 Clinical Research Site Challenges survey, covered **over 500 US sites** in February and March 2023 (wcgnewprod.wpengine.com) and placed technology at **18%** of responses, higher than in 2022 (wcgnewprod.wpengine.com). It was cited more often by academic medical centers (22%) than by non-academic sites (13%) (wcgnewprod.wpengine.com).

That survey should not be read as a 2026 benchmark. WCG has since fielded three further editions with different samples and category lists: **852 sites** in 2024 (www.wcgclinical.com), **611 sites** in 2025 (www.wcgclinical.com), and **more than 400 professionals** in 2026 (www.wcgclinical.com). The 2025 edition added a separate "sponsor-provided technology" category and a three-choice cap (www.wcgclinical.com).

Other site surveys point in the same direction while differing in method and sponsorship. A vendor-run 2023 survey reported that nearly 70% of respondents had six or more logins per study (www.advarra.com). A vendor-run 2026 survey reported that 50% of site respondents logged into five or more study-specific systems for an average trial (www.florencehc.com). These are associations, and they do not show that fewer logins improve outcomes. The 2025 Tufts Center for the Study of Drug Development (CSDD) survey of 387 site professionals did not separate sponsor-provided systems from site-owned ones (www.appliedclinicaltrialsonline.com).

The practical answer is a transparent, local scorecard and effort model. This report sets out seven scorecard fields (account creation, training time, repeated data entry, offline access, support, patient-facing handoffs, exit and export), the evidence to demand for each, and a site-hours formula with a fully hypothetical worked example in which total hours range from about 37 to about 139 per site depending on assumptions. Regulators set the guardrails: the sponsor should not hold exclusive control of investigator data (www.ema.europa.eu), training should precede use (www.fda.gov), and sponsors remain responsible for Part 11 compliance when they use service providers (www.fda.gov). Thresholds for go or no-go decisions belong to the reader; no industry norm is asserted here.

Introduction and Background

"Site technology burden" (also called technology overload or technology fatigue at sites) describes the work that sponsor-mandated or CRO-mandated software adds to a research site: creating accounts, completing training, remembering credentials, re-keying data, resolving access problems, and handing participants between tools. This report treats it as a procurement and workflow design problem, not a ranking of software brands. The decision it supports is narrow: before contracting and deployment, does the proposed combination of clinical trial management system (CTMS), electronic data capture (EDC), electronic informed consent (eConsent), electronic clinical outcome assessment (eCOA), electronic investigator site file (eISF), safety reporting and training tools create work that sites can absorb?

Scope and sponsor control. Sponsors choose most of these systems, and sites inherit them. That is why the buyer, not the site, holds most of the levers. It is also why regulators treat sponsor-provided systems as an area for explicit investigator safeguards. Under the International Council for Harmonisation (ICH) E6(R3) good clinical practice guideline, investigators should have control of the essential records they generate (database.ich.org), and for sponsor-deployed systems the sponsor should not have exclusive control of captured data (database.ich.org).

Why a source-led scorecard. Public discussion of site burden relies on a small number of survey figures that are repeated across vendor blogs, trade articles, and conference material. Several are vendor-run, several date from 2016 to 2023, and the populations differ. The 2023 WCG report is a useful example: the report's own wording is that "over half (52%)" of sites say their challenges affect their ability to open new trials (wcgnewprod.wpengine.com). The National Academies' 2024 workforce proceedings include the WCG report in a reference list only, with no in-text figure (www.nationalacademies.org), so a bibliography placement is not an endorsement.

Caveats of historical survey data. The 2023 survey asked "What are the top issues impacting your site today?" (wcgnewprod.wpengine.com). The 2023 report text does not state a per-item base or a cap on the number of choices, whereas the 2025 edition explicitly asked respondents to select their top three. Percentages from the two editions therefore cannot be compared as if they came from one instrument.

Disclosure. IntuitionLabs is a Veeva X-Pages Partner. Statements about vendor products, including Veeva's, are attributed to the vendors' own pages and described as vendor claims, and no product is recommended.

