SITE-SPONSOR CONSORTIUM

SIV COMPANION PAPER

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

Placement, reuse, and live discussion design

SIV 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 E (SIV Content Placement Checklist), Tool F (Reusable Core Readiness Content Map), and Tool G (Site Activation Training and System Needs Template). Together they show how to keep the live SIV focused on study-specific risk while moving reusable material into core readiness content, job aids, or other durable references.

Why the SIV needs redesign

The SIV is the clearest example of why training placement matters. In many studies, the SIV has become the primary venue for a wide range of topics, including universal clinical research expectations, sponsor/contract research organization (CRO) operating preferences, protocol science, eligibility, safety reporting, source documentation, trial file expectations, electronic data capture (EDC) entry, interactive response technology (IRT) workflows, central lab portals, imaging uploads, electronic patient-reported outcome (ePRO) devices, investigational product handling, and administrative readiness.

The issue is not that sites need less preparation. The issue is that different types of preparation are often collapsed into a single event. When reusable foundational content, vendor or platform mechanics, common operational expectations, and protocol-specific risks are presented together, the most critical study-specific information can become harder to identify and retain.

This has consequences for sponsors, CROs, and sites: Longer, less-focused SIVs consume study team time, increase follow-up and retraining needs, create avoidable rework, and can weaken site engagement at the point when study relationships are being established.

SIV time should therefore be treated as a limited resource and protected for content that varies materially by study, creates meaningful operational risk, or requires live discussion to confirm readiness. It should focus on where the protocol is nuanced, where risks are highest, where roles or handoffs must be clarified, and where errors could affect participant safety, data integrity, endpoint validity, or study timelines. International Council for Harmonisation (ICH) E6(R3) reinforces the case for keeping live SIV time focused on study-specific risk and protocol execution rather than re-teaching reusable foundational content.

What belongs in the SIV

Many of the most important SIV topics are highly specific to the protocol, investigational product, endpoint strategy, operational model, participant population, or site workflow. These topics should remain central to the SIV when they affect protocol execution, require sponsor/CRO-site alignment, or introduce expectations that differ materially from routine clinical practice or prior training.

Examples of content that should remain in the SIV:

- Protocol design
- Inclusion and exclusion criteria
- Endpoints
- Visit schedules
- Investigational product preparation and handling
- Dose modifications
- Prohibited medications
- Protocol-specific or endpoint-critical assessments
- Clinical procedures that differ materially from routine care
- Protocol-specific safety risks
- Adverse events of special interest (AESIs)
- Cohort governance
- Dose-escalation rules
- Study-specific data or publication requirements

The more complex the trial is, the more focused training and discussion should address study-specific operational risk. Moving non-study-specific content out of the live SIV creates more room for the content that truly requires interaction.

Of note, importance alone should not determine whether content belongs in the live SIV. Foundational topics such as Good Clinical Practice (GCP); human subjects protections (HSP); informed consent; attributable, legible, contemporaneous, original, and accurate (ALCOA); safety reporting; and investigator responsibilities should be included in live SIV discussion only when the protocol introduces a study-specific application, uncommon scenario, changed expectation, population-specific consideration, role-specific workflow, or risk that site personnel need to understand for that study.

The goal is not less training. It is better placement of training: reusable content taught once and referenced thereafter, vendor mechanics through role-based and timely platform support, and live SIV discussion for protocol-specific risk.

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.[1]

Figure 1. The three-layer model for SIV training

Separate reusable content, vendor micro-modules, and live protocol discussion.



Training time is spent where it changes what personnel actually do.

Layer	Purpose	Examples	Best delivery method
Layer 1: Reusable core site-readiness training	Confirm common research readiness that is largely stable across studies.	GCP and HSP principles, principal investigator (PI) oversight, delegation, informed consent principles, privacy, source documentation, data integrity, ALCOA, safety reporting fundamentals, protocol deviations, corrective and preventive action (CAPA), monitoring expectations, and trial file readiness.	Reusable module before SIV, at a reasonable interval, or through recognized evidence of prior competency.
Layer 2: Vendor/ platform micromodules	Teach tool mechanics and access requirements without consuming SIV time.	EDC, IRT and randomization and trial supply management (RTSM), electronic clinical outcome assessment (eCOA) and ePRO, central lab portals, imaging portals, safety distribution systems, access, login, navigation, query response, sample shipment, and image upload.	Short, role-based, asynchronous, just-in-time modules, job aids, platform training, or vendor certifications.
Layer 3: Live protocol-specific SIV	Use sponsor/ CRO-site time for study-specific risk, interpretation, and readiness discussion.	Protocol rationale, eligibility nuance, visit schedule, investigational product (IP) handling, protocol-specific or endpoint-critical assessments, unique safety risks, labs/imaging/procedures that materially deviate from routine care, endpoint-critical workflows, escalation pathways, and Q&A.	Live SIV discussion focused on protocol execution, operational risk, role clarification, and site-specific planning.

Identifying a study risk does not automatically mean that additional training is the right mitigation. Some risks may be better addressed through a job aid, case report form (CRF) guideline, system prompt, monitoring plan, workflow clarification, escalation pathway, point-of-use reminder, just-in-time refresher, or for-cause follow-up if an issue emerges during conduct. Training should be selected when it is the most appropriate way to improve readiness or reduce execution risk.

Recognition of reusable SIV core content should be based on an equivalence review, not on the name of the module or the organization that delivered it. Before accepting another sponsor's, CRO's, site's, or vendor's core SIV training as evidence of reusable readiness, the accepting sponsor/CRO should compare the prior training against its defined core content map, including topics covered, learning objectives, version or effective date, role relevance, completion or competency evidence, and any material gaps. Where the prior content is substantially aligned, the sponsor/CRO may recognize the reusable portion and assign only sponsor-specific, protocol-specific, role-specific, or risk-critical delta training.

Equivalence is not assumed; it is reviewed. Recognition is not automatic; it is documented. Delta training remains required where gaps exist.

SIV toolkit at a glance

Tool	What it does
Tool E: SIV Content Placement Checklist	Helps sponsors and CROs decide whether content belongs in reusable core training, vendor or platform micro-training, live SIV discussion, job aid/reference material, or study-specific delta training.
Tool F: Reusable Core Readiness Content Map	Identifies common content that may be standardized while preserving sponsor-specific and protocol-specific deltas for the live SIV or study-specific training.
Tool G: Site Activation Training and System Needs Template	Provides a consolidated view of systems, vendors, procedures, roles, evidence sources, timing, dependencies, and training placement decisions.

Teams ready to test this approach can use Tools E–G together with the main paper's call to action to pilot live-SIV redesign on one or two studies. The companion tools are designed to keep the live SIV focused on the content that requires interaction. Tool E is the first screen. Tool F is the content map for reusable readiness. Tool G helps keep startup planning from fragmenting across separate checklists and portals.

References

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[1] *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.