Patient Retention in Clinical Trials: Strategies & Impact

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Executive Summary

Patient retention is a critical determinant of clinical trial success. High dropout rates can introduce bias, undermine statistical power, delay trial completion, increase costs, and ultimately compromise the validity and reliability of trial results ([1] pmc.ncbi.nlm.nih.gov) ([2] pmc.ncbi.nlm.nih.gov). Seminal observations such as *Lasagna's Law* have long noted that "patient availability sharply decreases when a clinical trial begins" ([3] pmc.ncbi.nlm.nih.gov), highlighting that attrition is an endemic challenge. Contemporary analyses find that nearly half of trials lose more than 11% of participants, and loss to follow-up beyond ~20% is considered a serious threat to trial validity ([4] pmc.ncbi.nlm.nih.gov) ([5] pmc.ncbi.nlm.nih.gov). In practical terms, industry experience indicates that typical dropout rates vary by therapeutic area (e.g. ~8% in oncology Phase I trials) ([6] www.fiercebiotech.com) ([7] www.fiercebiotech.com), but can be far higher in challenging populations (e.g. ~26–44% in palliative cancer trials ([8] pmc.ncbi.nlm.nih.gov)). Even modest attrition forces investigators to inflate sample sizes (often by ~10–20%) to compensate. Recruitment and retention together now consume an estimated 30% of drug development timelines and billions of dollars annually ([2] pmc.ncbi.nlm.nih.gov) ([9] pmc.ncbi.nlm.nih.gov), so optimized retention is both a scientific and financial imperative.

To address this, trialists employ multifaceted strategies spanning trial design, participant support, and technology. Systematic reviews highlight that **no single "magic bullet" exists** and that effective retention typically requires deploying *multiple complementary approaches* ([5] pmc.ncbi.nlm.nih.gov) ([10] pmc.ncbi.nlm.nih.gov). Promising tactics include enhancing participant engagement and trust (through clear communication, patient-centered messaging, and staff rapport) ([11] pmc.ncbi.nlm.nih.gov) ([12] trialsjournal.biomedcentral.com); reducing burden (shorter visits, flexible scheduling, and remote monitoring) ([13] pmc.ncbi.nlm.nih.gov) ([11] pmc.ncbi.nlm.nih.gov); providing incentives or conveniences (stipends, travel reimbursements, or trial-branded materials) ([14] pmc.ncbi.nlm.nih.gov) ([15] pmc.ncbi.nlm.nih.gov); and leveraging technology (e-consent, e-diaries, telehealth, and AI-driven recruitment) ([16] pmc.ncbi.nlm.nih.gov) ([17] pmc.ncbi.nlm.nih.gov). Real-world case studies underscore the potential gains: for example, a mid-trial intervention in a diabetes study cut dropout from 45% to 16% ([18] pmc.ncbi.nlm.nih.gov), and a decentralized low-back-pain trial achieved **89%** study completion vs **60%** for the conventional arm ([16] pmc.ncbi.nlm.nih.gov).

This report provides a comprehensive analysis of patient retention in clinical trials. We review historical context, quantify the impact of poor retention, and examine the many factors driving dropout. We then present evidence-backed strategies (supported with data and expert opinion) to maximize retention, including both conventional and cutting-edge approaches. Multiple perspectives are considered—from trial sponsors and investigators to patients and regulators—and illustrative case studies are presented. Finally, we discuss emerging trends and future directions (such as decentralized trials and AI tools), and underscore that retention demands proactive planning and ongoing evaluation. Throughout, all claims are supported by peer-reviewed research and industry reports.

Introduction

Clinical trials depend on participants completing the prescribed follow-up to yield credible results. **Participant retention** (also called trial retention) refers to the *strategies and processes used to keep enrolled participants engaged in a trial and prevent withdrawals* ([19] pmc.ncbi.nlm.nih.gov) ([11] pmc.ncbi.nlm.nih.gov). Poor retention leads to missing outcome data and can introduce both bias and loss of statistical power ([1] pmc.ncbi.nlm.nih.gov) ([20] pmc.ncbi.nlm.nih.gov). Even "missing at random" data reduce power, while *differential* attrition (if dropouts differ systematically between arms or by health status) can bias results disastrously. Historical guidelines advise that losses under ~5% are generally acceptable, 5–20% quality-warning thresholds, and over ~20% a serious threat ([4] pmc.ncbi.nlm.nih.gov).

