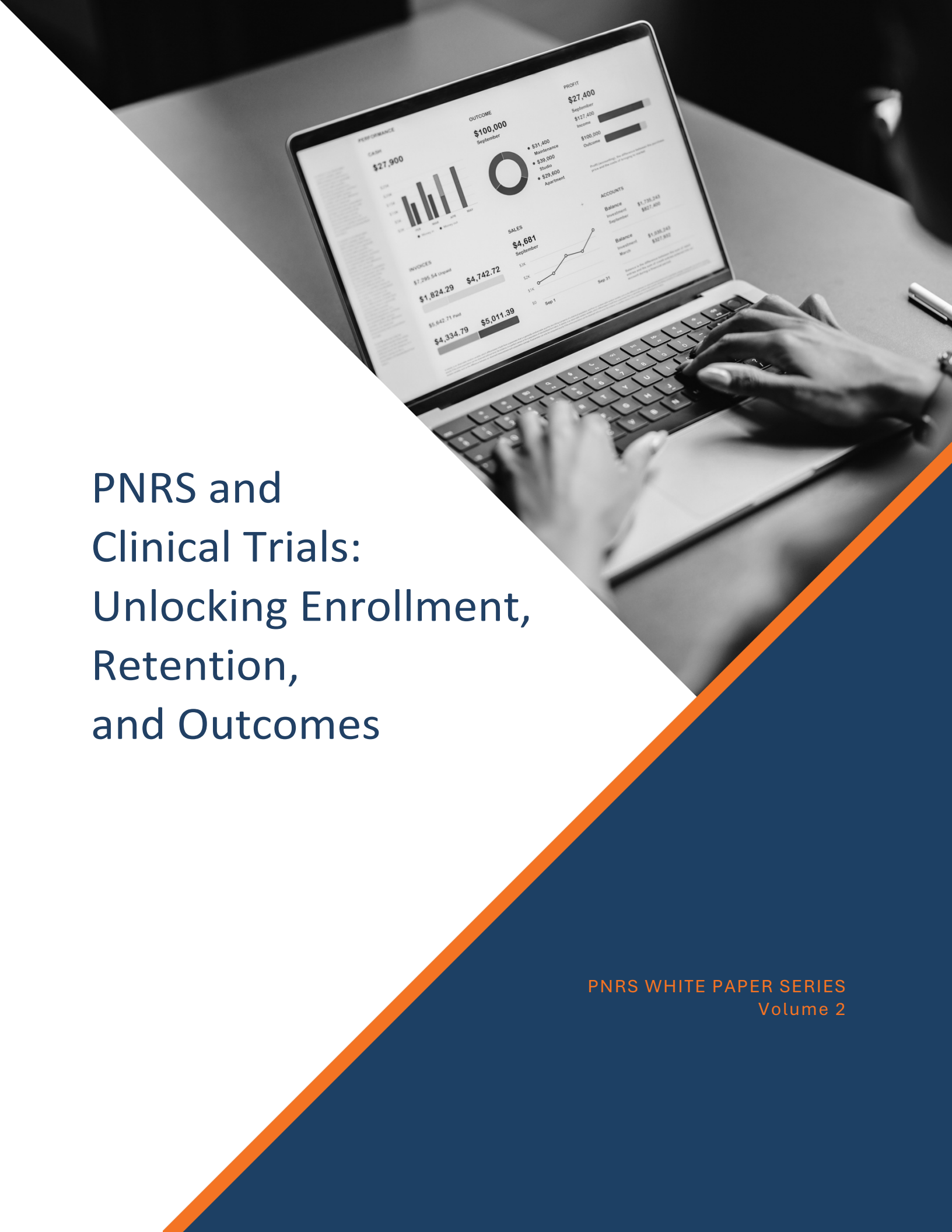




PNRS and Clinical Trials: Unlocking Enrollment, Retention, and Outcomes

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Introduction

Clinical trials remain the backbone of medical innovation, yet the system continues to suffer from well-documented inefficiencies: limited enrollment, disproportionate representation, and high attrition rates. Patient navigation, long proven in oncology and chronic care, has emerged as a critical solution to these challenges.

