SITE-SPONSOR CONSORTIUM

INDUSTRY FRAMEWORK

Reducing Redundant Site Training Through Competency-Based, Role-Based, and Reusable Training Models

Main framework paper for site training reform, SIV redesign, and EDC recognition

---

A three-paper series for sponsors, CROs, sites, and vendors

Site-Sponsor Consortium | An Advarra Initiative

Paper	Focus	Tool group*
Main paper	Shared rationale, framework, evidence standards, and companion resource map	A–D
SIV companion	Site initiation visit (SIV) redesign and reusable core readiness content	E–G
EDC companion	Training recognition, vendor alignment, and pilot implementation	H–K

* Links to each toolkit found on pg. 12 in Figure 7

Developed by the Advarra-facilitated Site-Sponsor Consortium—a collaborative, equally weighted coalition of sponsors, CROs, and commercial and institutional research sites—this paper is the entry point for the series. It explains why redundant site training persists, how qualification should be evaluated, where training should be placed, and why "recognition" is a better operational term than "waiver" for the decisions being made. The companion papers then expand the two implementation pathways: SIV redesign and electronic data capture (EDC) training recognition.

How to use this series

Start with the main paper for the shared framework and rationale. Use the SIV companion paper for live-startup redesign and the EDC companion paper for platform-level training recognition and vendor/process alignment. The downloadable tools are organized to match that split so readers can move from concept to implementation without hunting through a long single document.

Executive summary

Site training burden is no longer just a site issue. It is an industry-wide efficiency, quality, and startup challenge. This paper presents a practical framework to modernize training by:

- Documenting decisions and monitoring quality signals so training recognition remains transparent, consistent, and inspection-ready.
- Classifying training as reusable foundational or platform-level training, common operational content, true study-specific instruction, or change-driven/delta training before assigning it.
- Recognizing current, objective, role-relevant evidence instead of repeating training by default.
- Protecting live SIV time for protocol-specific risk, role clarification, operational planning, and sponsor/contract research organization (CRO)-site discussion.
- Reducing training-related activation delays by identifying reusable evidence before training is assigned, preserving SIV time for study-specific readiness, and assigning only the remaining role-based training needed for activation and conduct.
- Piloting EDC training recognition as the first scalable use case by using controlled vendor, EDC system, learning management system (LMS), or sponsor/CRO-accessible records before requesting duplicate evidence from sites.

The objective of this framework is not to replace defensible training practices—it is to determine whether equally defensible, evidence-based qualification decisions can reduce unnecessary burden without compromising participant protection, protocol execution, data quality, or inspection readiness.

Clinical trial site training is intended to prepare site personnel to execute a study safely, accurately, and consistently. In practice, however, training requirements often accumulate across sponsors, CROs, vendors, and sites in ways that create redundancy without necessarily improving readiness. Site personnel may repeatedly complete similar training on Good Clinical Practice (GCP), human subjects protections (HSP), general clinical procedures, vendor platforms, online study modules, and study-specific requirements across studies and sometimes within the same study.

The central premise of this paper is that qualification, not repetition, should be the guiding principle for site training. Foundational clinical trial and participant protection knowledge, general clinical capability, common operational content, and platform-level competency should be reused when there is current, relevant, and objective evidence that site personnel are prepared and remain qualified for the responsibilities assigned. Study-specific instruction should remain required, but it should focus on what is new, different, role-specific, or risk-critical for the protocol.

Evidence-based reuse of training does not prohibit post-startup corrective action: If monitoring, audits, performance trends, or repeated deviations reveal a genuine training gap, targeted retraining, verification, or other corrective and preventive action (CAPA) measures may still be needed.

1. Data foundation: Redundancy is measurable and predictable

The need for a more coordinated site training model is supported by recent industry data. The Society for Clinical Research Sites (SCRS) 2025 Cut >25 guidance, a data-driven playbook for reducing clinical site training burden, encouraged the industry to move toward a future state where training functions as a competency verification system focused on whether site personnel can safely and accurately execute the protocol.

SCRS identified several high-impact opportunities that align directly with this paper: implementing EDC training reciprocity and standardization, ensuring content appropriateness and respect for site expertise, and establishing broader training reciprocity frameworks. “Reciprocity” is commonly used in industry discussions about reducing duplicative training. For the operational model, however, this paper uses “recognition” to describe the action being taken: Current, objective, role-relevant evidence is reviewed against defined criteria and accepted when sufficient.

This distinction is important because recognition does not imply that training is waived, that another organization’s training is accepted automatically, or that study-specific instruction is no longer required.

EDC was identified as the leading source of training redundancy, with 67% of respondents identifying EDC as the top redundancy source. SCRS also reported that 64% of sites are required to take separate EDC training for each study, while only 11% of sponsors/CROs accept previously completed EDC training and 13% often accept it. Because many sites use the same EDC platforms across multiple studies, EDC is a practical first use case for training recognition. Even without solving every technology category at once, recognizing current platform-level competency where controlled evidence exists could reduce a meaningful portion of redundant training burden.

Figure 1. Redundancy is measurable

Three SCRS findings anchor the case for reusing evidence instead of repeating training by default.