Yet dropout is common. Surveys indicate that 50–60% of trials fail to meet enrollment targets and a quarter of trials report >10% outcome data missing ([4] pmc.ncbi.nlm.nih.gov) ([21] pmc.ncbi.nlm.nih.gov). Regulatory and methodology consortia have identified improving retention as a top priority for trials research ([22] pmc.ncbi.nlm.nih.gov) ([20] pmc.ncbi.nlm.nih.gov). In the UK, only ~56% of publicly funded trials reach full target recruitment without time extensions ([22] pmc.ncbi.nlm.nih.gov), and attrition further compounds these failures. Lost recruitment and retention cost both time and money: for example, one report estimates industry loses $600,000–$8 million *per day* of trial delays, with recruitment and retention largely driving such delays ([2] pmc.ncbi.nlm.nih.gov).

At the same time, ethical imperatives underscore retention: each human volunteer who contributes data expects that their participation yields useful results. Extending trials or repeating studies due to attrition exposes additional patients to experimental procedures unnecessarily. Regulatory guidance (e.g. </current_article_content>FDA and ICH) emphasizes preserving data from dropouts ([23] www.fda.gov) and minimizing unnecessary risks, underscoring why retention strategies are integral to both science and ethics.

Historical Context

The challenge of keeping participants engaged is long-recognized. In 1970, Lasagna articulated that *"the incidence of patient availability sharply decreases when a clinical trial begins"* ([3] pmc.ncbi.nlm.nih.gov), illustrating that simply recruiting a sufficient sample is a chief bottleneck for trials. This "Lasagna's Law" implies an immediate hit to study power. Over past decades, methodological reviews have lamented the dearth of rigorous data on retention tactics ([1] pmc.ncbi.nlm.nih.gov) ([20] pmc.ncbi.nlm.nih.gov), noting that most knowledge came from investigator "lessons learned" rather than hard trials.

Early systematic analyses identified many potential strategies but few high-quality evaluations. For example, a 2007 review found only 21 eligible studies and cataloged 368 different retention tactics grouped into 12 broad themes ([5] pmc.ncbi.nlm.nih.gov). It noted that trials employing a **larger number of strategies** tended to fare better: studies with average retention (~86%) used many methods, whereas low-retention studies often used fewer strategies ([5] pmc.ncbi.nlm.nih.gov). Cochrane updates (e.g. Gillies et al.) as of 2020 similarly found no retention intervention supported by "high-certainty" evidence ([24] pmc.ncbi.nlm.nih.gov). In other words, there is consensus that retention matters, but uncertainty remains about which singular approaches are most effective.

Advances in technology and trial design in recent years have introduced new possibilities. The shift towards *patient-centric* and *decentralized* trials—leveraging e-consent, telehealth and mobile apps—has created opportunities to reduce participant burden, but these modern methods also require careful evaluation to ensure they do, in fact, improve retention. This report brings together both classic and novel perspectives to address these questions comprehensively.

Impact of Dropouts and Importance of Retention

Loss of participants (attrition) directly undermines trial validity. Missing data can cause bias if those who drop out differ from those who remain ([1] pmc.ncbi.nlm.nih.gov) ([20] pmc.ncbi.nlm.nih.gov). For instance, if sicker patients are more likely to withdraw, then outcomes may appear better than they are. Moreover, dropouts dilute effect sizes and reduce statistical power, meaning that a trial may fail to detect a true treatment effect. Common wisdom suggests attrition below ~5% has minimal impact, but above ~20% the risks become severe ([4] pmc.ncbi.nlm.nih.gov). Walters et al. estimate that about half of trials lose more than 11% of participants ([4] pmc.ncbi.nlm.nih.gov), highlighting how widespread the problem is.

Attrition also drives cost. **Every percent increase** in dropout may force the sponsor to recruit more participants (and associated costs) to hit their sample targets. Delayed trials accrue site costs and overhead; for example, one analysis noted that a single day of trial delay can cost industry $0.6–8 million ([2] pmc.ncbi.nlm.nih.gov). When many trials routinely extend timelines or fail to hit recruitment goals, the cumulative losses are enormous. In extreme cases, trials may be halted for futility due to poor retention.

Lost investments aside, ethical considerations are paramount. FDA guidance explicitly recommends keeping data from participants who withdraw ([23] www.fda.gov), reflecting that every volunteer's data are valuable once collected. When participants do consent and begin participation, trialists have an ethical responsibility to make every reasonable effort to keep them engaged—balancing respect for autonomy with the imperative to gather sound evidence.

Finally, retention is a key quality metric. Regulatory reviews (e.g. ICH E9) urge transparency in reporting attrition, and journals increasingly expect detailed accounting of dropouts. Good retention practices demonstrate respect for participants and subjects' rights, and increase confidence in study conclusions.

Factors Influencing Retention

Retention is multifactorial. Broadly, barriers to continued participation can be categorized into participant-related factors, trial design factors, site/staff factors, and external/societal factors (see **Table 1**). In practice, most trials face a combination of these, and successful retention plans address multiple categories simultaneously.

