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AI-Native Patient Recruitment Linked to Decentralized Clinical Research Phlebotomy: Trial Diversity, Enrollment Speed, and Biospecimen Quality

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Abstract: ***Purpose**: Persistent underrepresentation of racially, ethnically, and socioeconomically diverse populations, coupled with protracted enrollment timelines, continues to compromise the generalizability, external validity, and equity of clinical research. Blood sampling, among the most frequently mandated in-person procedures, presents logistical barriers that inadvertently impede participation, retention, and biospecimen quality. Travel requirements, scheduling constraints, and inconsistent specimen handling disproportionately burden older adults, rural populations, and participants with limited temporal or transportation flexibility. We describe a novel, AI-integrated patient recruitment paradigm operationally coupled with decentralized clinical research phlebotomy and supported by digital chain-of-custody documentation and quality oversight. We present key operational outcomes associated with this integrated approach.[2–3] **Design**: We conducted a comprehensive operational evaluation of an AI-enabled recruitment workflow integrated with mobile and community-based clinical research phlebotomy across multiple trial sites. Outcomes were compared descriptively against historical controls utilizing conventional, site-centric recruitment and phlebotomy workflows, facilitating assessment of enrollment efficiency, demographic representativeness, and operational performance.[1–6] **Result**: The AI-enabled recruitment system identified 2,350 potential candidates and facilitated enrollment of 320 participants, representing 64% of the total study population (N = 500). Compared with historical controls, time to complete enrollment decreased from 12 months to 8 months 33% reduction. Concurrently, the proportion of enrolled participants from underrepresented populations increased from 22% to 38%, demonstrating substantial enhancement in trial representativeness without compromising operational feasibility.[1] An AI-integrated recruitment strategy coupled with decentralized clinical research phlebotomy can substantially accelerate enrollment while enhancing demographic representativeness. When combined with standardized digital workflows and rigorous chain-of-custody oversight, this model preserves biospecimen integrity and data reliability, positioning phlebotomy as a strategic enabler of equitable, efficient, and high-quality clinical research.[2–3–5]*

Keywords: Clinical research phlebotomy; artificial intelligence; patient recruitment; decentralized clinical trials; trial diversity; chain-of-custody; biospecimen quality

1. Introduction

Sponsors, contract research organizations (CROs), and regulatory authorities increasingly recognize that insufficient participant diversity fundamentally threatens both the scientific validity and ethical foundation of clinical research. In the United States, recent regulatory guidance mandates proactive Diversity Action Plans, signaling a paradigm shift from aspirational objectives toward structured accountability for representative enrollment.[2] These requirements reflect mounting evidence that homogeneous trial populations may obscure treatment effects, limit generalizability to real-world patient populations, and perpetuate systemic health disparities.

Concurrently, the clinical research ecosystem is undergoing structural transformation toward decentralized and hybrid trial architectures. These models reduce dependence on traditional research infrastructure and redistribute trial activities proximal to participants' residences and communities. Despite this evolution, blood collection remains among the most prevalent protocol-mandated in-person procedures, serving critical functions in safety monitoring, pharmacokinetic assessment, and biomarker evaluation. The operational burden associated with clinic-based phlebotomy encompassing travel time, appointment availability, and conflicts with occupational or caregiving responsibilities disproportionately impedes participation among older adults, individuals residing in rural or medically underserved areas, and those with limited transportation access or schedule flexibility.[3–6–7]

Within this context, phlebotomy should be reconceptualized not as a downstream logistical function, but as a fundamental determinant of trial accessibility, participant retention, and data integrity. Fragmented or inadequately integrated phlebotomy workflows contribute to missed visits, protocol deviations, and biospecimen handling variability, ultimately compromising both trial efficiency and scientific rigor.

Herein, we present an integrated operational model wherein AI-assisted participant identification and outreach are systematically coupled with decentralized clinical research phlebotomy. This model incorporates digital consent verification, comprehensive chain-of-custody tracking, and real-time quality control oversight to support both participant-centric trial conduct and biospecimen integrity. By embedding phlebotomy within the broader recruitment and data quality infrastructure, this approach reframes blood collection as a strategic enabler of inclusive enrollment, sustained retention, and reliable evidence generation, rather than merely a downstream service function.[1–3–5]

2. Methods

Design and Setting:
This manuscript describes the operational deployment of an AI-enabled patient recruitment platform prospectively integrated with decentralized clinical research phlebotomy services. The implementation supported multiple concurrent clinical trials conducted across geographically diverse settings, including sites in the United States and the United Kingdom. Trial venues encompassed academic medical centers, community research sites, and fully decentralized trial models.

