SITE-SPONSOR CONSORTIUM

EDC COMPANION PAPER

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

Recognition, evidence, vendors, and pilots

EDC companion paper supporting the main framework

Site-Sponsor Consortium | An Advarra Initiative

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

Supported tools

This companion paper is paired with Tool H (Electronic Data Capture [EDC] Training Classification and Role-Based Assignment Matrix), Tool I (EDC Training Recognition Policy Template), Tool J (EDC Vendor Training Requirements Checklist), and Tool K (EDC Recognition Pilot Plan Template). Together they operationalize training recognition for platform-level training and protect required study-specific instruction.

Why EDC is the first pilot

For the second practical application of this framework, this paper focuses on EDC training. Although the framework applies broadly, EDC represents the most immediate and practical opportunity for pilot implementation. EDC is required in nearly every clinical study, touches multiple site roles, and is repeatedly assigned even when the same platform has already been used across prior trials. Separating platform-level training from study-level training offers a simple, measurable way to evaluate training recognition.

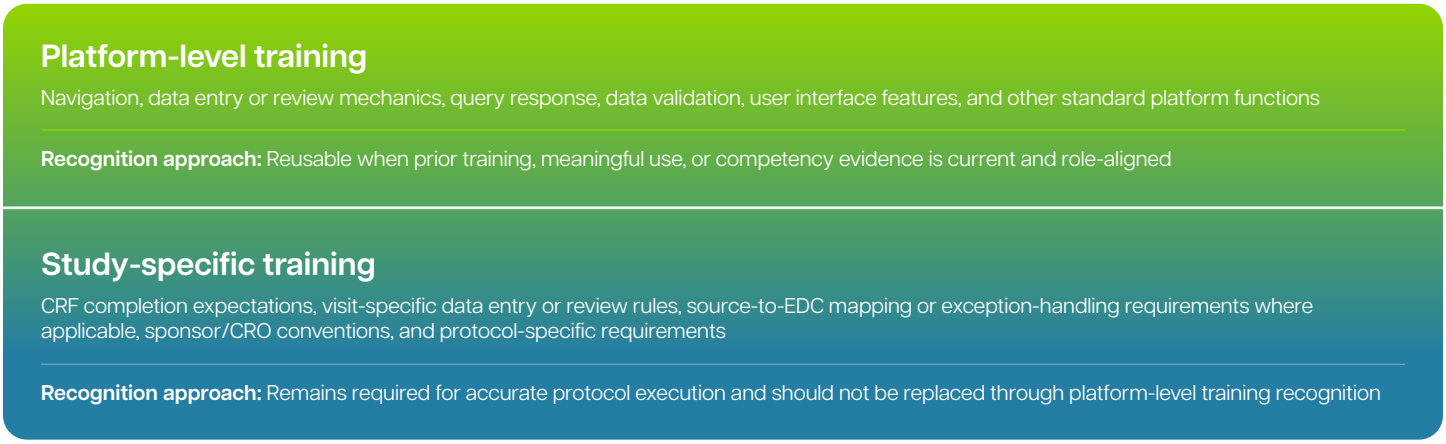
The EDC pathway is also attractive because the distinction between platform-level functionality and study-specific instruction is usually clearer than in many other domains. Platform-level training can often be reused when prior competency is current and role-aligned, while study-specific instruction can remain focused on case report form (CRF) expectations, workflow details, and protocol-specific data requirements.

The key question is not whether users need EDC training. They do. The question is whether the system should repeatedly re-teach the same platform mechanics every time a new study opens when controlled, attributable evidence already exists. International Council for Harmonisation (ICH) E6(R3) supports recognizing prior platform-level competency when evidence is current and verifiable, while reserving study-specific EDC training for protocol-driven differences.

This framework may become even more relevant as sponsors and sites adopt more direct data flows from site source systems—including electronic health records (EHRs), eSource platforms, and other source-data tools—into sponsor EDC environments. As workflows evolve, some site responsibilities may shift from manual data transcription toward data review, validation, exception management, and broader data stewardship. Training should evolve accordingly: Reusable competencies should be recognized where evidence is sufficient, while study-specific instruction remains focused on the configuration, mapping, review responsibilities, exception handling, and protocol-specific data requirements that differ for the study.

