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Does Perceived Digital Tool Adoption Help Minority Patient Accrual and Retention Compared to All Patient Accrual and Retention for Clinical Trials: Testing a United States Sample?

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Abstract

Using a complete-data sample of 80 online respondents from the United States (US) Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) listserv, this study tested two research questions, *RQ1 - does perceived Digital Tool Adoption (DTA) help minority patient accrual compared to all patient accrual for clinical trials?* and, *RQ2, does perceived DTA help minority patient retention compared to all patient retention for clinical trials?* An on-line anonymous survey was completed. Single-item Likert scales were used to measure respondent perceptions of the study variables. Neither research question was supported, i.e., statistically significant study results indicated that DTA does not help minority patient accrual versus all patient accrual and DTA also does not help minority retention versus all patient retention. Results also indicated that IF accrued, minority patients are more likely to be retained for clinical trials than all patients. This paper addresses an emerging issue for perceived clinical trial cancer patient management in the US, i.e., as DTA continues to evolve, making sure minority patient accrual and retention is done as effectively by cancer-treating organizations as all patient accrual and retention. Cancer-treating organizations need to constantly monitor that their DTAs are as applicable to minority patients as all patients, and if not collect feedback for necessary change.

Keywords: digital tool adoptions, clinical trials, patient accrual, patient retention

1. Introduction

The advent of the COVID-19 pandemic brought about an urgent need to accommodate patients participating in clinical trials, particularly those affected by diseases and conditions with high mortality and morbidity rates. However, prior to the pandemic, regulatory and operational challenges in the US hindered the full realization of decentralized clinical trials (DCTs), preventing them from gaining significant momentum (Ferranti & Schattgen, 2022). The urgent quest for effective treatments against the pandemic led to a surge in COVID-19 clinical trials, with approximately 1,557 new studies initiated in the US during this period, necessitating the reallocation, and refocusing of resources to combat the disease. In response, sponsors and investigational sites began transitioning to models that incorporated elements of DCTs, such as telemedicine consultations, utilization of wearable devices, and the shipment of investigational drugs directly to patients' homes (Manjrekar et al. 2022). The convergence of the pandemic's urgency and the need to provide accessible and effective treatments spurred the adoption of DCT approaches to address the unique challenges posed by the crisis (Ejezie et al., 2025). By embracing DCTs and integrating technologies that facilitate remote interactions and monitoring, researchers and healthcare providers aimed to ensure the continuity of clinical trials and enhance minority patient participation in the US. This research study explores the question, *does digitalization, the foundation of Decentralized Clinical Trials, help minority patient accrual and retention compared to all patient accrual and retention in the US?* To the authors' knowledge, little prior research has been done to explore this question.

1.1 The Research Issue

DiMasi et al. (2023) acknowledged that the DCT adoption experience in the US is promising though still in its early stages. They suggested that future research should focus on investigating relevant aspects of clinical trial operations where there is not currently adequate data. These aspects include the generalizability to the patient

population and advantages experienced by trial participants, such as enhanced access, convenience, and retention. Studies in the US have additionally acknowledged downfalls to DCTs, i.e. patient preference for on-site conduct and digital limited access (Adesoye, Katz & Offodile, 2023).

1.2 Minority Patient Participation in US Clinical Trials

In 2020, amongst thirty-two thousand participants in clinical trials in the US, only 8% percent were reported as Black and 11% Hispanic (Kelsey et al., 2022). The 2020 US census revealed that the population consisted of 12.1% Black and 18.7% Hispanic (Jenset et al., 2021) which revealed a major underrepresentation of two important demographic groups in US clinical trials. Lack of diversity within clinical trials has the potential significant consequence for treatment development without diverse population data, leading to the lack of generalizability and effectiveness of treatments for an inclusive patient population. Underrepresentation of minority patients in US clinical trials is attributed to several factors. Logistical hurdles created by social determinants such as poverty (Lee, Ow, Lie & Dent, 2016) and limited access to healthcare (Barrett et al., 2020), and lack of trust between the patient and researchers (Fink et al., 2023) contribute to underrepresentation.