Key Changes in the Evidence and Regulatory Baseline

Change 1: The 2023 survey is no longer the only, or the latest, WCG data point

The 2023 report sampled over 500 US-based sites, including academic medical centers, community hospitals, health systems, practices, and independent sites (prnewswire.com). WCG linked the technology ranking to staff training and the time required to navigate multiple systems (wcgnewprod.wpengine.com).

The 2024 edition surveyed 852 sites between April and June 2024 (www.wcgclinical.com). It reported that 19% of all sites named sponsor-provided technologies as a top challenge (www.wcgclinical.com). The 2025 edition received 611 responses between July and September 2025 (www.wcgclinical.com), listed "sponsor-provided technology (CTMS, eReg, eISF, etc.)" as a category (www.wcgclinical.com), and found that 22% of sites said

the number of technologies and vendors was the greatest driver of trial complexity (www.wcgclinical.com). The 2026 edition, announced on November 4, 2026, draws on more than 400 professionals, reports trial complexity cited by 41% of sites (up from 35% in 2025) (www.wcgclinical.com), with 35% seeing integrated systems that end duplicate data entry as a top automation opportunity (www.wcgclinical.com).

The takeaway is not a trend line. Sample sizes, geographies, category lists, and question wording changed from year to year, so the percentages are not like-for-like.

Change 2: Other surveys add system counts but differ in method and sponsorship

A 2022 Advarra and Society for Clinical Research Sites (SCRS) site survey, reported in a trade release, said 68% of sites used at least four to six sponsor-mandated systems per study (www.pharmoutsourcing.com). Advarra's 2023 survey reported nearly 70% of respondents with six or more logins per study (www.advarra.com) and 55% rating setup and training on sponsor technology as extremely or very burdensome (www.advarra.com). Veeva's 2025 site survey, which targeted 10,000 research site professionals (sites.veeva.com), lists managing multiple logins among its top challenges for all sites (sites.veeva.com). Florence's 2026 report found 46% of site respondents using five or more internal systems every day (www.florencehc.com).

The Tufts CSDD survey of 387 site professionals reported that nearly one in four sites (22%) said digital solutions had cost them revenue or profit (www.appliedclinicaltrialsonline.com), but the question did not differentiate sponsor-provided from site-owned systems (www.appliedclinicaltrialsonline.com). A deck titled "2026 Site Landscape Survey" hosted on the SCRS Site Solutions Summit domain reports that only 10.8% of sites use fewer than five systems (sitesolutionssummit.com) and that 71% spend 11 or more hours per month per staff member on required training (sitesolutionssummit.com); its "Who Responded" slide reports that 59.5% of respondents were North American sites (75 sites), which implies roughly 126 site respondents in total, while the deck does not name an organiser or originator; the figures are treated as conference-deck data rather than a fully documented or peer-reviewed survey. The WCG and CenterWatch 2025 Global Site Relationship Survey collected over 12,000 responses worldwide (www.centerwatch.com) and found that its technology category showed the lowest ratings (www.centerwatch.com).

Change 3: Regulators have moved the baseline on computerised systems

The regulatory baseline changed materially between 2023 and 2026. The ICH E6(R3) consolidated guideline was adopted on June 16, 2026 (database.ich.org). The European Medicines Agency (EMA) states that the principles and Annex 1 came into effect in the EU on July 23, 2025 (www.ema.europa.eu) and that Annex 2, covering decentralised and pragmatic trials, was adopted by ICH on June 3, 2026 and by the EMA's Committee for Medicinal Products for Human Use on June 25, 2026 (www.ema.europa.eu). The US Food and Drug Administration (FDA) announced its E6(R3) guidance in the Federal Register on September 9, 2025 (www.federalregister.gov) and says the guideline is intended to encourage the use of technology and innovations (www.fda.gov). We did not verify an FDA position on Annex 2, and FDA guidance is non-binding, so readers should check current status.