Clinical trials are the engine of medical innovation, yet their success depends on the ability to recruit, enroll, and retain diverse participants while maintaining operational efficiency. Despite decades of investment, the industry continues to struggle. On average, **80% of trials miss enrollment targets and 25–30% of patients drop out before completion.**^{1, 6, 7} These deficits are more extreme among minority and communities that live in poverty, and un- or underinsured, and have multiple co-morbidities. High-needs communities (racial minorities, rural populations, LGBTQ and patients with disabilities) are significantly under-represented and subsequently, undermine both scientific validity and regulatory approval.^{2, 11} These failures are not simply statistical — they represent lost opportunities for patients (poorer quality and quantity of life), costly delays for sponsors, and weakened confidence in the research enterprise.

At the heart of these challenges lies a visibility gap. Trial coordinators, sponsors, and Contract Research Organizations (CROs) can see who is enrolled and who has dropped out, but they lack structured, real-time data on why patients never enroll, make an informed decision to not enroll, or disengage before the trial's completion. Traditional systems like Clinical Trial Management Systems (CTMS) and Electronic Health Records (EHRs) were not designed to capture patient barriers, navigator interventions, or the social determinants of health (SDOH) that typically determines enrollment and retention in a study. Without these data, sponsors are left reacting to problems they may not even know exist, or after they've already jeopardized timelines and budgets.

The Patient Navigation Record System (PNRS) fills this critical gap. PNRS provides the missing infrastructure to capture, measure, and optimize navigation's impact across the clinical trial continuum — from initial screening to enrollment, in-trial support, and completion. Unlike CTMS or EHRs, PNRS focuses on the patient journey, documenting every barrier identified (transportation, financial toxicity, digital literacy), every intervention delivered (education, logistics coordination, psychosocial and cultural support), and every outcome achieved (successful enrollment, protocol adherence, retention).

By integrating with existing CTMS and EHR platforms, PNRS becomes the connective tissue of trial operations. It enables seamless data flow without adding reporting burden to coordinators or navigators, while giving sponsors and CROs unprecedented, real-time visibility into the human side of trial performance. The purpose is not only operational efficiency, but also scientific integrity: when barriers are addressed and outcomes tracked, trials finish on time, results reflect real-world populations, and the evidence base for new therapies is stronger. PNRS transforms patient trial navigation from an invisible support function into a measurable

driver of trial success. It operationalizes what sponsors and regulators have long called for: trials that are faster, more inclusive, and more resilient. As a result, PNRs is not just a tool — it is a new standard of infrastructure for clinical research in an era defined by equity, accountability, and decentralized participation.

A Wraparound Model for Modern Trials

With PNRs, navigation moves beyond fragmented, site-specific efforts and becomes a coordinated, wraparound service that benefits all people involved in the trials processes:

FOR PATIENTS	navigation provides clarity, trust, understandable information, and personalized support.
FOR COORDINATORS	navigation reduces workload by ensuring patients arrive informed, prepared, and supported – streamlining trial operations and minimizing protocol deviations.
FOR SITES	navigation strengthens trial performance and increases competitiveness for sponsor partnerships.
FOR SPONSORS AND CROs	navigation combined with PNRs produces real-time, data-driven visibility into navigation strengthens trial performance and increases competitiveness for sponsor partnerships., interventions, and outcomes across sites.

Clinical trial success hinges not only on scientific design but also on the ability to recruit, enroll, and retain participants through the full study lifecycle. Yet sponsors, CROs, and sites continue to face persistent challenges: enrollment shortfalls, underrepresentation of key populations, patient attrition, and escalating costs tied to delays. Patient navigation directly addresses these inefficiencies, making it a cornerstone of modern clinical trial strategy.

Patient navigators act as a bridge between participants and the often-complex trial environment. Their role begins at the point of eligibility screening, ensuring that every potential participant is assessed consistently and fairly. The majority of under-represented patients complain that they were never informed about clinical trial opportunities, or if they were, the explanation was not understandable for them to make an informed choice about taking part in the trial. Competency-trained Navigators provide clear, tailored education to patients and families — dispelling myths about research, clarifying risks and benefits, and building trust prior to the informed consent processes². Once the patient chooses to enroll, the patient typically is handed off to trial coordinators who will guide the patient through the trial. However, the navigator’s role is to remain involved with the patient throughout the trial.