Barrier Category	Examples/Impacts	Mitigation Strategies
Logistical/Scheduling	*Geographical distance*, travel time/cost, and inconvenient study schedules (e.g. work conflicts). Lost-to-follow-up is often due to moved residence or inability to attend ([25] pmc.ncbi.nlm.nih.gov) ([26] pmc.ncbi.nlm.nih.gov).	Decentralized or home visits; flexible timing; travel reimbursement or provision of transport; remote data collection (phone/online questionnaires) ([16] pmc.ncbi.nlm.nih.gov) ([11] pmc.ncbi.nlm.nih.gov).
Participant Burden	*Long trial duration*, frequent clinic visits, invasive or unpleasant procedures (e.g. blood draws, biopsies). Studies lasting months especially challenge busy or ill participants ([13] pmc.ncbi.nlm.nih.gov) ([11] pmc.ncbi.nlm.nih.gov).	Simplify protocol: reduce visit frequency, shorten assessments; use less invasive methods; ensure follow-ups are as brief as possible ([27] pmc.ncbi.nlm.nih.gov) ([13] pmc.ncbi.nlm.nih.gov).
Health Status	Serious illness progression or acute symptoms can force dropout (e.g. hospitalization, death, symptom burden) ([28] pmc.ncbi.nlm.nih.gov). Chronic fatigue or worsening disease often leads to withdrawal.	Provide medical support and symptom management; frequent check-ins; allow rest periods; transition participants to standard care if needed (while still capturing outcome data).
Perceived Lack of Benefit	Participants may feel the intervention isn't helping ("lack of efficacy") or worry about being in placebo arm ([13] pmc.ncbi.nlm.nih.gov) ([29] www.news-medical.net). If standard care seems preferable, motivation drops.	Clear communication of purpose and potential benefits; emphasize altruistic value of contributing to science ([12] trialsjournal.biomedcentral.com); engage physicians to encourage (counter physician discouragement) ([30] www.news-medical.net).
Psychological/Fear	*Fear of side effects* or procedures; anxiety about being "experimented on"; stigma (especially in HIV or psychiatric	Provide thorough, understandable education at consent; foster trust and rapport; offer counseling/support; mitigate fears via peer

Barrier Category	Examples/Impacts	Mitigation Strategies
	trials) ([31] www.news-medical.net). Dropout also follows negative publicity or rumors.	testimonials or success stories ([12] trialsjournal.biomedcentral.com) ([11] pmc.ncbi.nlm.nih.gov).
Communication/Trust	Misunderstanding of trial commitments, or lack of contact from the study team can disengage participants. Poor rapport with staff is frequently noted in dropouts ([32] pmc.ncbi.nlm.nih.gov) ([11] pmc.ncbi.nlm.nih.gov).	Assign a dedicated coordinator to maintain contact; `"personal touches"`: regular calls, thank-you notes, and birthday cards to show appreciation ([11] pmc.ncbi.nlm.nih.gov); training staff in empathy; multilingual materials.
Socioeconomic/Cultural	Financial constraints (lost wages, childcare costs), education level, language or cultural barriers. Participants in disadvantaged groups often have higher dropout risk ([33] www.news-medical.net) ([34] pmc.ncbi.nlm.nih.gov).	Offer stipends or reimbursements; flexible scheduling; patient navigators or advocates; culturally sensitive materials; involve community leaders; ensure representation in trial materials (multilingual consent, etc.).
Trial Design	Overly strict criteria, complex consent, or insufficient involvement of stakeholders. Excessive data collection points increase burden (observed as a top barrier) ([13] pmc.ncbi.nlm.nih.gov) ([27] pmc.ncbi.nlm.nih.gov).	During protocol design, involve patients and recruiters; streamline eligibility; eliminate unnecessary procedures; pilot test the protocol for feasibility; seek ethics board feedback on burden.
Site/Staff Factors	Inconsistent follow-up procedures, poorly trained staff, or lack of accountability at trial sites lead to loss. Investigator interest affects patient motivation.	Standardize retention plan at all sites; train and incentivize site staff on retention; monitor site performance to address issues early; create a site competition or recognition for good retention.

Table 1. Major barriers to retention and corresponding mitigation strategies. Sources: systematic reviews and trial reports ([25] pmc.ncbi.nlm.nih.gov) ([26] pmc.ncbi.nlm.nih.gov) ([13] pmc.ncbi.nlm.nih.gov) ([11] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov) ([31] www.news-medical.net).