For sponsor-deployed systems, E6(R3) states that access permissions granted to investigator site staff should follow the investigator's delegations (database.ich.org), and that investigators should notify the sponsor when access needs to change (database.ich.org). FDA's October 2024 Part 11 questions-and-answers guidance recommends a risk-based approach to validation (www.fda.gov), says training should occur before an individual uses a system (www.fda.gov), and lists records of staff training on electronic systems among items of interest in inspections (www.fda.gov). In the EU, the EMA computerised systems guideline says the sponsor should not have exclusive control of data entered in a computerised system (www.ema.europa.eu), that investigators should be able to download a contemporaneous certified copy (www.ema.europa.eu), and that hosting agreements should ensure investigator control (www.ema.europa.eu).

The Site Technology Burden Scorecard

Step 1: Inventory every site-facing system and repeated task

Start with a system inventory, because burden is a property of the whole stack and not of one product. For each system the study will ask sites to use, record these inventory fields:

- **Task:** what the system supports (for example consent, visit data entry, delegation log, safety reporting).
- **Role:** who performs it (investigator, coordinator, regulatory specialist, pharmacist).
- **Login:** separate credentials, single sign-on (SSO), or a site-owned identity.
- **Training:** the required modules and their duration per role.
- **Data entered:** the elements captured and whether they duplicate another system.
- **Integration:** connections to other study systems or the site's electronic health record.
- **Fallback:** what the site does when the system is unavailable.
- **Support owner:** sponsor, CRO, vendor, or site, named per system. Capture repeated tasks as well as systems, since one task such as updating a delegation record can recur across the eISF, EDC, and training tools.

The inventory should include systems the site would hold anyway, such as its own eISF or clinical trial management system, because FDA's guidance names an electronic investigator site file as an example of a system an investigator might deploy (www.fda.gov). The same guidance notes that FDA may request documentation of system validation during an inspection (www.fda.gov).

Step 2: Score seven fields with required evidence

Table 1 below sets out the seven scorecard fields, the question to put to a vendor, the evidence to request, and the published context that makes the field relevant. The weights are illustrative defaults for a hypothetical buyer and should be replaced with weights that reflect the protocol and the site population.

Field	Question to ask	Evidence to require	Published context	Illustrative weight
Account creation	How many accounts, credential types, and identity checks does each staff member need?	Account provisioning runbook, sample onboarding timeline, single sign-on (SSO) options and who administers them	ICH E6(R3) says site staff access permissions for sponsor-deployed systems should follow investigator delegations (database.ich.org); 21 CFR Part 11 requires limiting system access to authorized individuals (www.ecfr.gov)	15%
Training time	What is the minimum training per role, and can prior training be accepted?	Role-based curricula with durations, training-record acceptance policy, in-system help	FDA recommends training before use (www.fda.gov); the EMA guideline says all training should be documented (www.ema.europa.eu)	20%
Repeated data entry	Which data elements are entered in more than one system, and which are transferred automatically?	Data-flow diagram, integration specifications, field-level duplication list	FDA's electronic source guidance lists eliminating transcription of source data before eCRF entry as a goal (www.fda.gov)	20%
Offline access	What works without connectivity, and how is data protected if transmission fails?	Offline mode documentation, synchronisation rules, downtime procedure	The EMA guideline calls for procedures to prevent data loss if web access is interrupted (www.ema.europa.eu)	10%
Support	Who answers a site's question, in which hours and languages, and with what escalation path?	Support model, service levels, named owner per system	ICH E6(R3) says delegation to service providers does not transfer responsibility for trial conduct (database.ich.org)	15%
Patient-facing handoffs	Where does a participant move between tools, and what is the alternative path?	Participant journey map, paper or in-person option, provisioned device option	E6(R3) Annex 2 says participants may be offered a paper-based or in-person alternative (database.ich.org); the EMA guideline says participants should not be excluded for being unable or unwilling to use their own device (www.ema.europa.eu)	10%
Exit and export	Can the investigator obtain a complete certified copy, with audit trail, without sponsor mediation?	Export format specification, sample export, decommissioning plan	EMA guideline on certified copies (www.ema.europa.eu) and audit trails (www.ema.europa.eu); CDISC describes ODM as a vendor-neutral format for exchanging and archiving clinical data (www.cdisc.org)	10%