Clinical trial coordinators are the backbone of study operations, responsible for managing regulatory compliance, data collection, and trial logistics. Yet the increasing complexity of today’s trials means coordinators are often stretched thin, balancing protocol demands with patient needs that extend far beyond the visit schedule. This is where clinical trial navigators become invaluable: not as replacements, but as partners who amplify the work of coordinators and improve both the patient and site experience.

Navigators bridge the gap between patients and the trial system by addressing barriers that coordinators often lack the time or resources to manage. From arranging transportation and financial counseling to providing culturally sensitive education and psychosocial support. They

also interact with Coordinator, informing them of real-life events that may delay a patient or require some additional documentation (e.g., high blood pressure diagnosed after starting the trial). The navigators ensure patients feel informed, supported, and engaged. This allows coordinators to remain focused on their core responsibilities while knowing that patient needs are being met. The result is a stronger, more resilient trial team that ultimately leads to higher patient satisfaction and trial retention.

When navigation is embedded into trial workflows, the results are measurable. Navigation programs in underserved populations have been shown to produce substantial gains in trial enrollment, sometimes reaching participation rates of 61–86% among eligible minority patients². More recent work shows that structured navigation and financial counseling in multi-site studies leads to higher representation of underrepresented groups and better retention.^{3, 12}

Navigation + PNRS = A Complete Solution

Where true benefit is realized is when navigation moves beyond fragmented, site-specific efforts and becomes a coordinated, wraparound service that elevates the experience for every HCP and patient in the clinical trial ecosystem.

This integrated approach recognizes that every trial is unique, and therefore every navigation strategy must be customized. A decentralized oncology trial may require navigators to address digital literacy and remote monitoring challenges, while a cardiovascular device trial may demand intensive logistical support and financial counseling. PNRS allows these differences to be captured and monitored in real time, creating a feedback loop that informs trial design and monitoring, ensures resources are allocated effectively, and validates which interventions deliver the best outcomes for each population.

The true power lies in pairing human connection with easy-to-load data. Navigators provide the relational support that builds trust and keeps patients engaged, while PNRS captures every barrier, intervention, and outcome in real time. This integration not only demonstrates the ROI of navigation but also generates actionable insights that sponsors and CROs can use to refine trial design, recruitment strategies, and retention planning. By making trial support measurable, customizable, and transparent, PNRS and navigation together transform clinical trial operations into a complete, patient-centered, and performance-driven solution.

Proven Impact on Enrollment and Retention

Enrollment and retention remain the two greatest threats to trial success. Structured navigation directly addresses these challenges. Evidence demonstrates that navigation programs can substantially increase enrollment, particularly among historically excluded groups.^{2, 3} Retention rates of 70–80% have been reported in navigation-supported programs ~10–50% higher for underrepresented participants than those that lack navigation throughout the trial.^{1, 3, 5, 13}

Structured navigation directly addresses these challenges. Evidence from oncology and other therapeutic areas demonstrates that navigation programs can substantially increase enrollment, particularly among populations historically excluded from research. In some studies, navigation

interventions have driven enrollment rates of 40–50% among underrepresented groups, far outpacing traditional recruitment strategies. Navigators help patients overcome barriers such as transportation, financial strain, and mistrust of the research enterprise; barriers that coordinators recognize but often cannot resolve within the constraints of their role.

Retention gains are equally powerful. By maintaining ongoing contact, reinforcing education, and providing logistical and psychosocial support, navigators help patients remain engaged through trial completion. Studies report retention rates above 70–80% in navigation-supported programs, representing a 10–20% improvement compared with standard trial operations. Each patient retained not only preserves the integrity of study data but also prevents the costly need for replacement recruitment and prolongation of timelines.

These improvements are not one-size-fits-all. The impact of navigation varies depending on the therapeutic area, patient population, and trial design. A decentralized cancer trial may see the greatest retention benefit from navigators who provide digital literacy training and troubleshoot remote monitoring issues. A cardiovascular device trial, by contrast, may realize the largest enrollment boost when navigators address financial toxicity and coordinate travel for procedure-based visits. The critical point is that navigation is inherently adaptable, and with PNRs capturing every barrier, intervention, and outcome in real time, sponsors gain the ability to measure which strategies work best for which populations, across trials and sites.