Deep rooted historical mistrust (Smirnoff et al., 2018) in the US healthcare system from earlier unethical research practices (Morgan et al., 2024) has brought on a stigma for minority communities regarding clinical trials. Culturally insensitive communication and language barriers (Wong et al. 2020), and restrictive eligibility criteria (Kelsey et al., 2022) to participate in clinical trials are other factors that have unintentionally restricted minority patient participation in clinical trials. Another barrier is geographical since trials are often concentrated around academic medical centers posing an issue for geographically dispersed minority groups and populations (Beltrami, Masison, & Feng, 2023).

DCTs and the digitalization of clinical trials offer a solution to bridging gaps in minority population participation in clinical trials (DiMasi et al., 2023; Ejezie et al., 2025). Digital platforms offer the ability to improve outreach and education by providing an avenue to develop culturally appropriate outreach materials in multiple languages (Hardy-Abeloos et al., 2023). Digital platforms also facilitate ongoing education and information to participants throughout trials which could foster trust and open communication through the trial process. Digital screening tools and recruitment platforms can streamline enrollment processes by providing more accessibility and convenience for geographically dispersed populations (Weiner et al., 2023). Telemedicine and remote monitoring technologies (Blood et al., 2023) can further eliminate geographical barriers by allowing patients to participate from the comfort of their homes or local clinics without the burden of traveling long distances to research sites (Malwade et al., 2018). This facilitates accessibility in underserved areas. Digital tools can further facilitate the collection of data needed to analyze and help identify barriers and ensure equitable access to research opportunities (Ejezie et al., 2025). DCTs hold immense potential to improve minority participation in clinical trials. By addressing barriers and leveraging the strengths of digital technologies, a future where clinical trials are truly inclusive, reflecting the diversity of the population they aim to serve, seems more tangible to achieve. This will ultimately lead to more effective treatments and improved health outcomes for all.

1.3 Accrual of Minority Patients

Sanofi reported that 70% of prospective patients for trials live over two hours from clinical sites (Abdulai, 2021). The importance given to diversification reach of clinical trials that have historically only been accessible to those that lived within a certain distance from clinical sites was given much prominence during the pandemic. The assumption was made that DCTs for an oncology trial would lead to an increase in trial accruals. Insufficient or delayed accruals to clinical trials account for a significant percentage of the usage of the clinical trials budget (DiMasi et al., 2023).

Clinical trials evaluate the safety and efficacy of novel treatments. It is essential that clinical trials include people of various backgrounds such as race, ethnicity, and biological sex to help ensure all communities benefit from the drugs that are developed through trials (NIMHD, 2024). As noted above, minority representation is a problem that has plagued US clinical trials. To level this lack of minority representation on clinical trials, the US Food and Drug Administration (FDA) developed educational guidance with the aim to enroll underrepresented ethnic and racial populations in clinical trials (FDA, 2023). Researchers are making educational strides to engage communities and community leaders to encourage trust and undo the stigmas of the past (Reopell et al., 2023).

1.4 Retention of Minority Patients

While patient enrollment drives cost, the key is keeping patients on trial (DiMasi et al., 2023). The role of DCTs in the retention rates of patients at a cancer center is a driver of the financial benefit the cancer center obtains through a clinical trial. These financial benefits can be both tangible (per patient cost collected) and non-tangible

(increase in study completion timelines). Patient retention in clinical trials directly correlates with the success of clinical trials. If patients do not stay on a trial long enough it can lead to an early and wasteful end of the trial. DCTs, while mostly hybrid at cancer sites, are also linked with more accessibility for patients needing procedures for trials. One major driver complicating patient retention is the adverse/side effects the patient feels while on a clinical trial (Poongothai et al., 2023). Unsuccessful trials affect patient treatment options for the future and while not a direct financial effect, are important to consider for future morbidity and mortality rates for cancer centers. For DCTs to be possible, tools need to be incorporated at research sites to accommodate minority patients to be screened, treated, and followed off site. To summarize, the motivation for this study was to test if perceived Digital Tool Adoption (DTA) by cancer clinical trial sites helped minority patient accrual and retention compared to all patient accrual and retention.

1.5 Study Research Questions

This review leads to two general research questions (*RQ*) being tested:

RQ1 - does perceived DTA help minority patient accrual compared to all patient accrual?

RQ2 - does perceived DTA help minority patient retention compared to all patient retention?