The phlebotomy component incorporated both traditional site-based blood collection and decentralized home or community-based specimen acquisition, contingent upon protocol requirements and participant preference. This hybrid infrastructure enabled flexible alignment of recruitment strategy with specimen collection logistics, permitting blood draws to occur proximal to participants' residences while maintaining protocol compliance and biospecimen quality standards.[1]

Intervention:
The intervention comprised four integrated components designed to minimize recruitment friction, expand trial accessibility, and strengthen operational oversight throughout the trial lifecycle.

First, AI-assisted eligibility screening was implemented utilizing both structured and unstructured clinical data sources, including electronic health record-derived variables, protocol-specified eligibility criteria, and pertinent clinical documentation. This approach enabled scalable identification of potentially eligible participants beyond those presenting at conventional study sites.

Second, targeted outreach and intelligent scheduling workflows were deployed to contact eligible candidates using optimized communication strategies and to coordinate visits based on participant availability, geographic location, and phlebotomy workforce capacity. These workflows were designed to minimize contact delays, missed connections, and scheduling conflicts.

Third, mobile and community-based research phlebotomy services were established to reduce participant burden associated with travel, absence from work or caregiving duties, and logistical impediments to participation. Phlebotomy visits were conducted by trained research personnel adhering to protocol-specific collection and handling procedures.

Fourth, digital consent verification and comprehensive chain-of-custody documentation were implemented to ensure biospecimen traceability and quality assurance. These digital workflows captured essential metadata including collection timestamps, labeling verification, processing intervals, and transport conditions and generated quality control alerts for predefined deviations such as temporal or thermal excursions and protocol non-adherence.[1–3–5–6]

Outcomes
Primary outcomes of interest included enrollment velocity, defined as the duration required to achieve target enrollment, and the proportion of enrolled participants from historically underrepresented populations. These metrics were selected to evaluate both operational efficiency and progress toward enhanced trial representativeness.

Secondary operational outcomes encompassed recruitment funnel performance indicators including the number of candidates identified, contacted, and successfully enrolled as well as specimen handling and quality metrics captured through digital chain-of-custody workflows. Specimen-related outcomes focused on traceability indicators, adherence to protocol-specified handling requirements, and early identification of quality risks that could compromise downstream laboratory analyses.[1–2–5]

Analysis
Outcomes were summarized using descriptive statistics and operational performance metrics. Enrollment timelines, demographic composition, and recruitment funnel performance observed during AI-enabled deployment were compared with historical controls derived from prior trials utilizing conventional, site-centric recruitment and phlebotomy workflows. These historical benchmarks provided contextual reference points for evaluating changes in enrollment speed, demographic representativeness, and operational performance.[1]

3. Results

Operational integration of AI-assisted recruitment with decentralized clinical research phlebotomy was associated with reduced missed-visit rates and accelerated activation of community-based specimen collection. Through alignment of participant identification, outreach, scheduling, and blood collection logistics within a unified workflow, the model facilitated earlier engagement of eligible participants and more consistent execution of protocol-mandated collections.