Largest source of redundancy	Separate EDC training	Repeated documentation
67% EDC was identified as the top redundancy source in the SCRS survey	**64%** Sites report being asked to complete separate EDC training for each study	**60%** Sites asked to provide training evidence to multiple departments or individuals

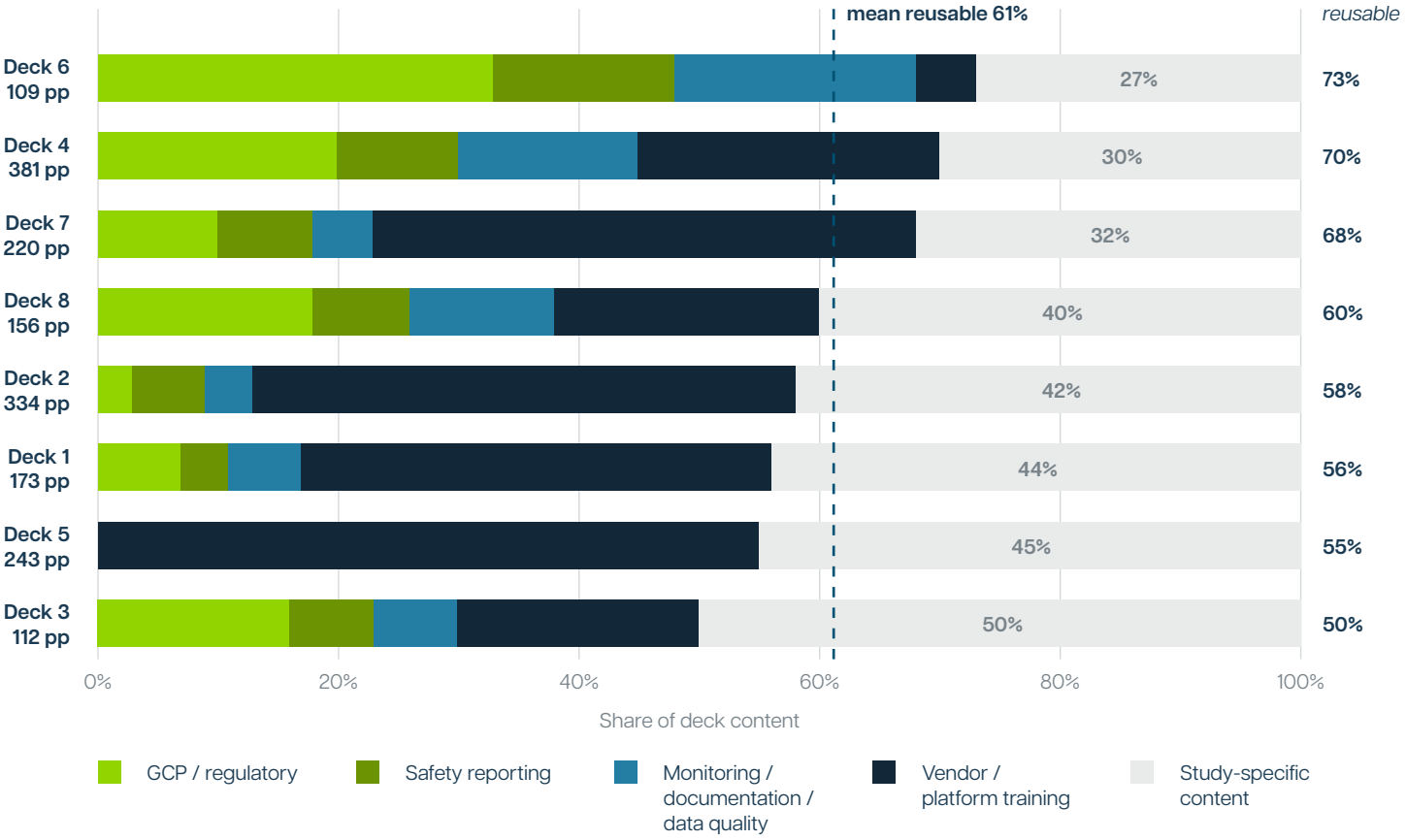
SCRS data also suggest that the burden is not isolated to a small subset of studies. At startup, 72% of training falls in the two-to-ten-hour range per site staff member per study, and respondents commonly reported substantial redundancy: 43% estimated 26% to 50% redundancy, 18% estimated 51% to 75% redundancy, and 5% estimated more than 75% redundancy. These findings support the need for a model that addresses not only whether training is assigned, but whether the assigned training is necessary, appropriately placed, role-based, and supported by reusable evidence.

Although this paper focuses its practical pathways on SIV redesign and EDC training recognition, SCRS data show that redundancy extends beyond EDC. Safety reporting systems, interactive response technology (IRT) and randomization and trial supply management (RTSM) software, electronic clinical outcome assessment (eCOA) and electronic patient-reported outcome (ePRO) devices, and lab, biospecimen, and shipment portals were also identified as recurring sources of redundant training. Documentation burden is similarly relevant: Repeated evidence requests show that the issue is not only what training is assigned, but also how training evidence is collected, stored, accessed, and reused. These examples are included not to expand the initial pilot scope, but to show why a reusable evidence model is needed beyond a single platform.

Redundancy patterns observed in SIV deck reviews

Figure 2. Reusable and study-specific content across 8 industry-sponsored multi-therapeutic SIV decks