Participant-Related Factors

Participants' personal circumstances and perceptions powerfully shape retention. Surveys show demographics (age, gender, socioeconomic status, education) and health status influence dropout. Vulnerable populations tend to have higher attrition: for example, elderly or frail patients drop out more due to comorbidities, cognitive issues, or transportation challenges ([35] www.news-medical.net). Pediatric trials often face retention hurdles as surrogate decision-makers (parents) may be wary of unknown long-term effects ([36] www.news-medical.net). Social factors (e.g. stigma around disease) can deter ongoing participation. A U.S. survey found that factors like distance and apprehension about being a "guinea pig" affected eligible patients' willingness to join or continue in trials ([37] pmc.ncbi.nlm.nih.gov). Recent research underscores that diversity factors – including race/ethnicity, culture, and language – also affect retention ([34] pmc.ncbi.nlm.nih.gov), prompting calls to integrate health equity considerations in trial design.

Psychosocial elements are important. Many participants drop out due to fears (side effects, procedures) or family/physician discouragement ([31] www.news-medical.net). Emotional support from study staff is therefore crucial. One single-center review found that 90% of their dropouts were lost to follow-up, often because participants changed phone numbers or moved away ([25] pmc.ncbi.nlm.nih.gov) ([26] pmc.ncbi.nlm.nih.gov). This illustrates that mobility and communication gaps frequently underlie attrition. Identifying who is "at risk" is also

key: for example, in one diabetes trial, being single, having chronic pain, or worse baseline function predicted dropout ([18] pmc.ncbi.nlm.nih.gov), suggesting that retention efforts might be targeted to such subgroups.

Trial Design Factors

The way a trial is designed can encourage or deter retention. Complex or burdensome protocols are the most frequently cited barriers to continued participation ([13] pmc.ncbi.nlm.nih.gov). In a survey of research coordinators, 60% cited *trial length* as the primary determinant of poor retention, followed by 43% citing participants' belief that the treatment had no benefit ([13] pmc.ncbi.nlm.nih.gov). Similarly, overly frequent or lengthy visits impose time and cost burdens on participants. For instance, reducing a 12-visit schedule can markedly improve retention.

Conversely, patient-centered design can boost commitment. Engaging patients early (via advisory boards or pilot testing) can ensure the protocol addresses real patient needs. The U.S. trial in prostate cancer (described later) emphasized **trust, communication, and setting clear expectations** from the outset, which facilitated subsequent retention ([12] trialsjournal.biomedcentral.com). Planning also extends to informed consent and education: documents and conversations that emphasize respect for volunteers and transparent information help participants commit to the full study. Indeed, a perspective piece reported that compassionate, accessible explanations by staff increased patient ease and compliance ([11] pmc.ncbi.nlm.nih.gov).

Inadequate eligibility criteria can indirectly affect retention. For example, excluding patients unwilling to complete long follow-up, or not anticipating the needs of high-risk patients, can lead to higher dropout. The case study below (MemAID trial) shows that changing inclusion criteria mid-study reduced dropout in that population ([18] pmc.ncbi.nlm.nih.gov). Thus, pragmatic, flexible criteria and process are preferred.

Site and Staff Factors

The trial staff and site environment play a pivotal role. Engaged, well-trained coordinators can form strong bonds with participants, which dramatically improves retention ([32] pmc.ncbi.nlm.nih.gov) ([12] trialsjournal.biomedcentral.com). One site reported dropout rates as low as 3–8%, directly attributing this success to *"appropriate/compassionate communication"* and rapport-building by coordinators ([32] pmc.ncbi.nlm.nih.gov). By contrast, inconsistent follow-up practices or turnover in staff can dissuade participants. Engaging the investigator's enthusiasm helps too: participants often take cues from their primary physician or study doctor's attitude.

To maximize retention, sponsors should invest in staff training focused on retention. Practical measures include keeping 24/7 contact lines, reminding participants politely of upcoming visits (via phone, text, or email), and personalizing interactions ([11] pmc.ncbi.nlm.nih.gov) ([13] pmc.ncbi.nlm.nih.gov). The human element (sense of being cared for) is repeatedly emphasized in the literature.

Finally, site location and setting matter. Studies have found that proximity to the patient's home is critical: distance to site is a well-known barrier ([38] pmc.ncbi.nlm.nih.gov). Having sites conveniently located or offering home visits can mitigate this issue (see case studies).

External and Societal Factors

External events and broader context can impact retention. The recent COVID-19 pandemic is a prime example: it forced many trials to switch to remote (virtual) visits, sometimes causing dropouts but also revealing the

potential of telemedicine to sustain follow-up. Going forward, agents like telecommunication, mobile apps, and home delivery of study medications (all accelerated by the pandemic) are increasingly incorporated to improve retention (see later section on technology).

