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Designing Clinical Research Participation as a Sociotechnical System: The TRIO Human-Centered Design Studio Method

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Abstract

Clinical and translational research recruitment and retention are often treated as isolated operational problems, although participation is produced by interacting people, tasks, technologies, organizational processes, community relationships, and environmental constraints. We conducted a retrospective cross-case analysis of 10 Trial Recruitment Innovation Office (TRIO) Design Studios held in 2021–2022 through Zoom, with Mural as the virtual whiteboard, to help different clinical trials and health researchers who were facing recruitment and retention problems. Each studio had available data including presentation from researcher discussing the problem, a post-Studio report and visual artifacts from Mural. Guided by sociotechnical systems and SEIPS concepts, we examined changes in problem representation, human-factors mechanisms, and redesign propositions. Across cases, TRIO Studios shifted attention from participant motivation or single recruitment tactics toward participation work systems. Artifacts externalized distributed knowledge, exposed participant and study-team work, expanded system boundaries, revealed handoff and feedback failures, and supported reframing. Recommendations coordinated changes across roles, workflows, technologies, organizational structures, and community relationships.

Keywords: SEIPS 2.0, SEIPS process modeling, Human-systems integration, Systems engineering, Translation research, Clinical trials, Recruitment

INTRODUCTION

Recruitment and retention remain persistent challenges in clinical and translational research. Common responses include revised outreach materials, additional recruitment channels, reminders, incentives, or greater staff effort. Yet these tactics do not perform consistently across studies. Wong et al. (2021) reviewed 141 recruitment and retention interventions across 96 studies and found that strategies addressed trust, comprehension, practical barriers, social influence, and incentives, but many randomized evaluations showed no significant benefit. Dobra et al. (2023) similarly identified a wide range of practical, informational, psychosocial, relational, protocol, and organizational factors shaping the clinical-trial journey. Together, this evidence suggests that recruitment and retention problems may

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reflect the fit between a study and the work system in which participation occurs, rather than the effectiveness of one tactic.

Human factors and sociotechnical systems theory provide a useful lens for this problem. SEIPS 2.0 conceptualizes performance as emerging from interactions among people, tasks, tools and technologies, organizational conditions, and internal and external environments (Holden et al., 2013). SEIPS 3.0 extends this view across journeys that span multiple local work systems and organizational boundaries over time (Carayo et al., 2020). Applied to research participation, a protocol creates work for participants and study teams: understanding information, coordinating with clinicians or family, scheduling, traveling, using technology, troubleshooting, following up, and maintaining relationships. Zayas-Caban and Rogers (2025) explicitly argue that patient ergonomics can illuminate recruitment, and retention and the context in which it occurs (Zayas-Caban and Rogers, 2025).

The Trial Recruitment Innovation Office (TRIO) Design Studio was developed to solve a key translational barrier in the development of new interventions to improve health (Sung et al., 2003). TRIO Studios employ a structured human-centered systems design approach for research teams facing recruitment and retention challenges in active, ongoing research studies (Basapur et al., 2021). Rather than beginning with a preferred solution, Studios externalize the problem through shared visual representations of processes, participants, stakeholders, failure points, causal relationships, and design opportunities. This study retrospectively analyzes ten Studios to ask: (1) how did the representation of the recruitment or retention problem change from the pre-Studio presentation to the post-Studio artifacts; (2) what human-factors mechanisms were visible in those artifacts; and (3) what kinds of redesign propositions emerged, and how broadly did they address the participation work system?

Visual representation is central to this approach because recruitment knowledge is typically distributed across investigators, coordinators, clinicians, technology specialists, operational staff, and community-facing partners. Process and journey maps can reveal transitions, handoffs, hidden work, and mismatches between how participation is designed and how it is experienced. Rather than treating recruitment as a funnel alone, the Studio asks how protocol demands, workflow, information, technology, organizational constraints, and external relationships combine across the participation trajectory. The analysis therefore focuses on changes in problem representation rather than only on the number or novelty of ideas generated.