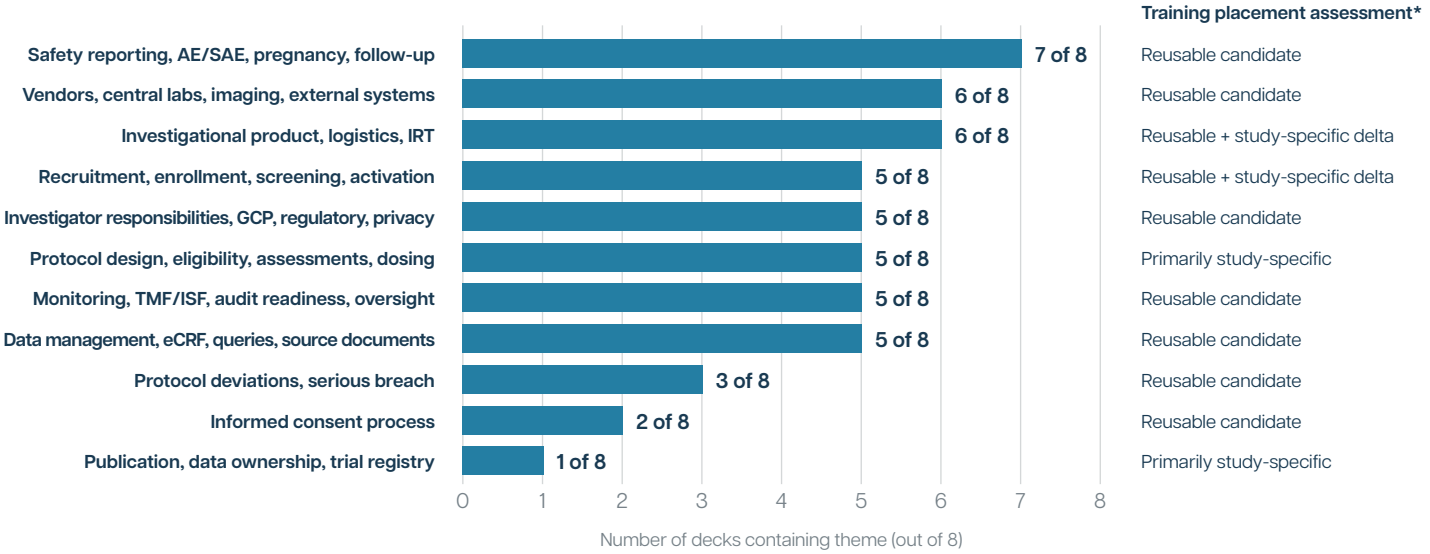
One participating multi-therapeutic site network reviewed eight recent industry-sponsored SIV decks and categorized the content as reusable or study-specific. **Reusable content represented 50% to 73% of each deck, with a mean of 61%**, suggesting that a substantial portion of SIV content may not require repeated live delivery for every study.



Color blocks show the four reusable content categories reported for each deck; study-specific content in gray is the remainder.
A ninth artifact was a standalone central-lab vendor module and was excluded. Source: participating site network content review, May 2026.

Figure 3. Recurring themes across eight industry-sponsored oncology SIV decks

A separate cancer center review examined eight recent industry-sponsored oncology SIV decks and identified recurring content themes. Safety reporting appeared in seven of eight decks; vendor, central-lab, imaging, and external-system content appeared in six; and several other topics—including GCP/regulatory responsibilities, monitoring/documentation, and data management—appeared in five of eight.



Note: Themes are not mutually exclusive; counts show the number of the eight oncology SIV decks in which each theme appeared. Bar length represents prevalence only.

*Placement assessments are qualitative and shown separately from prevalence. They map the original reviewer judgments to the Consortium's SIV Content Placement Checklist (Tool E), which considers protocol variability, risk if misunderstood, need for sponsor/CRO-site discussion or workflow planning, sponsor/CRO-specific differences, and whether live readiness discussion is required. Source: participating cancer center content review, May 2026.

The two reviews used different methods and should not be compared numerically. Together, however, they point to the same operational opportunity: substantial portions of SIV content are repeated across studies, and several content domains recur across multiple decks. The Consortium's SIV Content Placement Checklist (Tool E) and Reusable Core Readiness Content Map (Tool F) provide a structured way to determine which recurring content may be reusable and which content should remain study-specific.

2. Central framework: Qualification, placement, and purpose

Redundant site training persists because sponsors, CROs, sites, and vendors often treat all training as study-specific, even when much of it reflects reusable competency or common operational content. A more effective model separates training into three categories:

1. What personnel already know and can evidence
2. What training applies broadly and should be taught once
3. What is truly novel, role-specific, or risk-critical for the current study

In this framework, qualification asks whether personnel already have the knowledge, skill, experience, or documented evidence needed for the assigned responsibility. Placement asks where and when training content belongs: reusable training, job aid, vendor module, live SIV discussion, study-specific instruction, or point-of-use reinforcement. Purpose asks what readiness need or protocol execution risk the training is intended to address. If the purpose cannot be clearly linked to role, task, risk, or study execution, the training requirement should be reconsidered.

This framing is consistent with International Council for Harmonisation (ICH) E6(R3), which emphasizes that trial personnel should be qualified by education, training, and experience to perform their delegated responsibilities. E6(R3) also supports a proportionate approach to trial processes

and documentation, including training that corresponds to the activities site personnel are expected to perform, particularly where those activities go beyond their usual training and experience. While documentation expectations may vary by jurisdiction, regulator, inspection team, and study context, the underlying expectation is not that generic training be repeated for every study. Rather, sponsors, CROs, investigators, and sites should be able to demonstrate that study personnel are appropriately qualified for the tasks they perform.

ICH E6(R3) reinforces the central point of this paper: Training burden should be reduced by reusing current, objective, role-relevant evidence where it is sufficient, while reserving additional training for what is new, different, role-specific, or risk-critical.

Regulatory expectations and defensibility

This framework is not intended to reduce required training or shift accountability away from sponsors, CROs, investigators, or sites. Rather, it provides a structured way to meet regulatory and quality expectations by documenting that personnel are qualified for the responsibilities they are assigned to perform. In U.S. drug and biologic trials, sponsors are required to select investigators qualified by training and experience, and investigators are responsible for conducting the investigation according to the signed investigator statement, investigational plan, and applicable regulations while protecting the rights, safety, and welfare of participants. For device studies, comparable sponsor and investigator responsibilities apply. Training expectations may also arise from sponsor/CRO quality systems, institutional policy, institutional review board (IRB) expectations, funder requirements, or local law.[1]

The model therefore remains defensible only when recognition decisions are based on current, objective, attributable, retrievable, and role-relevant evidence; study-specific and risk-critical instruction remains required; and decisions are documented in a way that is traceable and reviewable. The framework does not assume prior training must be accepted automatically. It supports a documented determination of when existing evidence is sufficient and when additional training, targeted verification, or full retraining is needed.