Cultural context and policy environment also influence retention. Regulatory pressure for participant safety and data quality (e.g. from IRBs, funding agencies) means sponsors must plan retention carefully in advance. Conversely, excessive bureaucracy can hinder retention efforts. For instance, complex approval processes for retention interventions (like home visits) can slow their implementation. Community attitudes (e.g. media reports about trial risks) can also sway participant willingness.

In summary, retention is affected by a web of personal, logistical, and systemic factors. A successful retention plan is multifaceted and tailored to the study population.

Strategies to Improve Retention

Given the multi-causal nature of dropouts, **multifaceted strategies** are necessary. Below we detail the principal categories of retention strategies identified in the literature, along with evidence or expert opinion on their effectiveness. Many approaches overlap in practice, and the best programs use synergies among them.

Engagement, Communication, and Trust

A cornerstone of retention is building **trust and engagement** with participants. Multiple studies highlight that when participants feel respected, informed, and connected to the study, they are more likely to stay. This includes:

- **Clear and respectful information**: During consent and follow-ups, explaining the trial's purpose, requirements, and potential benefits in plain, friendly language is crucial ([11] pmc.ncbi.nlm.nih.gov) ([12] trialsjournal.biomedcentral.com). Workshops on health literacy suggest that demystifying procedures reduces anxiety (thus reducing dropout).
- **Personalized contact**: Consistent, friendly contact by the study team keeps participants engaged. Personalized reminders (phone calls, text messages, e-mails) before visits maintain a sense of responsibility and appreciation ([11] pmc.ncbi.nlm.nih.gov) ([39] pmc.ncbi.nlm.nih.gov). For example, sending reminder calls and even small gestures like thank-you notes or birthday cards has been recommended as a way to make participants feel valued ([11] pmc.ncbi.nlm.nih.gov). One trial site found that such "personal touches" and empowering participants in their care led to sustained compliance ([11] pmc.ncbi.nlm.nih.gov).
- **Physician and staff involvement**: Involving participants' own doctors or respected clinicians in recruitment and follow-up communications can improve retention. The prostate cancer e-consent trial found that **physician involvement and positive staff attitudes** ("attitude" theme) strongly facilitated retention ([40] trialsjournal.biomedcentral.com). Participants are more likely to stay if they sense their physician or study doctor endorses the trial. Training site staff to be positive and responsive is therefore key.
- **Community and family engagement**: Leveraging community networks and involving family can remove barriers. This may include organizing informational sessions in the community, holding participant "camps" or meet-ups, and engaging local leaders in endorsing the study. For example, one perspective recommended community involvement and setting up patient support events (e.g. group meetings, newsletters) as part of retention efforts ([41] pmc.ncbi.nlm.nih.gov). Where appropriate, forming patient advisory boards or peer-worker programs also helps (see PPI section).
- **Cohort "identity" and branding**: Creating a sense of belonging can be surprisingly effective. Some trial coordinators suggest using study logos on materials, giving out trial-themed items (pens, mugs, tote bags)

or naming the trial with a memorable acronym ([42] pmc.ncbi.nlm.nih.gov). These efforts reinforce commitment. (Indeed, the Cochrane review noted that offering a pen at recruitment increased questionnaire return rates ([14] pmc.ncbi.nlm.nih.gov).)

Critically, the quality of the relationship between participant and staff often makes or breaks retention. Investigators report that *empathy, cultural sensitivity, and 24/7 accessibility* of study personnel can yield retention rates above 95% even in disadvantaged populations ([43] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov). Table 2 (below) lists some communication-based strategies and their documented outcomes.

Simplifying and Adapting Study Design

Protocol and visits should be as convenient as possible. Key measures include:

- **Flexible scheduling**: Allowing participants to choose among different appointment times (including evenings/weekends) greatly reduces conflicts with work or schooling.
- **Fewer/shorter visits**: Consolidating assessments so a participant makes fewer trips reduces attrition. For example, if some study procedures can be combined into a single visit, or if remote data collection is used for certain measurements, participants are more likely to stay. Recent trials have implemented home-based follow-ups or telemedicine check-ins to lessen travel burden.
- **Home visits or local testing**: Where possible, conducting visits at the participant's home (or using local clinics/phlebotomy services) instead of requiring travel to a distant site can retain participants who otherwise would drop out ([25] pmc.ncbi.nlm.nih.gov) ([11] pmc.ncbi.nlm.nih.gov). This strategy often requires careful logistics but can pay dividends in retention.
- **Protocol complexity**: During protocol development, sponsors should ensure criteria are pragmatic. Complex eligibility (many exclusions), excessive data collection points, or burdensome diaries all raise dropout risk ([27] pmc.ncbi.nlm.nih.gov) ([13] pmc.ncbi.nlm.nih.gov). For instance, one suggestion is to screen out individuals unlikely to adhere ([44] pmc.ncbi.nlm.nih.gov), or modify criteria mid-study to include previously ineligible participants (as done in the MemAID trial) to improve retention ([45] pmc.ncbi.nlm.nih.gov) ([18] pmc.ncbi.nlm.nih.gov).
- **Participant convenience**: Provision of conveniences like parking vouchers, on-site childcare, meals during visits, or even entertainment/nursing for pediatric trials can reduce dropouts, especially for long studies. These have not always been formally evaluated, but are widely recommended by trialists (see, e.g., Smith et al. in *Clinical Researcher*).