Figure 1. Two layers of EDC training

Separate reusable platform mechanics from study-specific instruction.



EDC platform training should be recognized when evidence is current, role-relevant, and supported by controlled records.

Study-specific EDC instruction may be delivered through CRF completion guidelines, workflow supplements, annotated job aids, embedded system prompts, or targeted training modules. The delivery method should match the complexity, risk, and timing of the instruction.

Study-specific EDC instruction should be limited to what is truly study-specific. It should not re-teach basic navigation, standard data entry mechanics, or routine query response when those skills have already been established through prior platform-level training.

Acceptance criteria and proactive recognition

A workable EDC recognition model should start with controlled, attributable training evidence, preferably from vendor, EDC, learning management system (LMS), or sponsor/CRO-accessible systems before requesting duplicate evidence from sites. Evidence may include certificates, system-generated completion records, training dashboards, prior study records, role-based access or activity reports, documented meaningful use, or targeted test-out results. These records should be reviewed against defined criteria for recency, role alignment, platform version, and study configuration. Demonstrated use should reflect meaningful, role-relevant activity rather than incidental access, such as a single login. When evidence is incomplete or difficult to verify, a lightweight assessment, knowledge check, targeted verification, or refresher may be more appropriate than full retraining.

The goal is to move from site-submitted proof by default to sponsor/CRO or vendor-enabled evidence review whenever controlled, attributable, and retrievable records are available.

The EDC Training Recognition Toolkit provides four practical tools that move this process from ad hoc, site-submitted exception requests to proactive recognition based on verified training. As described earlier, the term “recognition” more accurately reflects that the competency requirement has already been satisfied through current, role-relevant evidence, rather than skipped or relaxed. When vendor records, sponsor/CRO records, site-provided records, or other validated evidence show that an individual has satisfied a reusable training requirement within the defined acceptance criteria, prior training or competency should be recognized by default unless a defined exception applies.[1]

EDC toolkit at a glance

Tools supporting the EDC companion paper

Tool	What it does
Tool H: EDC Training Classification and Role-Based Assignment Matrix	Helps study teams distinguish reusable platform-level training, common operational training, and true study-specific EDC instruction, then align training requirements with role, delegated responsibility, and evidence of prior competency.
Tool I: EDC Training Recognition Policy Template	Defines when prior platform-level EDC training may be recognized and how study-specific EDC instruction remains protected.
Tool J: EDC Vendor Training Requirements Checklist	Provides vendor-engagement questions and capability expectations to support reusable, role-based, evidence-driven EDC training.
Tool K: EDC Recognition Pilot Plan Template	Outlines a small, multi-stakeholder implementation approach that defines sponsor/CRO, vendor, and site roles while preserving required study-specific instruction.

The vendor checklist is especially important because training recognition only works when records can be found, read, and reused without forcing sites to rebuild the evidence trail each time a study opens. The pilot plan is the practical entry point for teams that want to start small and prove the model before scaling.

Core principles for reusable evidence

Training recognition should not be interpreted as permission to omit training necessary for participant protection, protocol execution, data integrity, or role-specific competency. Study-specific instruction remains required when needed for accurate protocol execution. Prior training or demonstrated competency may be accepted only when evidence supports current, meaningful, role-relevant readiness for the assigned task.

When prior training, certification, system records, platform use, or other objective evidence is accepted in lieu of full retraining, the decision should be documented using a consistent format such as Tool C: Training Recognition Decision Record Template.

Sponsors and CROs should align on vendor and training-provider expectations. For technology platforms, vendors should be able to generate reliable training completion records, make user training histories accessible in a consistent format, support role-based assignments, maintain access and training audit trails, and enable recognition or training-bypass workflows when prior training has already been completed and accepted under defined criteria.

For online training modules, sponsors and CROs should expect content to be modular, non-duplicative, role-based, and structured so that common operational content is not repeated unnecessarily across lessons. Sponsors and CROs should address these expectations during vendor selection and contracting, including requirements for vendor-maintained training histories, attributable completion data, reporting capability, evidence export or filing pathways, and record-retention expectations. Where vendors cannot support retrievable training and access documentation, sponsors and CROs should evaluate the operational burden this creates for sites and study teams before relying on that platform for future studies.