Given that expectations may vary across jurisdictions, regulators, inspection teams, and study contexts, organizations should define acceptance criteria that are appropriate for the applicable regulatory environment, sponsor/CRO quality standards, role, task, and study risk. This distinction matters because current practice often translates GCP and HSP expectations into repetitive study-by-study training obligations. Certificates, recency windows, and preferred documentation formats can become proxies for readiness. Yet repeated completion of generic training does not, by itself, evaluate comprehension, effectiveness, or the ability to apply knowledge in practice.

Qualification, not repetition

A competency-based model should allow prior training, professional certification, relevant experience, and demonstrated performance to support a qualification decision when that evidence is current, role-aligned, documented, and proportionate to study risk. Sponsors and CROs should define clear criteria for when existing evidence is sufficient and when targeted verification or additional training is needed, particularly when evidence is incomplete or outdated, when there is a material regulatory or process change, when study or task risk is higher, when role-specific gaps exist, or when study-specific requirements apply.

As an illustrative default, organizations may choose to treat documented GCP/HSP training completed within the prior two years as current for foundational evidence review, unless applicable requirements, organizational policy, or a material regulatory, guidance, process, or role change requires earlier updating. Organizations may also recognize active certification from a recognized clinical research professional organization as objective evidence of ongoing foundational GCP/HSP competency when the certification is current, independently verifiable, and relevant to the individual's assigned responsibilities.

When a material update affects foundational GCP/HSP expectations, organizations should consider whether a documented, focused addendum or targeted update is sufficient when the individual's underlying foundational training remains current and acceptable under sponsor/CRO-defined criteria, rather than requiring full repetition of the foundational course by default.

This competency-based framing is consistent with the international Joint Task Force for Clinical Trial Competency framework, which defines the knowledge, skills, and attitudes needed to conduct safe, ethical, and high-quality clinical research. Active professional certification, such as certification through the Association of Clinical Research Professionals (ACRP), may provide strong evidence of foundational clinical research competency when the certification is current, independently verifiable, and relevant to assigned responsibilities. Certification does not replace study-specific training, but it may support acceptance of prior foundational training or reduce the need for additional test-out assessments when the certification already demonstrates the relevant competency.[2]

Published analyses provide supportive, though not definitive, evidence that professional certification may correlate with protocol adherence or inspection outcomes. These findings support considering current, independently verifiable certification as part of a documented qualification assessment, not as an automatic substitute for required training.

Figure 4. Qualification and training placement framework

Panel A: Decision framework for foundational training acceptance

Decision question	Purpose
Is foundational training current?	Confirms that GCP/HSP knowledge is recent enough to support the assigned role.
Is there relevant and recent clinical research experience?	Shows that the individual has performed comparable responsibilities in practice.
Do assigned responsibilities align with prior evidence?	Connects evidence to delegated tasks such as consent, safety reporting, investigational product (IP) accountability, data entry, sample handling, or clinical procedures.
Does study, site, role, or task risk warrant more verification?	Identifies when knowledge checks, simulations, targeted retraining, or closer oversight are appropriate.

Panel B: A three-category taxonomy for site training

Category	Definition/examples	Training approach
Reusable foundational competency	Knowledge, skills, or professional competencies that are not unique to one protocol and may be demonstrated through prior training, certification, experience, or performance. Examples: GCP/HSP, professional certification, clinical research experience, phlebotomy competence, vital sign collection, basic electrocardiogram (ECG) setup, and general source documentation principles.	Do not re-teach by default. Verify through current, relevant evidence and use targeted verification or refresher training only when evidence is incomplete, outdated, role-misaligned, or risk warrants it.
Common operational content	Recurring operational expectations that appear across many studies or across multiple lessons within one study. Examples: adverse event/serious adverse event (AE/SAE) reporting basics, common sample-handling principles, standard query response expectations, source documentation expectations, recurring visit workflow concepts, and common data entry conventions.	Teach once, provide a durable reference or job aid, and reinforce only when the current study changes or a risk-based assessment of trial activities indicates the need for retraining.
True study-specific instruction	Protocol-specific risks, workflows, procedures, data requirements, timing, or decisions that differ for the current trial. Examples: visit schedule, eligibility nuances, specific labs and tubes, processing and shipping windows, dose preparation, study-specific safety risks or adverse events of special interest, case report form (CRF) completion expectations, and unique imaging or biospecimen workflows.	Remain required. Deliver in a targeted, role-based, timely way and avoid repeating content that has already been addressed elsewhere in the study.

3. Current site training process and structural inefficiencies

Clinical trial site training is rarely delivered as a single, coordinated program. Instead, it accumulates. By the time a site begins formal study training, much of the training footprint has already been determined by decentralized decisions. In a typical study, sponsors and CROs select the systems, vendors, assessments, and procedures that will be used in the trial, including EDC, IRT/RTSM, ePRO/eCOA, laboratory, safety, imaging, pharmacy, and other operational platforms. Each choice carries its own training, access, and documentation requirements. Those requirements then flow into activation checklists, regulatory packets, online training modules, vendor onboarding steps, startup plans, SIV decks, and monitoring responsibilities.

The SIV typically becomes the peak training event. It may combine protocol overview, eligibility criteria, safety reporting, randomization workflows, data entry expectations, vendor systems, laboratory procedures, operational requirements, and administrative readiness. In some cases, it may also revisit general principles like GCP; HSP; or attributable, legible, contemporaneous, original, and accurate (ALCOA).

