Evidence in the Literature on Investigative Site Usage and Experience with Virtual and Remote Clinical Trial Solutions

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The Partnership for Advancing Clinical Trials (PACT) Consortium, hosted and facilitated by the Tufts Center for the Study of Drug Development (CSDD), is a pre-competitive consortium of pharmaceutical and biotechnology companies, contract research organizations (CROs), and niche service providers. Founded in 2024 — with funding from the Reagan Udall Foundation, Medable, and member companies — PACT's mission is to gather empirical evidence to inform and guide the adoption and use of innovations supporting drug development planning, execution, analysis, and reporting.

EVIDENCE IN THE LITERATURE ON INVESTIGATIVE SITE USAGE AND EXPERIENCE WITH VIRTUAL AND REMOTE CLINICAL TRIAL SOLUTIONS

INTRODUCTION

Despite high awareness and use of virtual and remote technologies necessitated by the COVID-19 pandemic, empirical evidence evaluating the impact of these decentralized clinical trial (DCTs) components remains extremely limited. Tufts CSDD review of the peer-review literature found that of more than 16,500 articles published since 2022 on clinical trials executed with DCT component support, only 6% included qualitative or quantitative data from surveys and actual performance [figure 1].

This white paper synthesizes and summarizes data from this limited collection of peer-reviewed assessments. Drawing from these published studies, we examine how DCTs have impacted patient enrollment, clinical trial speed and efficiency. This distillation of results from scholarly research provides a early picture of where DCT solutions are delivering value, where challenges remain, and how future research can better support evidence-based adoption. Full reference citations are provided at the conclusion of this white paper.

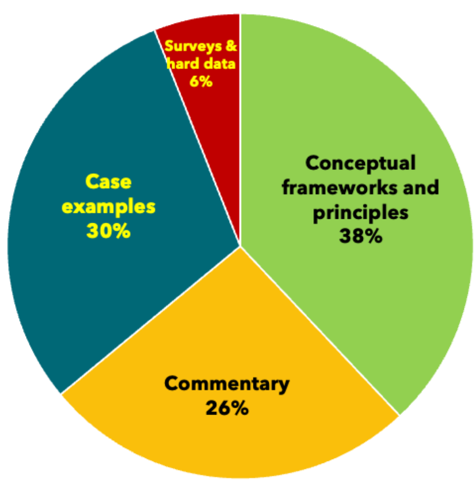

Figure 1: Tufts CSDD | Distribution of 16,790 articles in the literature since 2022

1| DCT COMPONENTS USED

TABLE 1

Reference	DCT Model (Fully Remote / Hybrid / Comparator)	Recruitment & eConsent	Data Capture (eDiary / Sensors)	Intervention Delivery	Participant Engagement (Reminders / Incentives)	Monitoring & Safety (Telehealth / Logs)
Anguera et al., 2016	Fully Remote	✅	✅	✅	✅	☐
Bot et al., 2016	Fully Remote	✅	✅	☐	☐	☐
Boulware et al., 2023	Fully Remote	✅	✅	✅	✅	✅
Chan et al., 2018	Fully Remote	✅	✅	☐	✅	☐
Elliott et al., 2024	Fully Remote[1]	✅	✅	✅	✅	✅
Griffith Fillipo et al., 2022	Fully Remote	✅	✅	✅	✅	☐
Lee et al., 2021	Fully Remote	✅	✅	☐	✅	☐
Lenze et al., 2020	Fully Remote	✅	✅	✅	✅	✅
Li et al., 2022	Fully Remote	✅	✅	☐	✅	☐
Lunn et al., 2019	Fully Remote	✅	✅	☐	✅	☐
McConnell et al., 2017	Fully Remote	✅	✅	☐	✅	☐
Naggie et al., 2022	Fully Remote	✅	✅	✅	☐	☐
Naggie et al., 2023	Fully Remote	✅	✅	✅	☐	☐
Nickels et al. 2021	Fully Remote	✅	✅	☐	✅	☐
Orri et al., 2014	Fully Remote	✅	✅	✅	☐	✅
Pratap et al., 2018	Fully Remote	✅	✅	✅	✅	☐
Reiersen et al., 2023	Fully Remote	✅	✅	✅	✅	✅
Skipper et al., 2020	Fully Remote	✅	✅	✅	✅	✅
Sullivan et al., 2011	Fully Remote	✅	✅	☐	☐	☐
Greer et al., 2024	Hybrid	✅	☐	✅	☐	✅
Jones et al., 2021	Hybrid	✅	☐	☐	✅	✅
McCarthy et al., 2023	Hybrid	✅	☐	✅	☐	✅
Stewart et al., 2023	Hybrid	✅	✅	✅	☐	✅
Giboin et al., 2025	Comparator (conventional trial + digital add-on)	☐	✅	☐	☐	☐
Jones et al., 2017	Fully Remote (Facebook arm) + Comparator (on-site arm)	✅	☐	✅	✅	☐
Sommer et al., 2018	Fully Remote (DCT arm) / Comparator (Conventional arm)	✅ (both arms)	✅ (both arms)	☐ (both arms)	✅ (only DCT arm)	✅ (both arms)