The overall aim is to minimize the **burden-to-benefit ratio** for participants. The more participants feel that staying in the study is easy and worthwhile, the more likely they will complete it.

Incentives and Support Services

Monetary and material incentives can improve retention, although evidence is mixed. In the Cochrane review, interventions combining a monetary reward with reminders or prenotification showed *moderate* evidence of benefit ([24] pmc.ncbi.nlm.nih.gov). For example, participants offered completion bonuses were more likely to return follow-up questionnaires. Other studies report that small tokens (pens, gift cards) can increase mail-in response rates ([24] pmc.ncbi.nlm.nih.gov). However, financial incentives must be used ethically (avoiding undue influence).

Support services can function as non-monetary incentives. Common examples are:

- **Reimbursements**: Paying for participant travel, lodging, or per-diem compensations acknowledges that participants invest time and resources. This is standard practice in many trials (especially large multicenter trials).
- **Health-related benefits**: Offering health screenings or ancillary health services (e.g. free blood pressure checks, vaccinations) to trial participants has been noted as a retention tool by some investigators.
- **Information and education**: Ensuring participants learn useful information about their condition or how to manage it can act as an incentive to stay (part of "attitude" in patient-centered design ([12] trialsjournal.biomedcentral.com)).
- **Participant camps or events**: At some sites, investigators organize group events or educational sessions for participants (and sometimes families) to reinforce community. These can take the form of one-day patient gatherings to share progress, or annual celebrations. This approach was highlighted in an Indian retention perspective as effective in LMIC settings ([43] pmc.ncbi.nlm.nih.gov).

Overall, incentives should be meaningful to the target population. What motivates a young healthy volunteer (money, free travel) may differ from motivations of an elderly patient (feeling helpful, receiving closer monitoring).

Patient and Public Involvement (PPI)

In recent years, engaging patients and the public in trial design – often called Patient and Public Involvement (PPI) – is advocated to boost both recruitment and retention ([46] pmc.ncbi.nlm.nih.gov). Meaningful PPI includes having patient representatives on protocol committees, involving patient advocacy groups, and seeking input on participant-facing materials.

Meta-analysis suggests PPI **modestly improves enrollment** (pooled OR ~1.16 for recruitment) ([46] pmc.ncbi.nlm.nih.gov). The evidence for retention is less clear, largely due to few high-quality studies; pooled data showed no statistically significant difference in retention with PPI (OR ~1.16, 95% CI 0.33–4.14) ([46] pmc.ncbi.nlm.nih.gov). However, intangible benefits include aligning the trial with participant priorities, which is presumed to improve engagement. Diamond et al. and others note that involving people with lived experience in trial design (setting realistic follow-up expectations, patient-friendly schedules) can plausibly reduce dropout even if trial data is lacking.

One way to incorporate PPI is through advisory boards or community liaisons who can identify potential retention barriers in advance. For example, the Ontario trials group reported appointing a local patient liaison who remained in contact with participants; such roles are increasingly viewed as best practice. ([12] trialsjournal.biomedcentral.com). Given that PPI in trial methodology is a growing area of emphasis (e.g. NIHR's expectation of active involvement ([47] pmc.ncbi.nlm.nih.gov)), sponsors should include PPI activities in retention planning, even as more data on their efficacy accumulates.

Reminder Systems and Follow-Up

Active participant tracking is a basic yet potent strategy. This includes:

- **Multiple contact methods**: Collecting extensive contact information (phone, email, address) and alternative contacts (friends/family) helps reduce loss-to-follow-up ([25] pmc.ncbi.nlm.nih.gov). Regularly updating this information at each visit minimizes outdated addresses.
- **Automated reminders**: Using text messaging (SMS), phone calls, or emails to remind about upcoming visits or to complete diaries. A growing body of evidence, especially from longitudinal cohorts, shows that regular

SMS reminders increase adherence to study tasks ([48] pmc.ncbi.nlm.nih.gov). For example, in one birth cohort, participants who received daily text prompts wore their study accelerometer significantly longer (165h vs 145h on average) than those without prompts ([48] pmc.ncbi.nlm.nih.gov). Though this was a cohort setting rather than an RCT, it illustrates the power of simple automated contact.