Because these principles are generally stable across studies, they should not be re-taught in the SIV by default. They should be discussed with new study personnel or when the protocol introduces a study-specific application, risk, workflow, or documentation expectation that changes how site personnel need to apply those principles in practice.

For example, if a protocol includes phlebotomy at multiple visits, qualified personnel generally do not need instruction on how to perform phlebotomy. What they need is clear, study-specific instruction on which samples are collected, when they are collected, how they are processed, what tubes or materials are required, and how samples are shipped and documented.

This should be taught once, made easy to reference (with a job aid or quick guide), and reinforced only where the protocol introduces a new or risk-critical difference. By contrast, if the protocol or lab manual requires a nonstandard needle, butterfly set, tube type, handling step, or other equipment choice that materially affects specimen integrity, that difference should be taught explicitly and reinforced, even for experienced site personnel.

A more intentional training model can support faster site activation by reducing avoidable retraining, late evidence collection, duplicative certificate requests, and unresolved training dependencies before site greenlight. It can also reduce sponsor/CRO follow-up, decrease documentation cycles, and allow sites to focus more quickly on participant-facing study execution.

Key inefficiencies

- Fragmentation across stakeholders: Training requirements originate from multiple parties and arrive through different systems, emails, portals, online modules, and documentation pathways.
- Event-based and module-heavy delivery: Training is concentrated into startup events or online modules regardless of role, relevance, prior experience, or when the information will actually be used.
- Proof of completion over demonstrated readiness: Completion records are often emphasized more than whether personnel are already qualified and prepared to perform assigned tasks.
- Intra-study repetition: The same study-specific instruction may be repeated across multiple lessons or visit modules even when one clear module, job aid, or reference would support performance more effectively.
- Inefficient change management: Protocol amendments, manuals, system updates, and operational changes may trigger broad retraining rather than targeted retraining based on who is affected and what changed.
- Duplicative documentation: Sites may maintain parallel records and respond to repeated requests because evidence expectations are inconsistent across sponsors, CROs, vendors, and studies.

- Overbroad role assignment or delegation: When site personnel are added to access lists, training rosters, Form FDA 1572s, or delegation logs before their actual study responsibilities are clear, training and documentation requirements may expand beyond the personnel expected to perform study tasks. At the same time, sites help prevent avoidable burden by keeping delegation records current, limiting assignment lists to actual study roles, and maintaining retrievable evidence of who was trained on what.
- Training fatigue and reduced retention: Repeated exposure to non-essential or already-known content or excessive amounts of content can reduce attention and make it harder for site personnel to retain new, protocol-specific, or risk-critical information.

These inefficiencies have consequences for all parties. Sponsor and CRO study personnel spend time tracking, reconciling, and aligning training records with delegation records, especially when site documentation is incomplete, missing, or unclear. Sites spend time completing repeat training, gathering documentation, and cascading sponsor/CRO requirements internally. The cumulative effect is a model that can prioritize proof of completion over demonstrated readiness, contribute to training fatigue, and take time away from participant-facing work and study.

Figure 5. Why redundant training matters

Redundancy is not one problem with one cost. Structural choices in how training is designed, assigned, and evidenced converge on three forms of repetition, and the resulting burden falls on sites, on sponsors and CROs, and on study execution.



The goal is not less readiness. The goal is better readiness with less unnecessary repetition.

Interpretive impact graphic, not a statistical chart. Causes are the structural inefficiencies named in Section 3; consequences are drawn from the same section and from the closing summary. Training fatigue and reduced retention is listed in the paper among the key inefficiencies and is placed here among consequences, because that is where it operates in the causal chain.

4. Target model: Lifecycle-based, coordinated, and reusable

A more effective model shifts from an event-based and module-heavy model to a lifecycle-based one. Training becomes a coordinated architecture spanning site personnel's foundational GCP/HSP training, study startup, and ongoing study conduct. In this model, training is not a single event or a collection of isolated online modules, but a structured system made up of reusable foundational competencies, common operational content, targeted study-specific instruction, role-based assignments, and ongoing just-in-time reinforcement.

Where sponsors or CROs need additional assurance that prior training reflects current understanding, a brief test-out assessment, knowledge check, workflow-based verification, or simulation may be more effective than requiring the completion of an entire course or module.

This approach supports the sponsor's responsibility to verify that site personnel are qualified, while preserving the investigator's obligation to ensure delegated study personnel receive appropriate site-specific, on-the-job training and oversight for the actual phase of the study, local workflows, and trial risks. It avoids unnecessary retraining when existing evidence is otherwise sufficient. Sponsor-provided training establishes a baseline; investigator-led site training and oversight ensure that baseline is applied correctly in the actual site context.

To avoid replacing redundant training with redundant verification, sponsors, CROs, and sites should define in advance what evidence or performance standard is sufficient for test-out, targeted verification, or simulation, and should keep the verification proportionate to the risk and complexity of the task.

Training effectiveness is influenced not only by content, but also by timing and context. Training that is shorter, targeted, and delivered close to the point of use is more likely to support retention and application than large volumes of front-loaded content delivered weeks or months before the relevant task is performed.

This makes the lifecycle model not only a burden-reduction strategy, but also a training-effectiveness strategy:

Information is more useful when it is delivered close to the moment site personnel need to apply it. Consistent with the monitoring plan and risk-based oversight approach, interim monitoring visits and routine touchpoints can be used to look ahead with site personnel to upcoming study activities, reinforce protocol-specific expectations, and identify gaps or questions before they affect participant safety, data integrity, or study timelines.

This does not replace the investigator's responsibility to ensure that delegated site personnel are qualified and appropriately trained. Rather, it creates a structured opportunity for sponsor/CRO and site teams to align on upcoming risks and readiness.[3] At the site level, the PI remains responsible for ensuring that delegated site personnel receive appropriate protocol-specific and site-specific training and oversight, including any on-the-job reinforcement needed for the actual phase of the study and local workflows.