SOCIOTECHNICAL FRAMEWORK FOR RESEARCH PARTICIPATION

We treated recruitment and retention as outcomes of a clinical-research participation work system. Five dimensions were used: people and roles; tasks and protocol demands; tools and technologies; organizational conditions; and community or environmental conditions. This framing follows SEIPS 2.0 and its emphasis on interacting work-system components (Holden et al., 2013). It also reflects SEIPS 3.0, in which journeys cross settings, organizations, technologies, and time (Carayon et al., 2020). Thus, a visible problem such

as low response, underrepresentation, missed visits, or loss to follow-up may be a downstream signal of conditions elsewhere in the system.

A second concept was distributed work. Participant work included cognitive, temporal, logistical, coordination, relational, emotional, and technology-related demands. Study-team work included screening, repeated outreach, scheduling, troubleshooting, documentation, relationship management, referral coordination, and cross-organizational work. Redesign can reduce work for one actor while increasing or relocating it for another. Virtual participation, for example, may reduce travel while increasing technology setup and support; clinician-mediated recruitment may improve credibility while adding clinical workflow demands.

A third concept was visual work-system representation. SEIPS-based process modeling links process steps with people, tasks, technology, organization, barriers, and facilitators (Wooldridge et al., 2017). Related pathway and dual-experience mapping approaches make interactions, dependencies, and perspective differences visible (Micocci et al., 2024; Parush et al., 2021). We therefore analyzed process maps, stakeholder maps, and opportunity frames as work-system representations rather than as workshop illustrations alone.

A fourth concept was the importance of boundaries and coordination. Clinical-research participation routinely crosses interfaces between clinician and recruiter, Electronic Health Records (EHR) and screening workflow, community organization and academic team, first contact and consent, digital tool and human support, and in some studies pediatric and adult care. Failures at these interfaces may appear downstream as poor response, missed visits, recruitment delay, or loss to follow-up even when individual actors perform their assigned tasks. Accordingly, the analysis examined couplings, handoffs, feedback loops, and information continuity, not only the presence or absence of individual work-system elements.

METHODS

We conducted a retrospective, practice-based multiple-case analysis of ten TRIO Design Studios. The Studio case, not an individual comment or sticky note, was the unit of analysis. Each case included three source types: a pre-Studio presentation prepared by the presenting research team; a facilitator-authored post-Studio report; and embedded images of collaboratively generated visual artifacts. The ten cases covered low-yield recruitment, underrepresentation, digital participation, clinical-workflow integration, community trust, participant burden, and long-term follow-up. All cases were pseudonymized as Studio 1-Studio 10; study titles, presenter names, institutional names, and identifying organizational details were removed or generalized.

The TRIO studios were 120-minute sessions run virtually that invited translation team members at 5 health institutions part of the Institute of Translational Medicine, a National Center for the Advancement of Translational Science (NCATS) funded Clinical and Translational Science Award program (Basapur et al., 2021). All the Studios followed a typical process of brief introduction to the studio process by the moderator, followed by the study team presentation, and then the problem-solving (see Figure 1).



Figure 1: Studio process.

The analyzed Studios were conducted in 2021-2022 as synchronous sessions using Zoom, with Mural serving as the collaborative virtual whiteboard. Sessions typically produced context or mind maps, stakeholder maps, opportunity framing, and idea clustering. Although the visual grammar differed sometimes, each Studio externalized the presenting problem so that relationships, dependencies, and potential redesign points could be examined collaboratively.

The pre-Studio presentations provided the baseline problem frame provided by the study team based on their experience: study purpose, target population, recruitment or retention process, observed problems, previously attempted strategies, and the question brought to the Studio. Post-Studio reports documented the discussion, methods, major insights, and recommended actions. Embedded artifacts included context and mind maps, stakeholder maps, problem-definition diagrams, process or leaky-pipe diagrams, How Might We frames, and solution clusters.