- **Scheduling prompts**: Phone reminders 24–48 hours before a visit reduce no-shows. Study coordinators may also send thank-you messages after visits to reinforce a positive relationship.
- **Tracking missed appointments**: Immediate follow-up if a participant misses a visit (calling the same day) shows commitment and can quickly reschedule, preventing drift.

These methods turn retention efforts into a continuous dialogue rather than a client-centered one-off.

Technology and Decentralized Approaches

Innovative technologies are transforming retention strategies:

- **Electronic consent (eConsenting)**: Using tablets or online platforms can improve understanding (via multimedia) and streamline enrollment, making it easier for participants to join and stay in the trial ([49] pmc.ncbi.nlm.nih.gov).
- **eDiaries and portals**: Digital patient diaries (for symptoms, medication, etc.) reduce paper burden and allow real-time monitoring of engagement. For instance, in the low-back-pain trial, an electronic diary was well accepted, and remote data capture tools facilitated the decentralized model ([16] pmc.ncbi.nlm.nih.gov). Such tools often include automated reminders (as noted above) to fill entries.
- **Telemedicine visits**: Replacing some in-person visits with video calls or phone check-ins significantly increases convenience. In the low-back-pain study by Sommer et al., a decentralized (telemedicine-based) arm not only recruited more patients but achieved *89% completion* vs *60%* in the traditional clinic arm ([16] pmc.ncbi.nlm.nih.gov). This provides strong evidence that remote follow-ups can boost retention. Across broader practice, the COVID-19 pandemic has shown that many study visits can be done remotely without loss of data integrity (with appropriate protocols).
- **Wearable and mobile monitors**: Wearable sensors (e.g. activity trackers, glucose monitors) and mobile apps engage participants by integrating with daily life. They can also reduce site visits. Research indicates that providing participants with useful devices (like a glucometer) can be incentivizing ([50] pmc.ncbi.nlm.nih.gov). Gamification (like progress dashboards or feedback) can further engage some populations (though evidence here is still emerging).
- **Artificial Intelligence (AI)**: AI and machine learning tools have been used primarily for recruitment (e.g. finding eligible patients in EHRs), but their predictive analytics may also identify at-risk dropout patterns. A notable example: in one trial, an AI platform (Deep 6 AI) identified 16 potential participants in *1 hour*, versus only 2 found by traditional methods over 6 months ([17] pmc.ncbi.nlm.nih.gov). While this example concerns recruitment, it underscores how technology can streamline subject management overall. Emerging systems may in future flag participants who miss visits frequently, prompting targeted outreach.

In sum, digital tools create a more participant-friendly experience. Table 2 below lists several tech-enabled strategies and their impacts on retention.

Staff Training and Site Management

Well-trained sites are the front line of retention. Sponsors should systematically orient site teams on retention plans. This includes:

- **Retention protocols**: Just as trials have standard operating procedures (SOPs) for recruitment, sites should have a written retention plan and checklists (following the *SWAT* model for Study Within A Trial ([51] pmc.ncbi.nlm.nih.gov)). These can cover regular data monitoring to flag dropouts early.
- **Performance monitoring**: Tracking each site's retention rates in real time allows prompt action. Underperforming sites might receive additional support or training.
- **Incentives for sites**: Some companies introduce site-level incentives (e.g. bonuses or co-authorship for high retention) to motivate coordinators. Although risks of site-level incentives must be managed carefully, positive reinforcement for engagement is common in industry practice.
- **Staff continuity**: Minimizing turnover of coordinators is critical since personnel changes can disrupt relationships. Sponsors often recommend "shadow" staffing so that multiple team members are familiar with each participant.

These measures ensure that sites do not inadvertently become retention barriers.

Special Measures for Hard-to-Reach Populations

Certain groups may need additional support:

- **Underserved or Low-Income**: Provide extra reminders, home visits, or even child care during visits. For example, "participant camps" (multi-session health camps) have been reported to improve retention in low-income settings ([43] pmc.ncbi.nlm.nih.gov).
- **Elderly patients**: Simplify instructions and ensure transportation assistance (e.g., ambulance services if needed). Regular wellness checks by phone can maintain connection.
- **Language/cultural barriers**: Employ multilingual staff, translate informed consent/diaries, and engage cultural liaisons. Providing interpreters or community health workers can help sustain participation.
- **Rural populations**: Decentralized trial models (as noted above) allow rural patients to participate without long travel. In the low-back-pain study, the decentralized arm had *"increased participation from rural areas"* ([16] pmc.ncbi.nlm.nih.gov), indicating that telemedicine effectively reached people miles from the site.