Lifecycle-based training should not be interpreted as delaying required training until after it is needed or redistributing the same burden across the study. Training required for activation, access, participant safety, protocol execution, or delegated study tasks should be completed before the relevant activity occurs. The purpose of a lifecycle model is to place training at the point where it supports performance, reduce premature or duplicative training, and use monitoring or routine touchpoints to reinforce upcoming risks, not to create additional follow-up burden during conduct.

This approach is also consistent with adult-learning principles: Training is more likely to be retained and applied when it is targeted, reinforced over time, and delivered close to the moment personnel need to use it.

For higher-complexity studies or first-in-study workflows, timely and contextual training may include structured simulation or rehearsal visits before the first participant is seen. These rehearsals allow site personnel to walk through key workflows using a mock participant, sandbox system environment, or fictional case, helping identify operational gaps before enrollment.

Figure 6. Current vs. target training models

Current model	Target model	What changes in practice
Event-based and SIV-centric	Lifecycle-based and stage-appropriate	Training is planned across startup, SIV, activation, interim monitoring visits (IMVs), amendments, and ongoing conduct rather than concentrated in one event.
Front-loaded and time-based	Timely, stage-appropriate, and competency-based	Training is delivered close to the point of use and aligned with activation, enrollment, amendments, and upcoming study activities. Test-out or verification can document competency when full retraining is unnecessary.
Study-by-study repetition	Reusable components plus targeted study-specific instruction	Foundational GCP/HSP, clinical skills, common operational content, and platform-level training are accepted when evidence is sufficient. New training focuses on what is novel, role-specific, or risk-critical.
One-size-fits-all	Role- and risk-based	Training assignments are linked to delegated responsibilities, role scope, study complexity, participant/data risk, task relevance, and performance.*
Fragmented ownership	Coordinated architecture	Sponsors, CROs, vendors, and sites align requirements, evidence expectations, timing, and documentation before training is assigned.
Documentation-driven	Performance- and evidence-driven	Completion records remain important, but acceptable evidence, test-out, prior experience, and targeted verification support readiness decisions.
Broad retraining after change	Targeted retraining after impact assessment	Amendments, system updates, new study personnel, and process changes trigger training based on what changed, who is affected, and the risk introduced.

**If monitoring, audit findings, or recurring deviations indicate a genuine training gap, retraining may be included as part of CAPA, even when prior documentation exists.*

5. Companion resources and tools

The publication series is designed to keep the main paper readable while still giving sponsors, CROs, sites, and vendors practical implementation tools. The shared tools support the overall framework. The SIV companion paper and tools help teams decide where content belongs in a live startup event, and the EDC companion paper and tools help teams decide when prior platform-level training can be recognized instead of repeated.

Figure 7. Tool map at a glance

Tool group	What it covers	Information it supports
Toolkit A–D	• Foundational acceptance criteria (Tool A) • Minimum evidence (Tool B) • Decision records (Tool C) • Pilot metrics (Tool D)	Main paper (shared rationale and framework)
Toolkit E–G	• SIV content placement (Tool E) • Reusable core readiness content (Tool F) • Site activation/system needs (Tool G)	SIV companion paper
Toolkit H–K	• EDC classification (Tool H) • Recognition policy (Tool I) • Vendor requirements (Tool J) • Pilot planning (Tool K)	EDC companion paper

6. Sponsor, CRO, and vendor alignment

The model does not require the industry to invent a new training infrastructure. Training records, completion histories, system activity data, certifications, site training records, vendor records, and recognition mechanisms already exist in many environments.

The real barrier is not lack of information, but lack of standardized acceptance criteria and consistent documentation of the training.

Sponsors and CROs should use vendor-generated training records and system histories before requesting duplicate evidence from sites. Sites should not be asked to download, transmit, and resubmit records that already exist in a controlled vendor or sponsor/CRO-accessible system. Sites support accurate role- and evidence-based training assignment by identifying which personnel require system access or study task assignment, what tasks they are expected to perform, and what evidence of prior competency is available.

Site-managed training programs may also support the model when they are structured, documented, role-relevant, and retrievable. For example, a site or network may use its quality function to deliver foundational expectations, a training team to reinforce common operational content, and site leadership to ensure study-specific instruction is completed and applied.

Sponsors and CROs should define when institutional training records, standard operating procedure (SOP)-based training, competency documentation, or other site-controlled evidence may satisfy foundational or common operational requirements under defined criteria.

Figure 8. Core principles for reusable training evidence

Principle	What it means in practice
Collect once, reuse broadly	Training evidence should be collected or verified once for each individual and relevant platform, competency, or certification; maintained in a controlled, retrievable location accessible to authorized parties for the study; and reused across studies when it remains current, relevant, role-aligned, and acceptable under defined criteria.
Use vendor records before requesting duplicate site evidence	When attributable, retrievable vendor records or sponsor/CRO-accessible system reports are available, those records should be used before asking sites to download, transmit, or resubmit certificates.
Accept equivalent evidence	Sponsors and CROs should avoid rigid format requirements when equivalent objective evidence is available, such as certificates, system-generated records, professional certification, prior sponsor/CRO records, relevant experience, or documented meaningful use.
Define minimum sufficient evidence	Organizations should define the minimum evidence needed to support a training decision. The goal is not to collect every possible record, but to collect enough evidence to support a risk-based and inspection-ready determination.
Separate reusable evidence from study-specific evidence	Documentation should distinguish foundational, clinical/procedural, common operational, or platform-level training from study-specific instruction.
Maintain a record-access roadmap	If evidence remains in a vendor or external system, sponsors and CROs should document where the record is maintained, how it can be retrieved, how long it will remain available, and what contingency plan applies if systems or vendors change.