The analysis was informed by SEIPS 2.0 and SEIPS-based process modeling (Holden et al., 2013; Wooldridge et al., 2017). Evidence was coded across five primary work-system dimensions: people and roles; tasks and protocol demands; tools and technologies; organizational conditions; and community or environmental conditions. We additionally coded participant work and study-team work. Human-factors mechanisms included work-system externalization, identification of participant and staff work, integration of distributed perspectives, system-boundary expansion, handoffs and feedback failures, problem reframing, and workload redistribution or trade-offs.

Analysis proceeded within cases and then across cases. For Research Question 1, we compared the initial and post-Studio problem representations across the observable performance problem, implied unit of analysis, attributed causes, system boundary, and locus of intervention. Changes were characterized as limited, moderate, or major. For Research Question 2, we coded the human-factors mechanisms visible in the artifacts. For Research Question 3, proposed redesigns were coded by the work-system components they targeted and characterized as an isolated tactic, a multi-component portfolio, or a coordinated sociotechnical bundle. A case-by-domain matrix then compared the ten Studios on initial problem representation, expanded boundaries, participant and staff work, sociotechnical dependencies, mechanisms, reframing, redesign targets, and degree of coordination. Patterns were retained only when traceable to the source presentations, reports, or artifacts, including weak or contradictory evidence. The analysis does not establish causal effects on enrollment or retention.

Within each case, evidence was coded at the level of a statement, visual relationship, process step, identified barrier, opportunity frame, or recommendation, while interpretation remained at the Studio-case level.

This prevented individual sticky notes from being treated as independent observations. Across cases, we looked for recurring patterns while preserving contradictory or weak evidence. For example, direct participant work was strongly represented in some cases and only indirectly represented in others; similarly, some recommendation sets formed integrated redesign bundles, whereas others remained broad portfolios without clear sequencing or ownership.

FINDINGS

Across the ten cases, the Studios shifted attention from an observable recruitment, retention, or participation problem toward a broader representation of the participation work system. Seven cases showed a major change in causal model or system boundary and three showed a moderate expansion of an already multifactorial frame. The consistent change was not simply the generation of more ideas; it was a change in the unit of analysis from the participant, recruiter, or outreach tactic toward interacting people, tasks, technologies, organizations, and environmental conditions.

Table 1: Cross-case summary of problem reframing and solutions.

Case	Initial Frame	Work-System Reframing	Solution Set
S1	Pandemic disruption	Protocol burden, family/referral/virtual pathways	Portfolio
S2	Low-yield recruitment	Trust; consent, technology, clinician handoff	Bundle
S3	Engagement barriers	Distrust, fragmented care, literacy, intermediaries	Bundle
S4	Underrepresentation	Digital entry, referrals, feedback, staffing, travel	Bundle
S5	Sample diversity	Stigma, channels, family, timing, primary care	Bundle
S6	Remote recruitment	Duration, logins, language, technology, staffing	Bundle
S7	Clinical app recruitment	Device fit; referrals, HER, governance, liability	Bundle
S8	Peer-support platform	Moderation, safety, trust, access, resources	Portfolio
S9	Long-term follow-up	Life stage, continuity, data ownership, records	Portfolio
S10	Community participation	Privacy, installation, partner capacity, reciprocity	Bundle

Problem reframing. Problems initially attributed to participant behavior were often reframed as work-system misfit. In one case, a desire for a more diverse sample became linked to reliance on familiar recruitment networks, stigma, family influence, language, timing, technology, staff composition, and missing primary-care and community pathways. In another, a digital-health recruitment problem became connected to device compatibility, clinician

referral, competing technologies, multisite workflow, EHR integration, legal concerns, and outcome definition. Stakeholder maps repeatedly expanded the system boundary to include family members, referring clinicians, community health workers, schools, advocacy and faith organizations, technology partners, and community-based organizations. In the long-term follow-up case, retention shifted from repeated contact to longitudinal continuity across changing addresses, clinicians, care systems, technologies, and life stages.