2. Method

2.1 Sample and Procedure

An online anonymous Qualtrics survey was sent to the US Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) listserv which compromises 650 subscribers from eighty-two academic and National Cancer Institute (NCI) designated cancer centers in North America at the time of the survey. The listserv serves as a resource available to clinical trials office staff to discuss best practices, solutions, and challenges that sites might be facing. Data collection was from 3/20/24 to 7/1/24. Three listserv reminders were sent to encourage participation and completion of the survey. There were no incentives for participation. The initial survey participation rate for the survey was 25%, i.e., 160 respondents. However, unfortunately there was also a large amount of missing data in the returned surveys, which reduced the complete data sample size to n = 80. University Institutional Review Board (IRB) approval, i.e., exempt review, for this study was given.

2.2 Survey Design Process and Measures

The survey was developed through pilot groups in a three-stage approach. Pilot groups consisted of individuals who had previously worked at clinical trial research sites as administrators, coordinators, or managers. The first stage consisted of five peers who were tasked with reviewing the survey and providing feedback on question content. In this stage, feedback defining terms was a common theme for example, *diverse patient population*, *patient accrual*, and *patient retention*. The term *diverse patient population* was changed to *minority patients*, with the term being defined *as those that identified as Black or African American, Hispanic, Asian, and other*. Accrual was defined as *signing of consent and start of treatment*. Patient retention was defined as *remaining on and completing a clinical trial*. The second stage of peer review consisted of the initial five as well as five additional reviewers. During this phase, question structure was the focus. Likert scale item models were questioned and restructured from sliding scales to multiple choice questions. The third stage included ten new pilot group participants as well as a digitalization vendor that works closely with research sites. The vendor was chosen to provide insight from an outsider perspective to understand how site vendors, clinical research organizations and industry partners might benefit from the survey. Additionally, the suggestion was made to keep the survey anonymous to maximize participation. The final survey was generated using Qualtrics software. Text below presents how the variables were defined and measured.

Digital Tool Adoption Level (DTA) -"To the best of your knowledge, to what extent has the Clinical Trials Office (CTO)/research office adopted digital tools or systems to enhance processes? (e.g.: eReg binders, eConsent platforms, wearable devices, screening tools, etc.), using the following response scale: 1 = No extent: no digital tools or systems adopted; 2 = Very minimally: There may be some initial exploration or pilot projects, but the overall adoption is limited; 3 = Minimally: Some steps have been taken towards adopting digital tools or systems for clinical trial processes, but the implementation is limited in scope and impact; 4 = Moderately: There are some initiatives in place, but there is room for further expansion and integration; 5 = Significantly: There is a substantial investment in digital technologies, leading to noticeable improvements in efficiency and effectiveness; 6 = Very significantly: There are transformative changes in clinical trial processes. The organization is a leader in leveraging digital technologies for enhancing trials; 7 = Completely: Fully embraced. The organization has integrated digital technologies seamlessly into its operations, leading to optimal efficiency and outcomes in clinical trials."

Minority Patient Accrual and Retention (Minority patients are defined as those that identified as Black or African American, Hispanic, and Asian) - "To the best of your knowledge, since the implementation of digital tools, minority patient accruals on clinical trials has:" (Patient Accrual = signed consent and started treatment). "To the best of your knowledge, since the implementation of digital tools, the retention of minority patients on clinical trials has:"(Retention = remaining/completing a clinical trial): 1 ==Strongly decreased; 2=Moderately decreased; 3=Slightly decreased; 4=Not changed; 5=Slightly increased; 6=Moderately increased; 7=Strongly increased.

All Patient Accrual and Retention – "Since the implementation of digital tools, as best you can estimate, patient accruals for all patients on clinical trials has." "To the best of your knowledge, since the implementation of digital tools, patient retention for all patients on clinical trials has:"1 ==Strongly decreased; 2=Moderately decreased; 3=Slightly decreased; 4=Not changed; 5=Slightly increased; 6=Moderately increased; 7=Strongly increased.