The table is a structure, not a verdict. The "Question" and "Evidence" columns are design choices by this report's authors, whereas the "Published context" column cites sources that give each field regulatory or empirical relevance. The weights total 100% and can be changed. If each field is scored on a local scale (for example zero to four) against stated evidence, two reviewers given the same documents should reach similar scores; if they do not, the evidence request was too vague.

Step 3: Interview vendors and sites

The EMA guideline says sponsors should determine during site selection whether site-deployed systems, such as electronic medical records and the investigator site file, are fit for purpose (www.ema.europa.eu), which supports asking sites about their own tools at the same time. ICH E6(R3) says the sponsor should have access to relevant information, such as standard operating procedures and performance metrics, when selecting and overseeing service providers (database.ich.org). For eCOA, the Critical Path Institute's eCOA Consortium says sponsors should perform due diligence on providers, typically a capabilities assessment and audit (c-path.org), and that bring-your-own-device studies should always include a provisioned device option (c-path.org).

Artifacts to request from each vendor:

- **Role-based training curricula** with durations.
- **A data-flow diagram** showing every integration and every manual step.
- **Offline and downtime procedures.**
- **A sample export** with audit trail.
- **The support model,** with a named owner and escalation path.

Run site interviews before vendor selection. A peer-reviewed survey of eCOA site experience concluded that sites generally did not feel well prepared to use eCOA (pmc.ncbi.nlm.nih.gov), which suggests asking about practice access and sandbox time. Useful site questions include:

- **Which of these systems do your staff already use daily,** and which would be new for this study?
- **How long did onboarding take** for the last comparable study, per role, and what part of that training repeated content already completed?
- **Which data would you enter twice,** and where does your electronic health record connect, if at all?
- **What happens when a system is down** during a visit, and who do you call?
- **Who at your organization approves new accounts** and removes them when staff leave?
- **What would you need to export** at study close to meet your own retention obligations?

Record answers as local estimates with the interviewee's role and date. Do not infer that a workflow is burdensome from vendor material or surveys alone.

Data Analysis and Evidence

Evidence matrix

Table 2 below summarizes the source-backed evidence discussed in this report, with year, population, originator, and the main caveat. It is deliberately a matrix of context rather than a ranking, because the surveys differ in who ran them, who responded, and what was asked.

Source and year	Population	Originator	Reported finding	Main caveat
WCG Site Challenges, 2023	Over 500 US sites, February to March 2023 (wcgnewprod.wpengine.com)	WCG (service provider)	Technology 18% of responses (wcgnewprod.wpengine.com)	US only; no stated per-item base or choice cap in the text read
WCG Site Challenges, 2024	852 sites, April to June 2024	WCG	19% named sponsor-provided technologies (www.wcgclinical.com)	Global sample and new category list
WCG Site Challenges, 2025	611 sites, July to September 2025 (www.wcgclinical.com)	WCG	22% said the number of technologies and vendors is the greatest driver of complexity (www.wcgclinical.com)	Top-three selection
WCG Site Challenges, 2026	More than 400 professionals (www.wcgclinical.com)	WCG	35% saw integrated systems ending duplicate entry as an AI and automation opportunity (www.wcgclinical.com)	Figure taken from WCG's release; full report gated
Advarra Study Activation, 2023	Over 500 North American professionals (www.advarra.com)	Advarra (vendor)	Nearly 70% had six or more logins per study	Vendor-run; press release only
Veeva Site Survey, 2025	10,000 invited site professionals (sites.veeva.com)	Veeva (vendor)	Multiple logins among top challenges (sites.veeva.com)	Vendor-run; completed responses not stated
Florence State of Clinical Trial Technology, 2026	Site and sponsor respondents	Florence (vendor)	46% of sites used five or more internal systems daily (www.florencehc.com)	Vendor-run; sample size not stated
Tufts CSDD site survey, 2025	387 site professionals (www.appliedclinicaltrialsonline.com)	Tufts CSDD with sponsor-side support	22% reported lost revenue from digital solutions (www.appliedclinicaltrialsonline.com)	Did not separate sponsor-provided systems (www.appliedclinicaltrialsonline.com)
CenterWatch and ACRP, 2016	252 global sites (www.biospace.com)	CenterWatch with ACRP	Sites managed on average a dozen systems from sponsors (www.appliedclinicaltrialsonline.com)	Ten years old; global sample
SCRS Site Landscape, 2023	About 550 respondents (myscrs.org)	SCRS (site trade body)	40% said staff spend five to 15 hours on training per study (myscrs.org)	Self-reported; page restates the survey