These reframings changed both the attributed cause and the locus of intervention. A slow recruitment rate could move from being interpreted as insufficient participant interest to a combination of eligibility rules, recruitment channels, technology requirements, staffing capacity, and delayed handoffs. Underrepresentation could become a consequence of where the study searched, who could enter the digital pathway, which clinicians recognized eligible participants, and whether community organizations had the capacity to support recruitment. In this sense, the Studios converted proximal symptoms into hypotheses about the configuration of the participation system.

Work-System Externalization and Hidden Work

Context maps, process maps, stakeholder maps and solution clusters placed previously distributed information into a shared visual representation. One remote cognitive-assessment case, for example, connected prescreening, consent, questionnaires, scheduling, technology requirements, assessment time, incentives, staffing, and recruitment channels; subsequent recommendations addressed sample size, participation time, study tasks, data sources, messaging, and technology access. Participant work was clearly represented in eight cases and partially in two. It included understanding eligibility and risk; waiting and repeated contact; travel and scheduling; coordinating with family, clinicians, employers, or caregivers; stigma and privacy concerns; and digital consent, devices, logins, connectivity, and troubleshooting.

Study-Team Work, Interfaces, and Trust

The artifacts also surfaced repeated outreach, manual screening, scheduling, technology support, referral coordination, community relationship management, and cross-institutional communication. Many problems occurred at interfaces: clinician-to-research-team referral, EHR identification to screening, first contact to consent, community organization to research team, digital tool to human support, pediatric-to-adult transition, and referring clinician to research-team feedback. Trust was correspondingly represented as more than an individual attitude. It was associated with who introduced the study, continuity of communication, privacy practices, technology design, institutional relationships, community intermediaries, and whether participation offered meaningful value.

The same representations also made workload redistribution visible. A clinician warm handoff could reduce uncertainty for a participant but add work to a constrained clinical workflow. Community-based recruitment could increase credibility but create relationship-management demands for both the research team and the partner organization. Remote participation

could reduce transportation while increasing device setup, connectivity, troubleshooting, and staff support. These trade-offs were important because several proposed solutions shifted work rather than eliminating it, making ownership and resource requirements part of the redesign problem.

Redesign propositions. No case ended with only one isolated recruitment tactic. Across the ten cases, proposals addressed at least four of the five work-system dimensions; seven cases produced relatively coherent sociotechnical bundles and three produced broader multi-component portfolios requiring further prioritization. Role redesign included clinician warm handoffs, community health workers, participant ambassadors, site champions, social-worker moderation, and dedicated follow-up roles. Workflow redesign included prescreening, shorter assessments, simplified logins, revised consent, referral feedback loops, community participation options, and life-stage-sensitive follow-up. Technology redesign included broader device compatibility, technology provision, in-person access points, customer relationship management systems, dashboards, EHR integration, and alternative data-collection methods. Organizational and community redesign included cross-institutional working groups, implementation agreements, trusted local recruiters, non-clinical sites, community-facing data products, and locally meaningful benefits. The stronger solution bundles aligned entry pathways, task demands, staffing, technologies, organizational ownership, feedback mechanisms, and community context.

Across cases, the recurring mechanism can be summarized as: externalize the work system, integrate distributed knowledge, identify hidden participant and staff work, expose couplings and handoff failures, expand the system boundary, reframe the problem, and generate sociotechnical redesign propositions. The evidence is strongest for externalization, boundary expansion, work identification, and reframing; because detailed interaction transcripts were unavailable, the data support the existence of integrated representations more directly than they support claims about how consensus was achieved during the Studio.

Five cross-case human-factors lessons followed from these patterns.

1. Recruitment and retention behaved as emergent work-system outcomes rather than single-point failures.
2. The protocol functioned as a work design for both participants and research staff; scientific requirements created cognitive, temporal, logistical, relational, and technological workload.
3. Trust was produced at sociotechnical interfaces through referral pathways, privacy practices, responsiveness, continuity, and perceived value.
4. Technology frequently relocated work rather than eliminating it, trading travel or paper-based effort for access, setup, troubleshooting, and support.
5. Effective redesign required attention to interactions among system components. The strongest recommendations did not optimize one touchpoint but coordinated roles, workflow, technology, organizational ownership, and community relationships around the participation journey.