Other Variables. CTO Role - *What is your role in the Clinical Trials Office (CTO)/Research Office (RO)?:* 1 = Associate Director/Medical Director (Medical Leader); 2 = Principal Investigator; 3 =Administrator (senior-level management responsible for overseeing the overall operations, finances and strategic direction of the CTO); 4 = Research Manager/Supervisor; 5 = Research Coordinator/Data Specialist; 6 = Other (please specify). Location - *Describe the location of your CTO/RO:*1 = Urban/City; 2 = Suburban (outskirts of a city); 3 = Rural; 4 = Other. Type of Institute - *Which of the following best describes the type of institution you represent?* 1= Academic medical center - Non designated; 2 = Academic medical center - National Cancer Institute (NCI) Designated; 3 = Freestanding cancer center dedicated solely to cancer research and care; 4 = Government laboratory or private research institute focused on cancer research; 5 = Hospital or clinic without a formal designation as a cancer center. *How long have you been part of the CTO/research office?,* where 1 = less than one year; 2 = 1 to 2 years; 3 = 2 to 5 years; 4 = 5 to 10 years; 5 = 10 to 15 years and 6 = over 15 years.

2.3 Data Analysis

Since general research questions are being tested, two-tailed tests for significance will be used (Pituch & Stevens, 2015).

3. Results

3.1 Sample Characteristics

Table 1 describes the complete-data sample participant characteristics, using the four variables identified in Table 1. Most participants were administrators (50%), from Academic – NCI designed Institutions (71%), located in an Urban/City (80%), and 70% had been part of the CTO/research office for at least five years.

Table 1. Sample Participants

Variable	Response	Frequency (Percentage)
CHTO Role	Associate Director/Medical Director	1 (1)
	Administrator	40 (50)
	Research Manager/Supervisor	22 (28)
	Research Coordinator/Data Specialist	7 (9)
	Other (e.g., Clinical Research Director, Regulatory Specialist, Clinical Trials Management	10 (12)
Institution	Academic – NCI designated	57 (71)
	Academic non-NCI designated	19 (24)
	Freestanding Cancer Center	4 (5)
Location	Rural	3 (4)
	Suburb	11 (14)
	Urban/City	64 (80)
	Other	2 (2)
How long have you been part of the CTO/research office	Less than one year	2 (3)
	1-2 years	2 (3)
	2-5 years	19 (24)
	5-10 years	22 (27)
	10-15 years	17 (21)
	Over 15 years	18 (22)

N = 80.

3.2 Variable Means, Standard Deviations and Correlations

Table 2 presents the continuous variable means, standard deviations and correlations among study variables. With listwise data, the sample size was reduced to n = 80. The mean for DTA of 4.88, is very close to the response scale of 5 (out of 7) which represented respondents perceiving their institutions making "a substantial investment in digital technologies, leading to noticeable improvements in efficiency and effectiveness." Looking at other variable means, using a paired sample t-test, the All Patient Accrual mean of 4.45 was significantly higher than the Minority Patient Accrual mean of 4.15, $t(79) = 2.77$, $p < .01$ (two-tailed); indicating that respondents perceived digital tool implementation had helped all patients for clinical trial accrual more than minority patients. The correlation of minority patient accrual to minority patient retention of $r = .71$ is significantly higher (Pituch & Stevens, 2015) than the correlation of $r = .31$, between all patient accrual to all patient retention, $z = 3.57$ (two-tailed). This suggests that IF accrued, minority patients are more likely to be retained for clinical trials than all patients.

Table 2. Means, Standard Deviations and Correlations of Study Variables

Variable Name	M	SD	1	2	3	4	5
1. Digital Tool Adoption Level[a]	4.88	1.01	(----)				
2. Minority Patient Accrual[b]	4.15[c]	.64	-.12[e]	(----)			
3. Minority Patient Retention[b]	4.10	.47	-.12[f]	.71**[d]	(----)		
4. All Patient Accrual[b]	4.45[c]	.87	.21[e]	.20	-.02	(----)	
5. All Patient Retention[b]	4.20	.46	.25*[f]	.24*	.26*	.31**[d]	(----)

Note. N = 80. * $p < .05$; ** $p < .01$ (both two-tailed)

[a] Digital Tool Adoption Level, 1 = no extent, to 7 = completely, fully embraced.

[b] Minority Patient Accrual; Minority Patient Retention; All Patient Accrual; All Patient Retention, 1 = strongly decreased to 7 = strongly increased.

[c] Significant difference in means, All Patient Accrual is higher than Minority Patient Accrual, $t(79) = 2.77$, $p < .01$ (two-tailed).

[d] Minority Patient Accrual – Retention correlation of .71 is higher than All Patient Accrual – Retention correlation of .31, $z = 3.57$ (two-tailed).

[e] Significant difference in correlations, $t(77) = -2.38$, $p < .05$ (two-tailed).