By increasing enrollment, broadening diversity, and improving retention, navigation supported by PNRs does more than enhance the patient experience—it safeguards timelines, protects budgets, and strengthens the evidence base on which regulatory approval depends. These are outcomes that no sponsor, CRO, or site can afford to overlook.

The Current State: Challenges for Sponsors and CROs

Despite billions of dollars invested annually in clinical research, trial operations remain plagued by inefficiencies that drive cost overruns, missed timelines, and underpowered studies.

Challenge Area	Key Statistics
Enrollment bottlenecks	80% of trials miss enrollment timelines; up to 20% enroll no participants (PMC, Confidence Research)
Underrepresentation	75% of participants are white; 7% Black (PCM Trials); FDA requires Diversity Action Plans (FDA, Reuters)
Retention	25–30% dropout rates; 90% of studies delayed due to recruitment/retention (Frontiers, ACRP, PMC)
Financial costs	\$500K–\$800K lost per day; up to \$8M/day (Tufts CSDD, Applied Clinical Trials, Antidote)

PNRS and Clinical Trial Equity

Equity in clinical trials not optional. It is a regulatory, scientific, and ethical imperative. Despite comprising over 40% of the U.S. population, racial and ethnic minorities account for <20% of trial participants.^{2, 11} In June 2024, the FDA issued draft guidance requiring Diversity Action Plans (DAPs) for pivotal trials, including enrollment goals disaggregated by race, ethnicity, sex, and age.⁴ PNRS is well positioned to help sponsors collect, track, and report these metrics while reducing site burden.

In June 2024, FDA issued draft guidance, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), that mandates certain sponsors to submit Diversity Action Plans (DAPs) for pivotal clinical trials (phase 3 or equivalent) and for certain device studies. These plans must include specific enrollment goals disaggregated by race, ethnicity, sex, and age; a rationale for those goals; and a concrete plan for achieving them. Importantly, DAPs are not only about demographics: FDA's guidance explicitly encourages consideration of additional dimensions of underrepresentation — for example socioeconomic status, disability, geographic location, pregnancy status — especially insofar as they relate to the disease or product's use population. The DAP requires sponsors to define enrollment goals by age, race, ethnicity, and sex but most sites lack the tools to consistently capture and address these equity-related factors.

As of mid-2025, the foundation of the DAP is still in effect statutorily under FDORA (the Food & Drug Omnibus Reform Act of 2022). Many of the required obligations for sponsors are still expected to apply. Although what policy changes may take affect is still yet to be seen, here is what we do know:.

1. STATUTE (FDORA) NOT REPEATED	FDORA, which requires sponsors of many Phase 3 / pivotal drug/biologic trials (and certain device trials) to submit a DAP, is still law. Sponsors are still bound by the act's requirements.
2. DRAFT GUIDANCE ISSUED	- In June 2024, the FDA issued a draft guidance titled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies". - The guidance lays out the expected contents of a DAP: enrollment goals by race/ethnicity/sex/age, rationale, strategies, monitoring, etc.
3. ADMINISTRATIVE & WEBSITE CHANGES/ UNCERTAINTY	- In early 2025, there was an executive order and related administrative actions that led to the removal of several DEI-related materials (including draft guidances) from the FDA website. - A court order restored the June 2024 draft DAP guidance to the FDA website in February 2025.

Given this environment, PNRS can play a strategic role in helping trial sponsors, trial sites, and CROs stay ahead by collecting and tracking demographic and barrier data now, in alignment with the draft guidance, so that updates or changes in final guidance can be absorbed with less disruption. Ensuring interoperability so data needed for DAPs (enrollment goals, retention, barrier mitigation) can flow smoothly from PNRS into CTMS / regulatory documentation will be critical, regardless of how DAP potentially is affected by policy updates. In addition, real-time monitoring of key metrics empowers stakeholders to adjust recruitment and retention strategies proactively. PNRS also generates documentation that can support waiver requests or demonstrate that barriers were actively managed, turning compliance with FDA DAP

requirements into actionable insights that help trial sites improve operations, sponsors accelerate timelines, and CROs strengthen trial delivery.