7. Application pathway at a glance

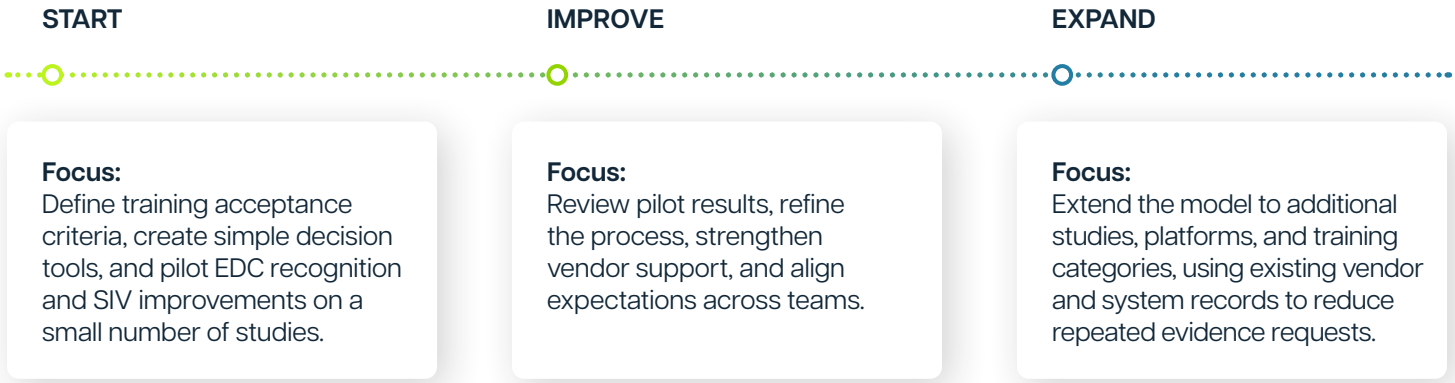
The remaining companion papers expand the two practical starting points in this main paper. The SIV companion paper explains how to decide what training belongs in the live SIV, what training belongs in reusable core readiness content, and how to treat training-equivalence reviews and delta training. The EDC companion paper explains how to recognize prior platform-level training, define minimum sufficient evidence of training, and pilot the model with vendor-supported records and controlled workflows.

8. Calls to action

Adoption does not need to begin at scale. A phased approach—starting with defined acceptance criteria and a small pilot, improving the process based on pilot results and stakeholder feedback, and expanding only after burden reduction and stable quality signals are demonstrated—allows sponsors, CROs, and sites to build confidence before the model is applied broadly.

Figure 9. Adoption roadmap

Start with criteria, improve with pilot feedback, then expand only after the model proves itself.



Sponsors/CROs

- Pilot the model on one or two studies.
- Define acceptance criteria up front.
- Use controlled vendor or sponsor/CRO records before requesting duplicate evidence from sites.

Investigators/Sites

- Keep delegation and training records clear, complete, and retrievable.
- Identify the roles and tasks study personnel are truly expected to perform.
- Agree to participate in pilots so the model can be tested in real workflows.

Conclusion

Effective site training is a shared responsibility across sponsors, CROs, investigators, sites, and vendors. The opportunity before the industry is not to reduce training indiscriminately, but to make training more purposeful, better targeted, and more closely aligned with the responsibilities site personnel are actually assigned to perform and their demonstrated competency to perform them. This requires a more disciplined way to determine when training is necessary, when prior evidence of training is sufficient, and when targeted reinforcement through training is more effective than repetition of the training.

SIV training and EDC training are two practical starting points. SIV training demonstrates how redundant content accumulates and provides limited utility for demonstrating effective investigator or site personnel training. EDC training demonstrates how platform-level training can be recognized and reused when evidence exists and study-specific instruction is preserved. Together, they show how the same model can reduce redundancy without weakening readiness.

The available data suggest that meaningful impact is possible because redundancy is concentrated in predictable areas: Reusable SIV content, EDC training, vendor/platform mechanics, and repeated evidence collection. Early pilots should evaluate not only reductions in duplicate training and startup burden, but also whether inspection-readiness indicators, quality signals, and operational performance remain stable under a recognition-based model.

Implemented well, this approach can:

- Reduce site burden.
- Support faster activation.
- Focus training on true protocol execution risk.
- Improve information retention and the site experience.
- Strengthen sponsor/CRO-site relationships.
- Enhance audit readiness by making training decisions more transparent and defensible.

The goal is not less readiness. The goal is better readiness with less unnecessary repetition.

Authors

Bendrick-Peart, Jamie
Senior Director, Innovation and Strategic Projects
AstraZeneca

Bird, Kyle
Vice President, Clinical Research,
Harvard Cancer Consortium

Brennan, Christina
Senior Vice President, Clinical Research,
Northwell Health

Byrne, Jennifer
Chief Executive Officer
Javara

Fisher, Nicholas
Executive Director, Research & Business Administration
Alvin J. Siteman Cancer Center at WashU Medicine & Barnes Jewish Hospital

Hughes, Tamara
Senior Vice President, Study Start-Up and Site Activation
ICON Plc

Liddy, Alison
Senior Vice President, Patient and Site Centric Solutions
IQVIA

Lovelett, Carly
Associate Director, Protocol Activation and Lifecycle Management (PALM)
Yale Center for Clinical Investigation

Moffett, Kristie
Senior Director, Human Subjects Research
Moffitt Cancer Center

Mudric, Timothy
Vice President, Clinical Development Strategy Enablement
PPD, part of Thermo Fisher Scientific

Neto, Emilio
Global Head of Country & Site Operations
Biogen

Orantes, Carlos
Chief Executive Officer
Alcanza Clinical Research

Rackley, Marisa
Vice President, Global Clinical Operations
Takeda

Rowe, Michelle
Vice President
HCA Healthcare Research

Senn, Christine
Senior Vice President, Site-Sponsor Innovation
Advarra

Spittal, Nick
Chief Operations Officer
Velocity Clinical Research

Walker, Brandi
Executive Vice President, Global Clinical Operations
Syneos Health

Wyglendowski, Ian
Vice President, Global Head of Strategic Clinical Partnering
UCB Biosciences

Acknowledgements

Many thanks to the following subject matter experts who contributed to this project.