[f] Significant difference in correlations, $t(77) = -2.81$, $p < .05$ (two-tailed).

3.3 Research Question Tests

The correlations shown in Table 2 provide these results. The test for *RQ1, does perceived DTA help minority patient accrual compared to all patient accrual?*, found a significant difference (Pituch & Stevens, 2015) in correlations, minority patient accrual, $r = -.12$ versus, all patient accrual, $r = .21$, $t(77) = -2.38$, ($p < .05$), such that DTA does not help minority patient accrual compared to all patient accrual. The test for *RQ2, does perceived DTA help minority patient retention compared to all patient retention?* also found a significant difference (Pituch & Stevens, 2015) in correlations, minority patient retention, $r = -.12$ versus, all patient retention, $r = .25$, $t(77) = -2.81$, ($p < .05$), such that DTA does not help minority patient retention compared to all patient retention.

3.4 Missing Data Analyses

Using independent samples t-testing (with a minimum n =25 in each group), an analysis of the complete-data respondents versus missing data respondents on the above five variables in Table 2, showed one significant difference, complete data respondents had a higher mean perceived DTA level ($M = 4.88$) than missing data ($M = 4.19$) respondents, $t(110) = 2.14$, $p < .05$(two-tailed).

4. Discussion

As noted earlier, it is crucial to explore how DTAs can be equitably utilized across all clinical patients to overcome barriers to participation in the US, such as lack of awareness, transportation difficulties, and mistrust of the healthcare system (Liu et al., 2021). Fink et al. (2023) noted that clinical trial participation by minority patients can be increased by dedicating more time to properly educating both patients and family members. By addressing the specific needs and challenges of minority populations, one can ensure that clinical research reflects the diversity of the patient population and ultimately leads to better health outcomes and generalizable results. As an exploratory study, clinical trial staff respondent perceptions showed that DTA does not help minority patient accrual or minority patient retention, compared to all patient accrual or all patient retention. Results also indicated that IF accrued, minority patients were more likely to be retained for clinical trials than all patients. Effort is needed to make sure that minority patient accrual and retention is done as effectively by cancer-treating organizations as all patient accrual and retention. Cancer-career organizations need to constantly monitor that their DTAs are as applicable to minority patients as all patients, and if not collect feedback for necessary change. This is a very important issue for perceived clinical trial cancer patient management.

4.1 Study Limitations and Future Research

With a larger complete-data sample size the study results could have been stronger (Pituch & Stevens, 2015). Potential confounding factors not included in the research design include clinical trial design issues (e.g., length),

as well as measurement limitations. For example, more specifically defining the accrual and retention response choices for the 7-point Likert scales, e.g., strongly decreased (more than 30%); moderately decreased (10 to 29%); slightly decreased (less than 10%)…could have helped clinical trial staff respondents choose a response and thus decreased missing data. This study presented a careful three-stage pilot process for survey measure development, including perceived DTA. However, the single-item measures used do not allow computing scale reliability estimates. The reliance on self-report online survey data typically generates some missing data. However, the large amount of missing data in this study i.e., 50%, could also be partially attributed to survey recipients not having necessary knowledge to answer the study variable questions, e.g., DTA level. Future research directing a survey to only be filled out by knowledgeable staff would be ideal. An upfront survey item to qualify (disqualify) participants having sufficient (insufficient) knowledge could be an option. The research design is a limitation, i.e., all self-report data, collected at one time. A stronger research design would first measure DTA level at Time 1 and then patient accrual and retention at Time 2 for stronger causal inference.

Future studies could benefit from larger, more representative samples, and include objective measures of DTAs. Objective measures such as electronic consent forms, wearable devices, remote monitoring technologies and translational technologies can help overcome geographical and financial burdens that are often barriers for patients to participate in trials (DiMasi et al., 2023). Thus, the ideal research design would use validated multi-item scales, employ a longitudinal research design, with objective DTA measures, and make sure that rural and suburban, as well as non-academic sites are also adequately sampled.

Understanding the nuances of DTA and its impact on minority patient accrual and retention is vital for improving the diversity and inclusivity of clinical trials (Adesoye et al., 2023; Ejezie et al., 2025). From a clinical trial cancer patient management standpoint, cancer-treating organizations in the US need to constantly monitor that their DTAs are as applicable to minority patients as all patients with rigorous research designs and follow-up.

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