Far beyond aspiration, PNRS operationalizes equity in clinical trials—capturing barriers, tracking interventions, and driving measurable outcomes. Through capturing of social determinants of health (SDOH), PNRS standardizes the documentation of barriers such as transportation, caregiving responsibilities, financial strain, or health literacy — making disparities visible and actionable. One of the most interesting and actionable data points is the tracking of navigator interventions- whether arranging transportation vouchers, interpreter services, or financial counseling, PNRS ties each intervention to measurable outcomes (e.g., increased enrollment of underrepresented groups, reduced dropout rates).

Data captured by PNRS is advantageous across all participants of a clinical trial:

FOR PATIENTS	Greater access to cutting-edge therapies regardless of race, income, or geography.
FOR SITES	Evidence that they are addressing disparities, positioning them as preferred trial partners.
FOR SPONSORS AND CROs	Confidence that diversity targets are being met, ensuring trial results are generalizable and regulatory requirements satisfied.

By Design: Real-Time Visibility for Sponsors and CROs

Perhaps the most impactful feature of PNRS, from both a trial design and monitoring perspective, is its ability to provide real-time visibility for sponsors and CROs. Historically, equity in clinical trials has been tracked retrospectively through delayed, inconsistent, and burdensome site-level reports. By the time disparities were identified, enrollment windows had often closed, leaving little opportunity to intervene. Sponsors are now accountable to the FDA’s Diversity Action Plan (DAP) requirements, yet most lack timely insight into which sites are struggling to recruit underrepresented populations. Site reporting remains fragmented, heavily dependent on coordinators already stretched thin, and often fails to capture the barriers patients face in ways that inform actionable change. Without real-time visibility, interventions arrive too late, leading to missed enrollment goals, underrepresentation, and costly trial delays.

PNRS directly addresses this gap by shifting equity monitoring from a retrospective exercise to a proactive, continuous process. Through anonymized, aggregate dashboards, sponsors and CROs gain immediate access to data that reveal which barriers are most common across sites—such as transportation, childcare, or language and which navigation interventions are successfully resolving them. Equity-focused metrics, including enrollment broken down by race, ethnicity, age, and sex, are tracked alongside navigator interventions, providing a clear picture of whether diversity goals are being achieved in real time. This enables sponsors to identify where challenges exist, allocate resources to underperforming sites, and refine recruitment strategies while the trial is still underway. Importantly, this visibility comes without adding to the site burden, since PNRS integrates directly with CTMS and EHR systems and eliminates the need for duplicative coordinator reporting.

The result is that sponsors and CROs can course-correct when necessary, during recruitment rather than explaining equity gaps after the fact. Regulatory readiness is strengthened, with DAP-aligned reporting available on demand, and sites receive targeted support at the exact moment it is needed. By making disparities visible and actionable, PNRS broadens representation, improves retention, and strengthens overall trial outcomes.

PNRS and the Future of Decentralized Clinical Trials

Decentralized clinical trials (DCTs) are reshaping the research landscape by allowing patients to participate from home or community settings. This model introduces new complexity: technology adoption, fragmented support, and higher risks of disengagement. Without robust infrastructure, many DCTs face the same pitfalls as traditional models at a greater pace- slow enrollment, uneven representation, and dropout rates that threaten both timelines and data integrity.^{8, 9, 10, 14, 18}

Patients in decentralized studies may lack reliable internet access, compatible devices, or digital literacy to engage with eConsent and ePRO platforms. The absence of routine in-person visits can lead to feelings of isolation and disengagement. Meanwhile, logistics such as home health visits, remote lab collections, and courier services require careful coordination across multiple vendors. These barriers increase burden on coordinators and can drive dropout rates even higher than in conventional trials. By combining human navigation with PNRS data infrastructure, decentralized trials become more than just a technological shift, they become accessible, inclusive, and resilient. Patients feel supported, coordinators are unburdened, and sponsors gain the transparency needed to accelerate timelines while strengthening data integrity.

PNRS provides the infrastructure to ensure that decentralized participation is equitable, efficient, and patient-centered. Navigators supported by PNRS can track and resolve barriers in real time, whether helping a patient troubleshoot telehealth platforms, arranging transportation for hybrid visits, or coordinating with home health providers. PNRS centralizes all of this activity into one interoperable system, documenting navigator interventions, patient barriers, and outcomes across multiple touchpoints. Early warning signs of disengagement, missed telehealth appointments, delays in submitting ePROs, are captured immediately, enabling proactive interventions that keep patients in the study.