1- Fully Remote, though a minority of participants completed in-person consent; all other trial activities were remote.

Table 1 summarizes the virtual and remote solutions that were used to support clinical trial execution. Recruitment Method specifies how participants were approached (e.g., web-based outreach, site-based approaches, hybrid models). DCT Model distinguishes between fully remote designs, hybrid approaches, and conventional comparators with digital add-ons; Recruitment & eConsent indicates whether digital enrollment tools were used; Data Capture refers to the use of eDiaries or sensors to collect outcomes; Intervention Delivery documents whether treatments were provided remotely; Participant Engagement reflects strategies such as reminders or incentives; Finally, Monitoring & Safety captures the use of telehealth or digital safety logs.

Many studies published in the peer-review literature largely executed fully remote designs, particularly those using digital platforms (e.g., Anguera et al., 2016; Bot et al., 2016; Lunn et al., 2019). Hybrid models were often used in trials that required clinical oversight, such as McCarthy et al., 2023 and Stewart et al., 2023. Conventional comparators with digital elements were rarer but evident in studies like Giboin et al., 2025 and Sommer et al., 2018. Across functions, recruitment and eConsent were the most consistently deployed features, followed closely by data capture. Monitoring and safety tools (telehealth, digital logs) were included primarily in drug intervention trials requiring safety oversight, such as Skipper et al., 2020 and Boulware et al., 2023.

Whereas the majority of DCTs employ remote recruitment and eConsent, there is wide variation in the extent to which they have integrated participant engagement and monitoring tools.

2| ENROLLMENT EXPERIENCE IN CLINICAL TRIALS WITH DCT

TABLE 2

Reference	Screen Failure	Enrollment Rate	Dropout Rate	Retention Rate	Adherence Rate
Anguera et al., 2016	NA	NA	59%	41%	44% (week 4)
Bot et al., 2016	65.5%	88.5%	16.9%	56.7% (≥1 task) 9.4% (≥5 task)	NA
Boulware et al., 2023	77.7%	13.7%*	Fluticasone: 8.3% Placebo: 10.3%	Fluticasone: 91.7% (656/715) Placebo: 89.7% (621/692)	Receipt adherence: ~92% (fluticasone), ~90% (placebo). Dosing adherence (took ≥1 dose): ~90% (fluticasone), ~87% (placebo).
Chan et al., 2018	NA	17.2% (all downloads) 20.8% (U.S. downloads)	16.1%	58.7%	NA
Elliott et al., 2024	NA	NA	<10%	83%	83–93% across arms
Giboin et al., 2025	NA	NA	NA	NA	~70% adherence to digital motor tests
Greer et al., 2024	5.4%	44.1%*	4.5%	50.4%	Video 78% In-person 82%
Griffith Fillipo et al., 2022	NA	NA	47%	53%	~65%
Jones et al., 2017	49.3%	53.7%	40%	NA	NA
Jones et al., 2021	NA	3.4%	4.1%	79.2%	81 mg: 85.9% 325 mg: 47.3%
Lee et al., 2021	59.9%	NA	NA	NA	NA
Lenze et al., 2020	62.4%	36%	24.3%	75.7%	NA
Li et al., 2022	NA	51.7% (Phase 1) 78.5% (Phase 2)	NA	NA	Baseline completion: 51.7% (Phase 1) 78.5% (Phase 2)
Lunn et al., 2019	NA	NA	1.45%	65.8% (2017 AQ); 47.9% (2018 AQ); 37.4% (2018 AQ Supp.)	NA