The matrix shows three patterns without implying a causal one. First, system counts in vendor-run surveys cluster around "five or more", but the questions differ (logins, internal systems, sponsor-mandated systems), so the numbers are not interchangeable. Second, the Tufts CSDD survey reported financial impact but not a system count. Third, the oldest figure, the 2016 survey, already reported a dozen sponsor-provided systems per site on average (www.appliedclinicaltrialsonline.com), with high-volume sites reporting login information for at least 40 or 50 systems (www.appliedclinicaltrialsonline.com), so the issue predates decentralized trial tools.

A 2019 SCRS survey commissioned by a software vendor found respondents prioritised a single point of data entry (83%) and single sign-on (74%) (www.biospace.com). Taken together, the figures support asking the question, not a specific answer.

What the evidence does not show

None of the sources above measures site hours for a defined stack. A 2023 systematic review of electronic consent, covering 37 publications and 13,281 participants (pmc.ncbi.nlm.nih.gov), found that eConsent took more time than paper consenting in several head-to-head studies (pmc.ncbi.nlm.nih.gov), and it notes that no included study assessed workload across a whole trial (pmc.ncbi.nlm.nih.gov). A sponsor-authored account of an eConsent pilot reported site staff views on consent time as mixed: 23% said eConsent was faster and 23% said it was more time-consuming (www.appliedclinicaltrialsonline.com). A single-center time-and-motion pilot of electronic source data capture found a difference of 151 seconds per case, with 1,603 seconds for eSource and 1,754 seconds for non-eSource (pmc.ncbi.nlm.nih.gov), which is small and from one site. A German feasibility analysis found 67 of 274 case report form variables (24%) were automatically transferable from health records (www.jmir.org), though it reported no time saved. The honest summary is that duplicate-entry savings are plausible, site-specific, and unmeasured in public sources.

Protocol design also drives site burden independently of software. A Tufts CSDD and TransCelerate analysis reported an average of 5.9 million datapoints per Phase III protocol (pmc.ncbi.nlm.nih.gov) and attributed a share of site burden to non-core procedures (pmc.ncbi.nlm.nih.gov), using a score built by summing procedural burden scores across the number of times each procedure is performed (pmc.ncbi.nlm.nih.gov). Earlier Tufts work defined investigative site work burden as the product of work effort units per procedure and procedure frequency (pmc.ncbi.nlm.nih.gov). A 2024 Tufts CSDD survey of 355 respondents argued that existing measures of site burden offer only an incomplete view (link.springer.com), which supports measuring burden locally. Software burden should be separated from protocol burden when reading any site complaint.

Worked Calculation Using Hypothetical Inputs

The site-hours model

The model estimates the added site effort from a proposed stack. It is a planning tool, not a prediction, and every input is a local estimate to be replaced by values from site interviews and vendor evidence:

Site hours = (onboarding hours per system × number of systems) + (number of staff × training hours per staff member) + (duplicate-entry minutes per participant × planned participants ÷ 60) + recurring support hours

The inputs are defined as follows:

- **Onboarding:** account creation, access approval, and system setup, per system.
- **Training:** hours per staff member across all systems.
- **Duplicate entry:** minutes per participant for data entered a second time that an integration could remove.
- **Recurring support:** site time spent on tickets, resets, and access changes over the study.