For sponsors and CROs, PNRS transforms DCT oversight from reactive to proactive. Anonymized, aggregate dashboards highlight which barriers are most prevalent across sites and which interventions are working, providing actionable insights for mid-trial adjustments. This visibility not only reduces site burden by eliminating redundant reporting but also supports compliance with FDA's Diversity Action Plan (DAP) requirements by documenting outreach, interventions, and enrollment trends across geographies.

Conclusion: Redefining Clinical Trial Success with PNRS

Clinical research is at a crossroads. The cost of delays, the demand for diversity, and the rapid rise of decentralized models have stretched traditional trial infrastructure to its limits. Enrollment

bottlenecks, patient attrition, and fragmented reporting remain the most persistent threats to scientific progress and sponsor ROI. Coordinators alone cannot solve these challenges, and patients cannot be left to navigate them on their own.

The combination of structured navigation and the Patient Navigation Record System change this equation. Navigation provides the human connection, trust, education, and barrier resolution, while PNRS delivers the data infrastructure that makes those efforts visible, measurable, and actionable in real time. Together, they do more than improve trial performance: they transform the experience for patients, empower coordinators, strengthen sites, and give sponsors and CROs the transparency they need to manage trials proactively rather than reactively. The result is faster enrollment, broader representation, higher retention, and stronger data integrity, all achieved while reducing site burden and aligning with regulatory expectations. PNRS ensures that trials are not only completed on time but are inclusive, efficient, and trusted by the very patients they seek to serve.



About the Authors

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References

1. Sae-Hau, W., Finlay, T., & Vardy, J. (2021). Overcoming barriers to clinical trial participation: Outcomes of a National Clinical Trial Matching and Navigation Service for Patients With a Blood Cancer. *JCO Oncology Practice*. Volume 17, Number 12. <https://doi.org/10.1200/OP.20.01068>
2. Ghebre, R. G., Jones, L. A., Wenzel, J. A., Martin, M. Y., Durant, R. W., & Ford, J. G. (2014). State-of-the-science of patient navigation as a strategy for enhancing minority clinical trial accrual. *Cancer*, 120 Suppl 7(0 7), 1122–1130. <https://doi.org/10.1002/cncr.28570>
3. Makhnoon S, Robles F, Lee JL, Grant D, Rojas M, Gao A, Pezzia C, Eluri V, Sadeghi N, Zhang S, Hulsey T, Renn R, Williams EL, Kitzman H, Gerber DE. Implementation of a Patient Navigation Program to Support Representative Participation in Cancer Clinical Trials. *Cancer Med*. 2025 Aug;14(15):e71125. doi: 10.1002/cam4.71125. PMID: 40751412; PMCID: PMC12317281.
4. U.S. Food & Drug Administration. (2024). Diversity action plans to improve enrollment of participants from underrepresented populations in clinical studies: Draft guidance for industry. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies>
5. Poongothai, S., Anjana, R. M., Aarthy, R., Unnikrishnan, R., Narayan, K. M. V., Ali, M. K., Karkuzhali, K., & Mohan, V. (2023). Strategies for participant retention in long term clinical trials: A participant -centric approaches. *Perspectives in clinical research*, 14(1), 3–9. https://doi.org/10.4103/picr.picr_161_21
6. Harris, L. K., Skou, S. T., Juhl, C. B., Jäger, M., & Bricca, A. (2021). Recruitment and retention rates in randomised controlled trials of exercise therapy in people with multimorbidity: a systematic review and meta-analysis. *Trials*, 22(1), 396. <https://doi.org/10.1186/s13063-021-05346-x>
7. Song, L., Qan'ir, Y., Guan, T., Guo, P., Xu, S., Jung, A., Idiagbonya, E., Song, F., & Kent, E. E. (2021). The Challenges of Enrollment and Retention: A Systematic Review of Psychosocial Behavioral Interventions for Patients With Cancer and Their Family Caregivers. *Journal of pain and symptom management*, 62(3), e279–e304. <https://doi.org/10.1016/j.jpainsymman.2021.04.019>
8. Hanley, D. F., Jr, Bernard, G. R., Wilkins, C. H., Selker, H. P., Dwyer, J. P., Dean, J. M., Benjamin, D. K., Jr, Dunsmore, S. E., Waddy, S. P., Wiley, K. L., Jr, Palm, M. E., Mould, W. A., Ford, D. F., Burr, J. S., Huvane, J., Lane, K., Poole, L., Edwards, T. L., Kennedy, N., Boone, L. R., Bell J., Serdoz E., Byrne L.M., Harris, P. A. (2023). Decentralized clinical trials in the trial innovation network: Value, strategies, and lessons learned. *Journal of clinical and translational science*, 7(1), e170. <https://doi.org/10.1017/cts.2023.597>
9. Jean-Louis, G., & Seixas, A. A. (2024). The value of decentralized clinical trials: Inclusion, accessibility, and innovation. *Science (New York, N.Y.)*, 385(6711), eadq4994. <https://doi.org/10.1126/science.adq4994>
10. Mokshagundam, S., McGree, M. E., Fought, A. J., Ishitani, K. P., Langstraat, C. L., Yadav, S., Dowdy, S. C., & Kumar, A. (2024). An Argument for Decentralized Clinical Trials in Gynecologic Oncology. *O&G open*, 1(2), 5. <https://doi.org/10.1097/og9.0000000000000005>
11. King, S., Trabanino, S., Azizi, Z., & Rodriguez, F. (2024). Leveraging Social Determinants of Health to Enhance Recruitment of Underrepresented Populations in Clinical Trials. *Methodist DeBaakey cardiovascular journal*, 20(5), 81–88. <https://doi.org/10.14797/mdcvj.1447>