McCarthy et al., 2023	88%	64.6%	3.2%	96.8%	NA
McConnell et al., 2017	NA	81.7%	88.6 (7-day completers) 90.7% (walk test)	9.3%	41.5% (≥4 days) 10.2% (walk test)
Naggie et al., 2022	13.7%	70.5%	11.6%	88.4%	NA
Naggie et al., 2023	88%	66%	NA	92.6%	NA
Nickels et al. 2021	74.1%	76% (67.8% good-faith)	10.8% (audit) 7.5% (data insufficiency)	92.5% (sufficient data)	83.35% (PHQ-9 tasks)
Orri et al., 2014	48%	49.8%	86.4%	13.6%	NA
Pratap et al., 2018	76.9%	100%	66.5%	33.5%	NA
Reiersen et al., 2023	72.9%	100%	18.4%	NA	60.3% (Fluvoxamine) 74.5% (Placebo)
Skipper et al., 2020	75%	37.4%	19.6%	80.4%	77% (HCQ) 86% (Placebo)
Sommer et al., 2018	Decentralized 76.1% Conventional 66.7%	Decentralized 42% Conventional 83.3%	Decentralized 11% Conventional 40%	Decentralized 89% Conventional 60%	Decentralized 63% Conventional 83.4%
Stewart et al., 2023	93%	72.9%	NA	NA	93.6% fluvoxamine 97.7% placebo
Sullivan et al., 2011	29.6%	77.1%	30.5%	69%	NA

Table 2 presents evidence of the impact of virtual and remote solutions on patient enrollment performance.

Screen Failures are defined as the proportion of individuals assessed but found ineligible; Enrollment Rate is defined as the percentage of screened or eligible participants who were ultimately enrolled in the study; Dropout Rate refers to the percentage of enrolled participants who discontinued before completion; Retention Rate is defined as the percentage of participants who completed the clinical trial; Adherence Rate captures how well participants followed the protocol requirements.

Table 2 shows wide variation between studies, reflecting differences in trial design, target populations, and the ways digital tools were implemented. Trials that incorporated all five DCT components often achieved strong retention (75–90%) but also reported high screen failure rates (frequently above 60%). This pattern suggests that while comprehensive DCT designs can promote continuity once participants are enrolled, they may introduce recruitment challenges that limit initial enrollment. Hybrid designs showed similarly mixed outcomes: some demonstrated exceptionally high retention (e.g., McCarthy et al., 2023, ~97%) or strong adherence (e.g., Stewart et al., 2023, >90%), while others exhibited more modest retention (Jones et al., 2021) or lower rates (Greer et al., 2024). These findings underscore that recruitment and participant support strategies must be tailored to the trial's design and population context rather than relying solely on the breadth of digital components deployed.

Using Kruskal–Wallis tests to compare performance outcomes across categorical study features, we found that Monitoring and Safety components were significantly associated with both Enrollment Rate ($p = 0.045$) and Adherence Rate ($p = 0.028$). These results suggest that the presence and design of digital monitoring tools—including remote safety checks, telehealth visits, or digital symptom tracking—may play an important role in how effectively participants enroll and remain engaged throughout a trial. However, a larger sample and additional analyses are needed to confirm these relationships and better isolate the independent impact of monitoring and safety systems on participant behavior.