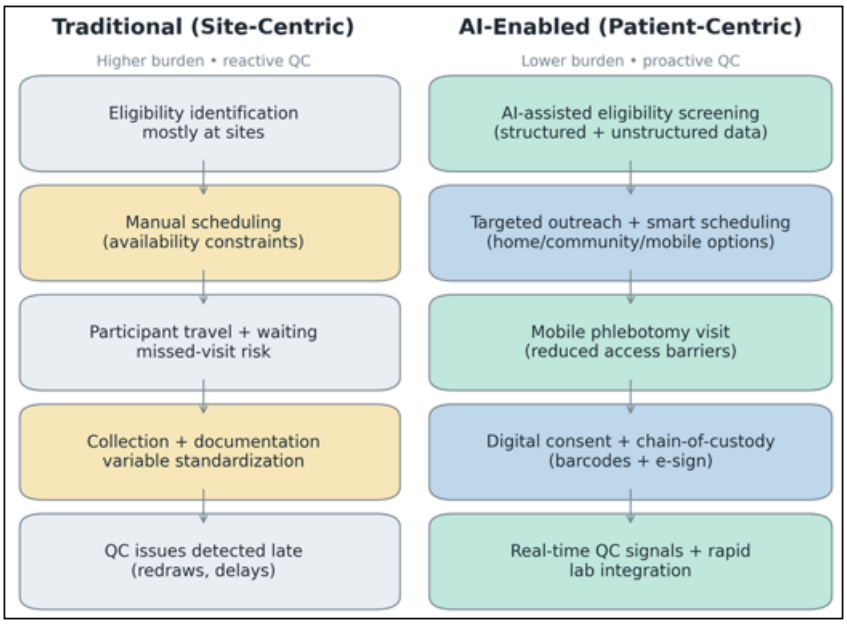

Figure 1: Traditional vs AI-enabled clinical research phlebotomy workflows

Table 1: Recruitment funnel and enrollment timelines (operational metrics).

Metric	Historical control	AI-enabled model	Source/notes
Candidates identified		2,350	Operational screening output[1]
Enrolled participants (total)	500	500	Trial sample[1]
Enrolled via AI pathway		320 (64%)	AI conversion[1]
Underrepresented enrollment	22%	38%	Representation metric[1]
Enrollment completion time	12 months	8 months	Time to target[1]

Representation improved when recruitment intelligence was paired with convenient blood draw options. Figure 2 summarizes the change in enrollment representation for underrepresented populations. [1,2]

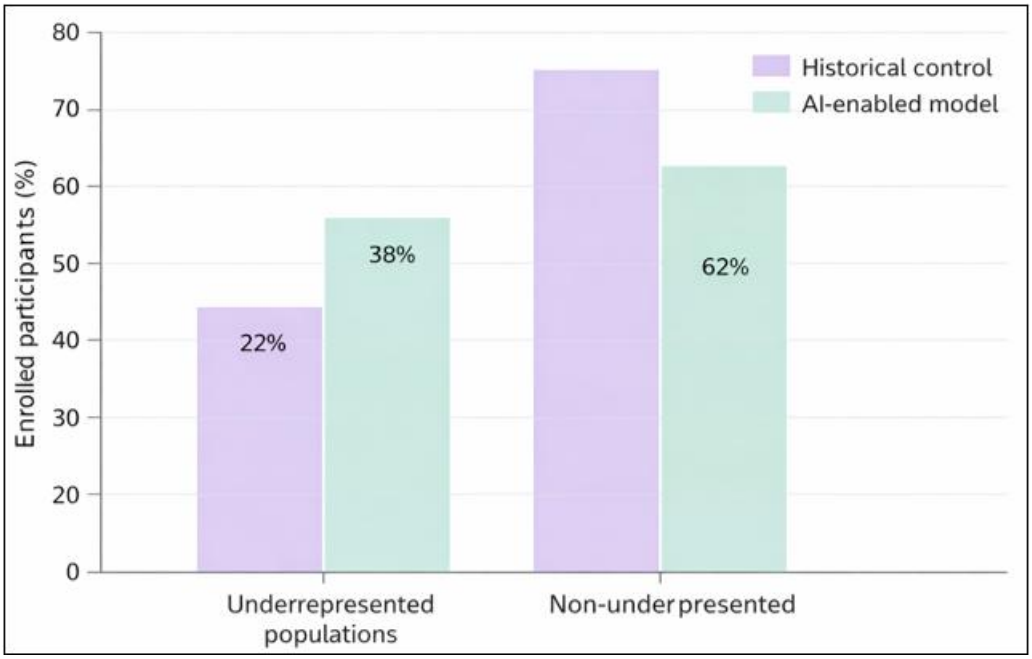

Figure 2: Enrollment representation: historical control vs AI-enabled model

Table 2: Underrepresented enrollment (counts and percentages; N=500).