Braker, Charita
Manager, Clinical Research Education
HCA Healthcare

Champoux Bohnke, Danielle
Associate Director, Strategic Site Solutions
IQVIA

Cook, Jeremy
Senior Manager, Learning & Development Programs
Velocity Clinical Research

Funkhouser, Kevin
Global Head, Site Solutions
Syneos Health

Gorman, Kerry
Senior Director, Strategic Site Solutions
IQVIA

Hewett, Jan
Senior Vice President, FDA Regulatory Advisor
Advarra

Kesler, Leah Marie
Director of Quality Assurance and Training
Alcanza Clinical Research

Kunic, Jelena
Head Site Activation Management
Syneos Health

Mado, Anna
Vice President, FSA Project Management
ICON Plc

O'Mahony, Bridget
Executive Director, Project Management
PPD, part of Thermo Fisher Scientific

Pfeiffer, Richie
Senior Director, Strategy and Insights, Patient First Digital Solutions
PPD, part of Thermo Fisher Scientific

Rafferty, Paloma
Vice President, Learning & Development
Association of Clinical Research Professionals

Scott, Christen
Senior Director, Clinical Data Management
PPD, part of Thermo Fisher Scientific

Thomas, Natalie
Director, Clinical Operations
PPD, part of Thermo Fisher Scientific

Vulcano, David
Chief Executive Officer
Association of Clinical Research Professionals

References

Association of Clinical Research Professionals. ACRP Certification.

Fraulini NW, Marraffino MD, Garibaldi AE, Johnson CI, Whitmer DE. Adaptive training instructional interventions: A meta-analysis. Military Psychology. 2025;37(5):479-493. doi:10.1080/08995605.2024.2377884.

Haeusler J-MC. Certification in good clinical practice and clinical trial quality: A retrospective analysis of protocol adherence in four multicenter trials in the USA. Clinical Research and Regulatory Affairs. 2009;26(1-2):20-23.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline: Guideline for Good Clinical Practice E6(R3). Final version. Adopted 6 January 2025.

Joint Task Force for Clinical Trial Competency. Core Competency Framework for Clinical Research Professionals.

Martinengo L, Ng MSP, Ng TDR, Ang YI, Jabir AI, Kyaw BM, Tudor Car L. Spaced Digital Education for Health Professionals: Systematic Review and Meta-Analysis. Journal of Medical Internet Research. 2024;26:e57760. doi:10.2196/57760.

Office for Human Research Protections. Investigator Responsibilities FAQs. U.S. Department of Health and Human Services. Accessed August 5, 2026.

Society for Clinical Research Sites. Cut >25 in 2025: Strategic Guidance for Industry Partners: Data-Driven Playbook for Reducing Clinical Site Training Burden. 2025.

Thompson CP, Hughes MA. The Effectiveness of Spaced Learning, Interleaving, and Retrieval Practice in Radiology Education: A Systematic Review. Journal of the American College of Radiology. 2023;20(11):1092-1101. doi:10.1016/j.jacr.2023.08.028.

TransCelerate BioPharma Inc. Site Qualification and Training: GCP Training Mutual Recognition Program.

U.S. Food and Drug Administration. E6(R3) Good Clinical Practice: Guidance for Industry. September 2025.

Vulcano DM. CPI™ Certification as Predictor of Clinical Investigators' Regulatory Compliance. Drug Information Journal. 2012;46(1):84-87.

---

[1] For example, Office for Human Research Protections (OHRP) states that the U.S. Department of Health and Human Services (HHS) HSP regulations at 45 Code of Federal Regulations (CFR) part 46 do not require investigators to obtain training in HSP, although OHRP strongly recommends appropriate training and notes that other requirements, including National Institutes of Health (NIH) requirements for key personnel in NIH-sponsored or NIH-conducted human subjects research, may apply.

[2] Published analyses support considering professional certification as objective evidence in a broader qualification assessment. In one retrospective analysis of four multicenter U.S. trials, investigator certification was associated with fewer protocol deviations, particularly when both the investigator and clinical research coordinator were certified. A separate analysis of certified principal investigators (CPIs) found more favorable FDA inspection outcomes among certified investigators than non-certified investigators in the dataset reviewed. These studies have limitations and should not be read to mean that certification automatically replaces required training. However, they support the principle that current, independently verifiable professional certification may serve as meaningful evidence of foundational GCP/HSP competency when aligned with the individual's assigned responsibilities and accepted under sponsor/CRO-defined criteria.

[3] Education literature on adaptive training, spaced learning, and retrieval-based practice supports the general principle that training design, timing, and reinforcement influence learning and retention. The framework applies these principles operationally by favoring targeted, role-relevant, point-of-use training over large volumes of front-loaded content.

About the Site-Sponsor Consortium

The Site-Sponsor Consortium is a collaborative, equally weighted coalition of sponsors, CROs, and commercial and institutional research sites. Our mission is to expedite clinical research—while upholding the highest ethical and legal standards—by co-creating process efficiencies and breaking down operational silos to improve site performance, streamline trial execution, and support the delivery of safe, effective therapies.