3| ENROLLMENT DURATION IN MONTHS

TABLE 3

Reference	Enrollment Duration
Anguera et al., 2016	5
Bot et al., 2016	6
Boulware et al., 2023	6
Chan et al., 2018	21
Elliott et al., 2024	NA
Giboin et al., 2025	NA
Greer et al., 2024	~59
Griffith Fillipo et al., 2022	NA
Jones et al., 2017	~6.8
Jones et al., 2021	39
Lee et al., 2021	9
Lenze et al., 2020	4
Li et al., 2022	Phase 1: ~4 Phase 2: ~16
Lunn et al., 2019	24
McCarthy et al., 2023	~9.5
McConnell et al., 2017	7
Naggie et al., 2022	7.5
Naggie et al., 2023	~ 5
Nickels et al. 2021	NA
Orri et al., 2014	NA
Pratap et al., 2018	7
Reiersen et al., 2023	~5
Skipper et al., 2020	1.5
Sommer et al., 2018	4
Stewart et al., 2023	~5
Sullivan et al., 2011	1

Table 3 presents the enrollment duration of clinical trials utilizing DCT components. Enrollment Duration is defined as the time from the first patient in (FPI) until the last patient enrolled (LPI).

A correlation analysis was conducted to explore whether any trial characteristics were associated with key performance indicators, including screen failure, enrollment, dropout, retention, and adherence rates. Among all examined variables, Screen Failure Rate demonstrated a statistically significant relationship with Enrollment Duration ($r = -0.57$, $p = 0.027$). This inverse association suggests that trials with longer enrollment windows tended to experience lower screen failure rates, possibly because extended recruitment periods allow sites to identify and qualify participants more effectively, easing the initial screening burden. No other statistically significant linear relationships were observed between the remaining predictors and the four other performance outcomes. These findings underscore that while digital and operational design factors may influence participant engagement and retention, time allocated for recruitment remains a critical driver of early trial success.

4| WORKFORCE, HEADCOUNT, OPERATIONAL CHANGES

TABLE 4

Reference	Allocation of Resources	Training Requirements
Anguera et al., 2016	+30% to Technology Onboarding (web portal + app development/licensing) +00% to Remote Support ("very little contact") +19% to Full Time Staff (3 salaried staff + 2 volunteers) +7% to Participant Payments +44% Other (β testing, licensing, additional costs not further specified)	• Digital literacy • Protocol comprehension (consent quiz) • Technical troubleshooting skills
Bot et al., 2016	NA	• Digital literacy (participants must be comfortable using iPhone in English) • Ethics/protocol comprehension (5-question consent quiz)
Boulware et al., 2023	**NA**	• Electronic/written consent • Self-administration of inhaler • Daily symptom & safety reporting by participants
Chan et al., 2018	NA	• Participant comprehension quiz on consent (risks, benefits, privacy, data sharing) • App-based onboarding process
Elliott et al., 2024	NA	• Participant instruction in device use (visual aids, daily diaries) • Technical troubleshooting (device adherence monitoring, actigraphy, luxometer) • Digital literacy (DocuSign, REDCap) • Regulatory & HIPAA/VA privacy compliance
Giboin et al., 2025	NA	NA
Greer et al., 2024	NA	• Training on video conferencing platform use • Training on principles of early palliative care • Review of clinician intervention guide • Annual retraining sessions
Griffith Fillipo et al., 2022	NA	NA
Jones et al., 2017	+$10,235.53 (~$50/day) to Facebook Ads (technology onboarding) +293 staff hours to on-the-ground recruitment +Ongoing staff effort for ad creation/monitoring	• Skills in ad design and monitoring • Applying IRB and information security protocols • Identity verification procedures (phone, duplicate checks)
Jones et al., 2021	NA	NA
Lee et al., 2021	NA	NA
Lenze et al., 2020	+4500 total staff hours (~30 hours/participant)	NA
Li et al., 2022	NA	• Participant-side digital literacy • Technical troubleshooting
Lunn et al., 2019	• $390,000 total design & development costs • $875 monthly recurring cloud/third-party costs • External resource allocation: THREAD Research & Analog Republic for design, QA, coding, infrastructure	• User acceptability testing with community members • Participant-facing support via Zendesk
McCarthy et al., 2023	NA	NA
McConnell et al., 2017	NA	NA
Naggie et al., 2022	NA	NA