Qualifying findings were also retained. Direct patient or community participation was not documented in every Studio, so some participant perspectives were represented through investigators, coordinators, clinicians, or community-facing staff rather than first-person co-design. Not every recommendation set was implementation ready. Some required new infrastructure, cross-institutional agreements, or substantial resources, and several reports did not specify sequencing, ownership, or implementation measures. One case focused more on designing a participation-support platform than on a conventional recruitment problem and therefore served as a useful contrast case. These differences temper the claim that all Studios operated identically while strengthening the broader observation that the visual methods consistently expanded the work-system representation.

DISCUSSION

The central contribution is a shift from recruitment and retention as isolated operational failures to recruitment and retention as emergent work-system outcomes. Proximal metrics such as response, screening, enrollment, missed visits, or loss to follow-up identify where performance is poor but do not necessarily explain why. The cross-case findings show how protocol requirements, staffing, technology, communication, referral pathways, organizational processes, community relationships, and everyday participant constraints can combine to produce those outcomes. This interpretation extends SEIPS concepts into clinical-research participation and suggests a practical principle: before intensifying a recruitment tactic, examine the work-system conditions producing the observed result.

A second contribution is the Studio as a temporary participatory work-system analysis environment. Investigators, coordinators, clinicians, technology staff, and community-facing partners each hold partial knowledge of the participation system. Visual artifacts place these partial representations into a common inspectable space. The approach helps externalize the system, integrate distributed knowledge, expose hidden work and dependencies, expand the system boundary, reframe the problem, and identify redesign opportunities.

A third contribution is that systems representation generated different types of proposed intervention. The more developed recommendations changed roles, tasks, technologies, organizational processes, and community relationships together. Importantly, redesign often redistributed rather than eliminated work: virtual participation can reduce travel while increasing troubleshooting; clinician-mediated recruitment can strengthen trust while adding clinical work; community recruitment can improve local credibility while requiring training, compensation, and relationship management. Human-factors evaluation should therefore ask whose work changes, where the work moves, and what resources make the redesigned system sustainable.

For practice, this suggests four design checks before selecting or implementing a recruitment intervention: map both participant and study-team work; inspect handoffs, feedback loops, and actors outside the formal study boundary; evaluate technology as part of a human-technology-organization

system rather than as a neutral channel; and test whether the proposed solution simply transfers burden to clinicians, coordinators, or community partners. Multi-component recommendations also require an implementation architecture specifying sequencing, ownership, resources, dependencies, and measures of whether the redesigned system is functioning as intended.

The analysis also suggests that the value of a TRIO Studio lies partly in creating a shared problem representation before solution selection. Recruitment teams often enter with a proximal question such as how to increase response, reach a population, or improve follow-up. When those questions are mapped against the participation trajectory, the intervention target can move upstream to the design of the protocol, the division of labor, or the interface between organizations. This matters for implementation because a seemingly simple tactic may depend on changes elsewhere in the system. The Studio therefore creates an intermediate design product - a negotiated representation of the work system - that can guide later implementation planning and evaluation.

Limitations include the retrospective use of practice-generated materials, analysis of work-as-described rather than direct observation of work-as-done, inconsistent documentation of direct patient or community participation across cases, and absence of systematic downstream implementation and outcome data. Also, not every studio is providing a full set of solutions, common themes generated from among solutions are from across studios. Future prospective studies should evaluate Studio fidelity, changes in work-system understanding, adoption of recommendations, participant and staff workload, coordination demands, unintended consequences, and associations between implemented redesigns and recruitment or retention outcomes.

CONCLUSION

Clinical research participation can be understood as a sociotechnical work system rather than a sequence of isolated recruitment tasks. Across ten TRIO Design Studios, shared visual representations expanded system boundaries, surfaced participant and study-team work, exposed dependencies and handoff failures, and supported multi-component redesign. The Studio contribution is therefore not simply more recruitment ideas; it is a structured human-centered systems design process for converting a visible participation symptom into an inspectable work system and translating that representation into coordinated redesign propositions.

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