Sponsor and CRO implementation will be easier when training evidence can be identified before duplicate training is assigned. The target state is a searchable, role-aware evidence pathway that allows authorized sponsor/CRO personnel to determine whether current, relevant training evidence exists before assigning new training.

Sponsors and CROs should use vendor-generated training records and system histories before requesting duplicate evidence from sites. Sites should maintain clear, complete, retrievable references to those records when training evidence is held in a controlled vendor or sponsor/CRO-accessible system, rather than being asked to download, transmit, and resubmit records that already exist there. This reduces repeated manual requests, preserves audit readiness, and lets clinical research associates (CRAs) verify readiness without chasing the same evidence study after study.

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. However, sites generally do not control the training package, vendor systems, recognition rules, or evidence standards that determine whether redundancy is reduced. Those changes require sponsor, CRO, and vendor action.

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 not be required to accept internal site training automatically, but they 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 2. 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.

Figure 3. Pilot metrics for measuring training recognition and reuse impact

Metric category	Examples
Training efficiency	Average EDC training hours per staff member per study, reduction in platform-level training assigned, and reduction in generic SIV slides or live SIV time spent on reusable content.
Recognition and evidence reuse	Percentage of users whose prior training, meaningful use, or other objective evidence was accepted; number of duplicate evidence requests avoided; and use of vendor records before site-submitted documentation.
Operational speed	Recognition turnaround time, site activation cycle time, time from training package release to training clearance or activation-ready status, and delays related to training completion or system access.
Quality, compliance, and readiness signals	Documentation completeness for recognition decisions, audit or inspection-readiness concerns, training-related support inquiries, protocol deviations or data-quality signals where training is a plausible contributing factor, and site and CRA feedback on readiness. These indicators should be interpreted in context and should not be treated as directly attributable to training without further review.
Site experience	Site feedback on clarity, relevance, redundancy, and whether the training package respected prior experience.

Pilot implementation should be evaluated using both efficiency and quality measures. Tool D: Pilot Metrics Tracker provides a structured way to monitor whether training reuse, SIV redesign, or EDC reciprocity reduces burden without creating adverse quality, readiness, or inspection signals.

To assist organizations in creating internal pathways toward implementation, consider the following roadmap.

Figure 4. Adoption roadmap

Phase	Focus
Start: standardize decisions	Finalize acceptance criteria, decision record template, SIV placement checklist, reusable core readiness content map, EDC recognition policy, vendor checklist, site activation template, and training classification tools. Define and communicate the GCP/human subjects protections (HSP) evidence sources, certification types, institutional training records, or training providers that may be accepted under sponsor/CRO-defined criteria, and the plan for personnel whose evidence does not meet those criteria. Use them on one or two EDC pilot studies and selected SIV redesign efforts.
Improve: build confidence	Review pilot metrics, identify process barriers, refine criteria, improve vendor reporting, and clarify documentation expectations across clinical operations, data management, quality, compliance, training, and startup teams.
Expand: scale and expand	Apply the tested model to additional studies, sponsors, CROs, vendors, systems, online modules, SIV content, and procedure-based training categories. Explore automated recognition, dashboard evidence, and technology-enabled decision support only after the underlying rules are clear.

This companion paper is intended to make the EDC pathway concrete without expanding the scope beyond what the industry can pilot now. The right first step is to recognize current platform competency where evidence already exists, preserve study-specific instruction, and keep the burden of change on the organizations that control the systems, records, and decision rules.

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.

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

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] This model is conceptually aligned with prior industry efforts to reduce duplicative training, such as Good Clinical Practice (GCP) mutual recognition, but the EDC use case is operationally different. EDC recognition is primarily intra-platform: The same vendor or sponsor/CRO-accessible system may hold attributable records of prior platform training, role-based access, or meaningful use. It is not intended to create blanket cross-vendor equivalence between different EDC platforms or unrelated training providers.

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.