Worked example (Hypothetical Example)

Assume a hypothetical site is asked to use six systems, with five staff members, 20 planned participants, and an 18-month study. All values below are invented for illustration and are not survey findings or benchmarks.

- **Onboarding:** 2 hours per system, so 6 × 2 = 12 hours.
- **Training:** 5 staff × 8 hours each = 40 hours.
- **Duplicate entry:** 10 minutes per participant × 20 participants ÷ 60 = 3.3 hours.
- **Recurring support:** 1.5 hours per month × 18 months = 27 hours.

The base case is about **82 hours** per site. *Table 3* below shows a one-at-a-time sensitivity test and a combined low and high case, using the same invented inputs.

Scenario (Hypothetical Example)	Onboarding (h/system)	Training (h/staff)	Duplicate entry (min/participant)	Support (h/month)	Total site hours
Base case	2	8	10	1.5	**82.3**
Training 4 h per staff member	2	4	10	1.5	62.3
Training 12 h per staff member	2	12	10	1.5	102.3
Onboarding 1 h per system	1	8	10	1.5	76.3
Onboarding 3 h per system	3	8	10	1.5	88.3
Duplicate entry 5 min	2	8	5	1.5	80.7
Duplicate entry 20 min	2	8	20	1.5	85.7
Support 0.5 h per month	2	8	10	0.5	64.3
Support 3 h per month	2	8	10	3.0	109.3
Combined low case	1	4	5	0.5	**36.7**
Combined high case	3	12	20	3.0	**138.7**

In this invented example, training and recurring support move the total most, while duplicate entry matters little at 20 participants. That changes with enrollment: at 200 planned participants and 10 minutes per participant, duplicate entry alone would be about 33 hours. The sensitivity test is the useful output. It shows which assumption a buyer must confirm with sites before contracting, and it keeps the debate focused on measurable inputs instead of a headline login count. The totals should be multiplied by the number of sites and compared with a threshold the buyer sets, as discussed below. They should not be compared with the survey figures, which measure perceptions and counts and not hours.

Implementation Considerations and Process Changes

Pilot, change control, and the support owner

Treat the scorecard as a gate in study start-up. Pilot at a few sites that represent the range in the study (for example an academic center, an independent site, and a site with a mature site-owned system set), measure the model's inputs directly (actual onboarding and training time, tickets raised, duplicate entries observed), and update the estimates. A large Tufts CSDD survey of sponsors and CROs found that the study start-up process averaged 5 to 6 months in total (pubmed.ncbi.nlm.nih.gov), which indicates how much time sponsors already allow for start-up work; a stack that adds avoidable steps competes for that time.

Change control matters because stacks drift: a new vendor is added mid-study, a version changes a workflow, a training module is reissued. FDA recommends that training be conducted before an individual uses a system (www.fda.gov), so a system change that adds a workflow is a natural trigger for retraining, and the EMA guideline says all training should be documented (www.ema.europa.eu). Define who approves a change that adds a login or a retraining requirement, and require the change request to carry an updated scorecard. The procurement file should hold:

- **The system inventory** and its owners.
- **Scorecard inputs and weights,** with the evidence received for each field.
- **Pilot results** and the revised site-hours estimates.
- **Thresholds** chosen by the buyer and who approved them.
- **Change-control records** for each added or modified system. Name one **support owner** per system and one escalation owner for the whole stack. A scorecard that records "vendor" as the support owner for six systems has not assigned an owner.

GCP, validation, and records

Good clinical practice (GCP) obligations stay with the sponsor and the investigator when a service provider is used. ICH E6(R3) says delegating activities to service providers does not transfer responsibility for trial conduct (database.ich.org), and FDA says regulated entities are responsible for ensuring electronic records meet applicable Part 11 requirements (www.fda.gov). The agency also recommends considering the provider's policies that allow the regulated entity to oversee the provider's activities (www.fda.gov) and a plan ensuring the sponsor has access to data throughout the regulatory retention period (www.fda.gov). The International Society for Pharmaceutical Engineering (ISPE) notes that electronic systems need validation when they are used in ways that affect participant safety, data integrity, or essential records (ispe.org) and that E6(R3) expects risk-based oversight throughout the engagement with service providers (ispe.org).