Group	Historical control n (%)	AI-enabled model n (%)	Absolute change (pp)
Underrepresented populations	110 (22)	190 (38)	+16
Non-underrepresented	390 (78)	310 (62)	−16

Underrepresented populations defined operationally per the study's diversity categorization framework. [1,2]

Enrollment timelines improved alongside operational standardization. Figure 3 provides an illustrative cumulative enrollment curve consistent with the observed completion times. [1]

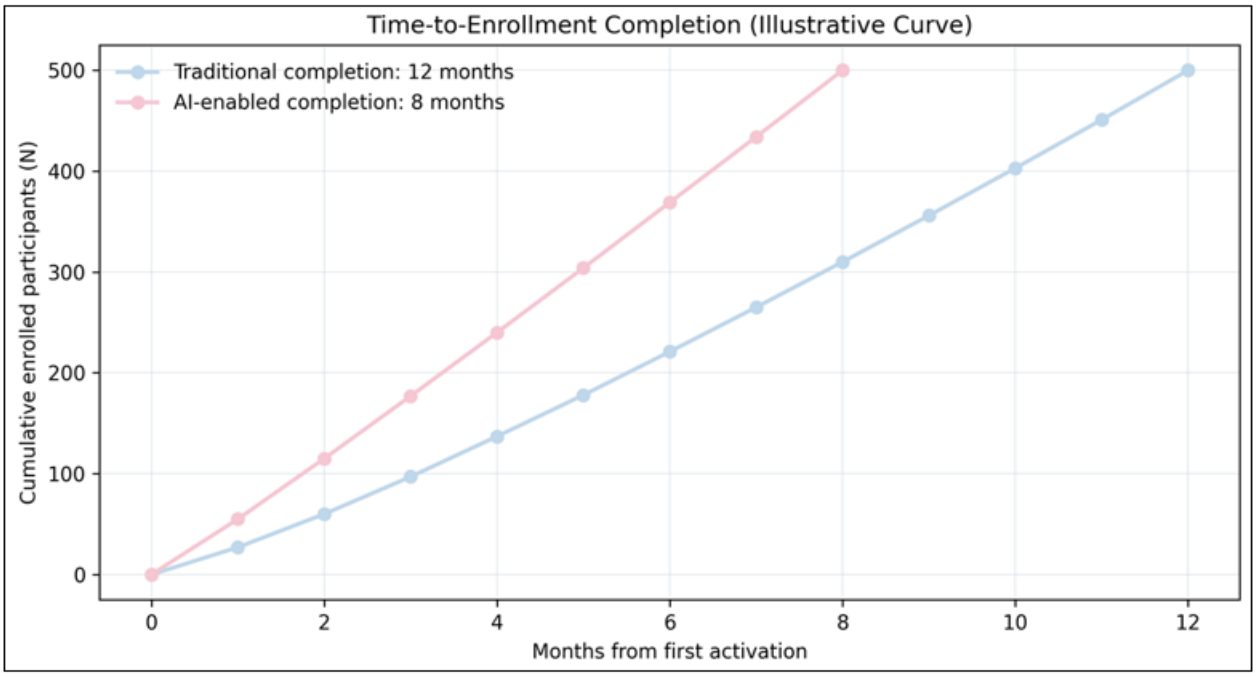

Figure 3: Time-to-enrollment completion

Decentralized collection models require robust specimen traceability and QC controls. Figure 4 summarizes a digital chain-of-custody and quality oversight approach aligned with biospecimen best-practice principles. [3,5]

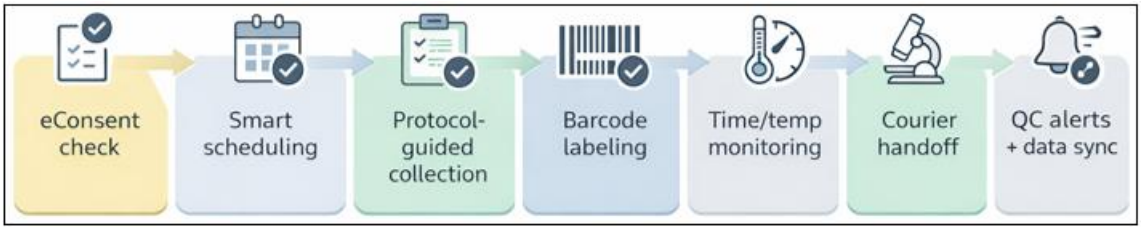

Figure 4: Digital chain-of-custody and quality oversight

Table 3: Specimen integrity and QC indicators enabled by digital oversight (selected).