Naggie et al., 2023	NA	NA
Nickels et al. 2021	• Resources invested in technology/app development (sensor integration, chatbot UI). • Resources for fraud detection audit ("good faith users"). • Resources for participant compensation management (3 cohort system).	NA
Orri et al., 2014	+ to Technology Platforms (web portal, eConsent, eDiary, remote shipment) - to Site Operations (no on-site visits, reduced transportation/monitoring)	Digital literacy (mobile e-diary use, validated before recruitment) • Protocol comprehension (multiple-choice consent test)
Pratap et al., 2018	US $7,540 (participant payments) US $4,601 (website/enrollment/database) US $14,471 (recruitment: $5,725 Spanish Craigslist, $946 English Craigslist, $7,800 social media)	NA
Reiersen et al., 2023	NA	• Instructions for participants on use of devices (pulse oximeter, BP monitor, thermometer) • Instructions for completing online surveys
Skipper et al., 2020	NA	• Participant comprehension quiz before consent
Sommer et al., 2018	• 56% of decentralized patients required extra technical support calls • Ongoing staff monitoring of data flow and follow-up when missing data occurred	• Interactive training video on eDiary use • Training on patch sensor use and pairing • Mandatory quiz to ensure understanding • Patient guide and phone support available • Additional support needed for majority of decentralized patients
Stewart et al., 2023	NA	NA
Sullivan et al., 2011	NA	NA

Table 4 summarizes reported resource allocation and training requirements across DCT technology-supported clinical trials. Allocation of Resources refers to the distribution of personnel, time, infrastructure, and financial investment across trial operations, including technology deployment, participant support, and staffing; Training Requirements capture the skills and competencies required of participants, investigators, and staff, such as digital literacy, technical troubleshooting, and protocol comprehension.

The findings illustrate wide variation in both the scope of resource allocation and the type of training needed. Some studies provided detailed financial or operational breakdowns, such as Anguera et al., 2016, which devoted significant resources to technology onboarding and full-time staff, or Lunn et al., 2019, which reported nearly $400,000 in design and development costs alongside recurring technology expenses. Lenze et al., 2020 similarly highlighted the intensity of staff commitment, with ~4,500 hours devoted to supporting participants. By contrast, many other studies did not quantify operational investments, pointing to a lack of standardized reporting in this area.

Training requirements reflected the nature of the intervention: app-based trials often emphasized digital literacy and comprehension quizzes (Bot et al., 2016; Chan et al., 2018), while medication-based trials required education on inhaler use or device monitoring (Boulware et al., 2023; Reiersen et al., 2023). More complex interventions demanded layered training, such as Sommer et al., 2018, where participants needed instruction on sensors, eDiaries, and protocol comprehension quizzes, supported by ongoing staff troubleshooting. Collectively, the table highlights that decentralized designs frequently shift operational burden toward technology platforms and participant-side digital engagement, underscoring the importance of adequate training and infrastructure investment to ensure data quality and participant compliance.