12. Ebrahimi, H., et al. (2024). Barriers to clinical trial implementation among community cancer centers. *JAMA Network Open*. <https://doi.org/10.1001/jamanetworkopen.2024.8739>
13. Anastasi, J. K., Capili, B., Norton, M., McMahon, D. J., & Marder, K. (2024). Recruitment and retention of clinical trial participants: understanding motivations of patients with chronic pain and other populations. *Frontiers in pain research (Lausanne, Switzerland)*, 4, 1330937. <https://doi.org/10.3389/fpain.2023.1330937>
14. Bolajoko, O., Fullwood, D., Colissa, M., Merriweather, A., Merriweather, C., & Odedina, F. T. (2024). Decentralized Clinical Trials at Home: Commentary on Caregivers' Burden. *Cancer control : journal of the Moffitt Cancer Center*, 31, 10732748241305581. <https://doi.org/10.1177/10732748241305581>
15. Lamberti, M. J., Dirks A., Kikuchi N, Cervantes NP, Getz K. (2024). An examination of the use of patient recruitment and retention tactics for global studies. *Applied Clinical Trials Online*. <https://www.appliedclinicaltrialsonline.com/view/an-examination-of-the-use-of-patient-recruitment-and-retention-tactics-for-global-studies>
16. Pratap, A., Neto, E. C., Snyder, P., Stepnowsky, C., Elhadad, N., Grant, D., Mohebbi, M. H., Mooney, S., Suver, C., Wilbanks, J., Mangravite, L., Heagerty, P. J., Areán, P., & Omberg, L. (2020). Indicators of retention in remote digital health studies: a cross-study evaluation of 100,000 participants. *NPJ digital medicine*, 3, 21. <https://doi.org/10.1038/s41746-020-0224-8>
17. Hung, M., Mohajeri, A., Almpiani, K., Carberry, G., Wisniewski, J. F., Janes, K., Janes, B., Hardy, C., Zakeri, G., Raymond, B., Trinh, H., Bretner, J., Cheever, V. J., Garibyan, R., Bachstein, P., & Licari, F. W. (2024). Successes and Challenges in Clinical Trial Recruitment: The Experience of a New Study Team. *Medical sciences (Basel, Switzerland)*, 12(3), 39. <https://doi.org/10.3390/medsci12030039>
18. Petrini, C., Mannelli, C., Riva, L., Gainotti, S., & Gussoni, G. (2022). Decentralized clinical trials (DCTs): A few ethical considerations. *Frontiers in public health*, 10, 1081150. <https://doi.org/10.3389/fpubh.2022.1081150>