Consent and retention rules vary by jurisdiction, and readers should confirm them locally with qualified regulatory counsel. In the US, 21 CFR 50.27 requires that a copy of the consent form be given to the person signing (www.ecfr.gov), and the FDA and Office for Human Research Protections (OHRP) electronic consent guidance says subjects should have the option to use paper or electronic consent (fda.gov) and that OHRP permits electronic signatures only if they are legally valid where the research is conducted (fda.gov). For electronic investigator systems, the EMA guideline says the investigator should be able to grant and revoke access to the eConsent system for monitors and inspectors (www.ema.europa.eu). Retention periods differ by

jurisdiction and by role, and sponsor contracts or other rules may require longer retention than the examples here. Under 21 CFR 312.62(c), a US investigator retains required records for 2 years following the date a marketing application is approved for the drug for the indication under investigation or, if no application is filed or approved for that indication, until 2 years after the investigation is discontinued and FDA is notified (www.ecfr.gov), while Article 58 of EU Regulation 536/2014 requires the sponsor and the investigator to archive the content of the clinical trial master file for at least 25 years after the end of the clinical trial, unless other Union law requires a longer period, and subject to national law for subjects' medical files (eur-lex.europa.eu). The UK's new clinical trials regulations came into force on April 28, 2026 (www.hra.nhs.uk), and transitional rules should be checked. Privacy obligations for participant data also vary by country and should be reviewed with privacy specialists; this report does not assess them.

Integration and single sign-on claims

Vendors describe several ways to reduce logins, and each should be tested against the scorecard rather than accepted. TransCelerate describes the Shared Investigator Platform as a response to sites using many platforms, each requiring unique login credentials (www.transceleratebiopharmainc.com), and as housing multiple sponsors while allowing integration with other clinical systems (www.transceleratebiopharmainc.com). Among vendor pages, Advarra describes single sign-on that lets site staff use their own site-sanctioned credentials to access key systems, including sponsor-provided technology (advarra.com); Veeva lists one login across its applications on its SiteVault plans page (sites.veeva.com); and Florence lists single sign-on that enables one login across platforms (florencehc.com). These are vendor claims about their own products. A stack that mixes vendors gets the benefit of such features only if identity and data connections work across them, which is a question for the scorecard's evidence request.

Ownership of records is a related question. Veeva states on its plans page that the customer site owns and controls its own data, including regulatory and source documents (sites.veeva.com). Data exchange standards help here: CDISC describes ODM as a vendor-neutral, platform-independent format (www.cdisc.org) and Define-XML as transmitting metadata that describes tabular dataset structure (www.cdisc.org). SCRS recommends that sponsors and CROs share application programming interfaces (APIs) to make site integration easier (myscrs.org). None of these replaces a tested export during a pilot.

Setting procurement thresholds

Thresholds should be set by the reader, not taken from this report. State the decision rule before scoring. Examples a sponsor might adopt:

- **A site-hours ceiling** chosen with its site advisory group.
- **A minimum score** that every field must reach.
- **A redesign trigger** when any field scores zero (for example, no export path).

Record the thresholds in the procurement file alongside the inputs. Fewer logins do not automatically improve outcomes: a single system with a poor fit may add more training and support time than three well-integrated ones, which is why the model counts hours and not systems.

Implications and Future Directions

For sponsors and CROs, site burden can be handled as a design and procurement input with a documented method. A scorecard turns qualitative site complaints into questions that vendors can answer with artifacts, and a site-hours model makes the cost of each additional system visible before contracts are signed. The buyer's documentation also records oversight, though it does not substitute for the regulatory requirements described above.