5| PARTICIPANT RECRUITMENT AND RETENTION

TABLE 5

Reference	Recruitment Method	Patients Screened	Patients Enrolled	Patients Randomized	Patients Completed	Evaluable Patients
Boulware et al., 2023	Hybrid	14,851	NA	2,042	NA	1,277 (656 fluticasone, 621 placebo)
Elliott et al., 2024	Hybrid	NA	140	NA	104	NA
Lenze et al., 2020	Hybrid	1337	181	181	115	152
McCarthy et al., 2023	Hybrid	17,320	NA	1,331	1,288	1,288
Naggie et al., 2022	Hybrid	13,731	3,457	1,800	1,591	1,591 total (817 ivermectin + 774 placebo)
Naggie et al., 2023	Hybrid	18,525	2,213	1,459	NA	1,432 (708 ivermectin vs 724 placebo)
Reiersen et al., 2023	Hybrid	2,475	670	670	NA	547
Sommer et al., 2018	Hybrid	318	23	NA	19	NA
Stewart et al., 2023	Hybrid	23,435	1,208	1,208	NA	1,175
Giboin et al., 2025	Site-based	NA	NA	NA	NA	1,048 (total contributing data; includes 1,008 HD + 40 controls)
Greer et al., 2024	Site-based	2,833 approached	1,250	1,250	630	620
Anguera et al., 2016	Web/App-based	2,923	1,098	626	450	626
Bot et al., 2016	Web/App-based	48,104	14,684	NA	8,320 (≥1 task)	9,520 broad-sharing cohort (but only 8,320 had usable data
Chan et al., 2018	Web/App-based	58,182 app downloads (48,054 U.S.)	10,010	NA	NA	5,875 (submitted survey data)
Griffith Fillipo et al., 2022	Web/App-based	NA	215	215	114	NA
Jones et al., 2017	Web/App-based	1,435	256	248	NA	NA
Jones et al., 2021	Web/Portal-based	~450,000 approached	15,076	15,076	~ 11,940 (≥51% follow-up)	NA
Lee et al., 2021	Web/App-based	25,000	10,036	NA	NA	NA
Li et al., 2022	Web/App-based	NA	17,556 (Prior removing malicious actors)	NA	NA	10,768
Lunn et al., 2019	Web/App-based	NA	13,932	NA	NA	NA
McConnell et al., 2017	Web/App-based	NA	48,968	NA	4,552 (7-day completers) - 4,990 (6-min walk test)	20,345
Nickels et al. 2021	Web/App-based	2360	465	NA	NA	384
Orri et al., 2014	Web/App-based	456	118	18	16	18 (safety) / 17 (efficacy)
Pratap et al., 2018	Web/App-based	4,502	1,040	274	NA	348

Skipper et al., 2020	Web/App-based	6,924	491	491	395	423
Sullivan et al., 2011	Web/App-based	30,559	9,005	NA	6,258	9,005

Table 5 summarizes participant flow for clinical trials using DCT components. Recruitment Method specifies how participants were approached (e.g., web-based outreach, site-based approaches, hybrid models); Patients Screened indicates the total number of individuals initially assessed for eligibility; Patients Enrolled reflects those who consented and entered the study; Patients Randomized shows the subset allocated to study arms in randomized controlled trials; Patients Completed represents those who reached study endpoints; Finally, Evaluable Patients includes the participants whose data were included in the analysis dataset.

Web/App-based recruitment methods consistently reached much larger pools of potential participants compared to hybrid or site-based approaches. For example, Jones et al., 2021 approached ~450,000 individuals through digital outreach, Chan et al., 2018 recorded 58,182 app downloads (48,054 in the U.S.), McConnell et al., 2017 enrolled 48,968 participants via an app, and Sullivan et al., 2011 screened 30,559 participants through online methods. Notably, Sullivan et al., 2011 achieved this scale within a remarkably short recruitment cycle time of just 1 month, underscoring the speed that web-based campaigns can deliver. However, this came at the cost of low conversion rates, with only a small percentage of those screened ultimately completing or contributing analyzable data.

6| KEY TAKEAWAYS & NEXT STEPS

This summary of studies in the literature provides case examples on the use and early impact of decentralized clinical trials components.

Across the published studies, reporting was inconsistent and often incomplete, with wide variation in how recruitment, retention, and adherence were defined and measured. These limitations make it difficult to compare outcomes or draw firm conclusions about best practices. Closing this evidence gap will require more robust methods, standardized and consistently gathered metrics, and systematic reporting of operational and performance data.

In addition to robustly gathering actual use data from sponsor companies and contract research organizations, the PACT consortium has now expanded its focus to include data from investigative sites using their own virtual and remote solutions and those provided by study sponsors. We look forward to compiling and analyzing this data, and to providing benchmarks on virtual and remote solutions use and its impact in future white paper reports.

PACT
Partnership for Advancing Clinical Trials

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EVIDENCE IN THE LITERATURE ON INVESTIGATIVE SITE USAGE AND EXPERIENCE WITH VIRTUAL AND REMOTE CLINICAL TRIAL SOLUTIONS

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