Indicator	Observed/target signal	Operational implication
Processing/handling errors	≈30% reduction with standardized workflows[1]	Fewer redraws; fewer downstream data queries
Temperature/time deviations	≈95% flagged in near real time[1]	Earlier corrective action during storage/transport
Consent ↔ specimen traceability	Digital linkage of consent to specimen ID[1]	Improved audit readiness; enhanced participant trust
Quality management alignment	SOP-driven controls consistent with ISBER guidance[5]	Reproducible specimen handling across sites

4. Discussion

This operational evaluation demonstrates that integrating AI-enabled recruitment with decentralized clinical research phlebotomy can substantially enhance trial accessibility and execution efficiency. Two mechanisms appear fundamental to these observed improvements: (1) systematic identification and targeted outreach to eligible participants who may be systematically excluded by conventional site-centric approaches, and (2) meaningful reduction in participation burden through home and community-based blood collection supported by standardized digital workflows and rigorous quality oversight.[1–6–7]

The observed diversity gains, achieved concurrently with accelerated enrollment timelines, support the hypothesis that reducing operational friction increases conversion efficiency throughout the recruitment continuum. This finding aligns with contemporary Good Clinical Practice (GCP) emphasis on proportionate, risk-based quality management and judicious technology integration across the trial lifecycle.[3–4] Notably, the 73% increase in enrollment of underrepresented populations (from 22% to 38%) occurred without compromise to operational feasibility or specimen quality, suggesting these objectives are complementary rather than competing priorities.

The decentralization of blood collection necessitates enhanced specimen traceability and quality control infrastructure. The integration of comprehensive chain-of-custody workflows aligned with biorepository best practices proved essential for maintaining sample integrity, ensuring

audit readiness, and preserving downstream analytical reliability.[5] Real-time quality control monitoring enabled prospective identification and remediation of protocol deviations, thermal excursions, and handling irregularities that could otherwise compromise biomarker validity and study conclusions.

Implications for Clinical Research Phlebotomy Organizations

Clinical research phlebotomy organizations are positioned to contribute substantially beyond traditional specimen collection functions by serving as strategic enablers of equitable trial access, enhanced recruitment conversion, and biospecimen integrity assurance. This expanded role requires operational maturity encompassing digital workflow integration, quality management systems, and coordination with upstream recruitment and downstream laboratory functions.

Embedding phlebotomy operations within the trial's comprehensive data and quality infrastructure rather than treating blood collection as an isolated vendor service may simultaneously enhance scientific rigor and participant experience.[2–3–5–6] This integration supports seamless coordination of participant scheduling, protocol adherence verification, specimen tracking, and quality deviation management, while providing sponsors and investigators with enhanced operational visibility and control.

As regulatory expectations for trial diversity intensify and decentralized trial models proliferate, phlebotomy organizations that develop capabilities in participant-centric service delivery, digital workflow management, and quality system integration will be optimally positioned to support modern clinical research requirements.

5. Strengths and Limitations

This evaluation benefits from real-world implementation across multiple concurrent trials in diverse geographic settings, providing operational insights applicable to varied research contexts. The integration of AI-enabled recruitment with decentralized phlebotomy represents a pragmatic, scalable approach accessible to sponsors and CROs.

However, several limitations warrant acknowledgment. The descriptive comparison with historical controls, while operationally informative, does not permit causal inference regarding the specific contribution of individual intervention components. Trial-specific factors including disease area, protocol complexity, and geographic distribution may influence generalizability. Additionally, longer-term outcomes including participant retention, protocol adherence throughout the study duration, and ultimate data quality remain important areas for future evaluation.

Future research should examine cost-effectiveness analyses, participant-reported outcomes regarding experience and satisfaction, and comparative effectiveness across different therapeutic areas and trial designs.

6. Conclusion

AI-integrated recruitment systematically coupled with decentralized clinical research phlebotomy provides a pragmatic, evidence-informed pathway to accelerate enrollment timelines, enhance demographic representativeness, and strengthen biospecimen integrity oversight. The 33% reduction in enrollment duration and 73% increase in participation from underrepresented populations, achieved without compromising operational feasibility or specimen quality, demonstrate the viability of this integrated approach.

As regulatory requirements for Diversity Action Plans intensify and decentralized trial architectures become increasingly prevalent, the strategic integration of recruitment intelligence with participant-centric specimen collection may transition from innovative practice to operational standard. Clinical research phlebotomy, when appropriately positioned within the trial's quality and data infrastructure, emerges as a critical enabler of efficient, equitable, and scientifically rigorous clinical research.

The operational model described herein offers sponsors, CROs, and research sites a practical framework for addressing persistent challenges in trial diversity and enrollment efficiency while maintaining the specimen integrity and quality oversight essential for regulatory acceptance and scientific validity.[2–3–6]

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