For evidence, the clearest gap is measurement. The public literature has perception surveys, system counts, and small time studies, but no controlled estimate of hours per system, per site, for a defined stack. Peer-reviewed work on eCOA found that sites generally did not feel well prepared (pmc.ncbi.nlm.nih.gov), and a Tufts CSDD survey noted that existing burden measures were incomplete (link.springer.com), so a standard, shared instrument is a plausible next step. A site readiness framework published in 2023 described site initiation as fragmented and duplicative (pmc.ncbi.nlm.nih.gov), which suggests that technology readiness could be added to harmonised site assessments.

For regulation, the E6(R3) rollout continues: Annex 2 on decentralised and pragmatic trials reached adoption in June 2026 (www.ema.europa.eu), and EMA states that Annex 2 will come into effect in the EU on 15 January 2027, while implementation dates in other regions should be checked. FDA's training recommendation for decentralized trials, which asks that training be provided to all parties using electronic systems (www.fda.gov), implies that decentralized components add training scope for sites. AI and automation are also appearing in site responses: WCG's 2026 release reports that 35% of sites see integrated systems that end duplicate data entry as a top opportunity (www.wcgclinical.com). Whether such tools reduce site hours is an empirical question for local pilots.

The scorecard and site-hours model work without any adviser or product.

Frequently Asked Questions (FAQs)

How many systems do clinical trial sites use per study? Public sources give different counts for different questions. A vendor-run survey reports five or more study-specific systems for half of site respondents (www.florencehc.com), a 2016 CenterWatch and ACRP study reported a dozen sponsor-provided systems on average (www.appliedclinicaltrialsonline.com), and a 2022 SCRS poll cited in the SCRS white paper said 60% of sites at one meeting used 20 or more systems daily (myscrs.org). Count the systems in your own stack instead.

What is site technology fatigue, and is it measured? The phrase is informal. Surveys measure related items, such as the share of sites naming technology among top issues (18% in 2023 (wcgnewprod.wpengine.com)). No single validated fatigue scale was found.

Does reducing logins reduce site burden? Not automatically. The surveys associate multiple logins with burden, and a Veeva author argues for fewer log-ins and better collaboration with sponsors (globalforum.diaglobal.org), but no source reviewed here shows that a login count causes outcomes. The site-hours model counts training, duplicate entry, and support in addition to access.

How should sponsors evaluate eClinical vendors for site burden? Use the scorecard fields, require the evidence listed, and add the regulatory checks: oversight information for providers (database.ich.org), validation documentation (www.fda.gov), investigator access to certified copies (www.ema.europa.eu), and a tested export.

What does a sponsor's technology procurement need to document? At minimum, the system inventory, scorecard inputs and weights, the pilot results, the thresholds chosen, the support owners, and the change-control procedure. Regulators place responsibility for system compliance on the regulated entity (www.fda.gov).

Which eConsent and eCOA issues affect site workload most? Evidence is limited. The eConsent review found no study that assessed workload across a whole trial (pmc.ncbi.nlm.nih.gov), and eCOA guidance asks for provisioned device options (c-path.org). Both belong in the patient-facing handoffs field.

Can the 2023 WCG survey be used as a current benchmark? No. It is a US survey from early 2023, and WCG has fielded later editions with different samples (www.wcgclinical.com). Cite it as historical context.

Conclusion

Site technology burden is real enough to be measured and uncertain enough to be measured locally. The published evidence supports three limited statements: technology appears among site concerns in repeated surveys, the reported number of systems and logins per site is often five or more in vendor-run research, and regulators expect sponsors to keep investigators in control of their data and to train users before use. It does not support a universal benchmark, a causal link between login counts and trial outcomes, or a figure for hours saved by any product.

The scorecard and site-hours model cover seven fields, require artifacts as evidence, separate hypothetical inputs from survey data, and leave thresholds to the organization that owns the decision. Applied before contracting, with pilots at representative sites and change control afterward, they turn a vague concern into inputs that can be inspected, challenged, and updated as the 2026 and later survey data mature.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

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