Summary of Evidence and Best Practices

Table 2 below synthesizes examples of retention strategies from the literature and their observed effectiveness. While no single tactic is foolproof, each can contribute. Experts agree that deploying a **"retention toolkit"** covering multiple themes is best practice ([5] pmc.ncbi.nlm.nih.gov) ([52] pmc.ncbi.nlm.nih.gov).

Strategy Category	Example Interventions	Evidence/Outcome
Reminders & Follow-Up	Phone/SMS/email reminders, thank-you notes, birthday cards ([11] pmc.ncbi.nlm.nih.gov); schedule tracking and contact updates ([25] pmc.ncbi.nlm.nih.gov) ([53] pmc.ncbi.nlm.nih.gov).	Increases compliance: one cohort using daily SMS had higher device-wear time (165h vs 145h) ([48] pmc.ncbi.nlm.nih.gov). Personalized calls and notes are *anecdotally* linked to higher retention (e.g. one site cites ~3–8% dropout with such communication ([32] pmc.ncbi.nlm.nih.gov)).
Financial/Social Incentives	Monetary completion bonuses, voucher reimbursements; small gifts (pens, trial merchandise) ([24] pmc.ncbi.nlm.nih.gov) ([15] pmc.ncbi.nlm.nih.gov).	Moderate evidence: Cochrane review found *monetary rewards + prenotification* and giving a pen modestly improved follow-up rates ([24] pmc.ncbi.nlm.nih.gov). Reimbursements (travel, parking) are considered standard practice for

Strategy Category	Example Interventions	Evidence/Outcome
		reducing dropouts, though not always formally studied.
Patient Engagement & Support	Active participant involvement (advisory boards); ensuring staff treat participants as equal partners ([12] trialsjournal.biomedcentral.com) ([43] pmc.ncbi.nlm.nih.gov); counseling and flexibility for issues.	High retention with engaged approaches: The BC Healthy Connections trial (disadvantaged mothers) achieved 80–91% follow-up at five timepoints using intensive support and home visits ([54] pmc.ncbi.nlm.nih.gov). Studies note that empathy and 24/7 staff availability can yield retention >95% ([43] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov).
Decentralized/Tech Methods	Telemedicine visits, eConsent, mobile apps/e-diaries ([16] pmc.ncbi.nlm.nih.gov) ([55] pmc.ncbi.nlm.nih.gov); provision of home monitoring devices.	Effective in pilot: A Switzerland study reported 89% retention in a telehealth arm vs 60% in a standard arm ([16] pmc.ncbi.nlm.nih.gov). Digital technologies also received high patient satisfaction ([56] pmc.ncbi.nlm.nih.gov). Systematic reviews urge user-friendly tech to support patient autonomy ([55] pmc.ncbi.nlm.nih.gov).
Protocol Simplification	Streamlined eligibility, fewer assessments, and shorter visits ([27] pmc.ncbi.nlm.nih.gov) ([13] pmc.ncbi.nlm.nih.gov); trial-specific planning (e.g. narrative protocols anticipating retention challenges).	Generally accepted benefit: shorter trials and pragmatic criteria have consistently been recommended by experts ([27] pmc.ncbi.nlm.nih.gov) ([13] pmc.ncbi.nlm.nih.gov). Trials using fewer and more patient-friendly procedures tend to retain more participants (specific metrics vary).
PPI and Community Involvement	Early involvement of patient representatives; community outreach events.	Limited trial data: Systematic review found a non-significant improvement in retention with PPI (OR~1.16) ([46] pmc.ncbi.nlm.nih.gov). However, participant feedback suggests involvement can boost trust and ongoing engagement. Community-based retention programs have improved follow-up in observational research.

Table 2. Examples of retention strategies and evidence. Sources: systematic reviews, trials and expert reports ([24] pmc.ncbi.nlm.nih.gov) ([12] trialsjournal.biomedcentral.com) ([48] pmc.ncbi.nlm.nih.gov) ([54] pmc.ncbi.nlm.nih.gov) ([11] pmc.ncbi.nlm.nih.gov) ([43] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov) ([57] pmc.ncbi.nlm.nih.gov) ([46] pmc.ncbi.nlm.nih.gov).

Case Studies and Examples

To illustrate how retention strategies play out, consider these case studies:

1. MemAID Diabetes Memory Trial (Isaza-Pierrotti et al., 2022): This clinical trial investigated intranasal insulin in older adults with type 2 diabetes. Initially, 244 participants were enrolled, but dropouts soared (28.1% of those at risk) during the 24-week treatment. The investigators implemented enhanced retention measures mid-study — including protocol modifications and increased participant support per NIH guidance ([58] pmc.ncbi.nlm.nih.gov) ([18] pmc.ncbi.nlm.nih.gov). Retention strategies included higher remuneration (up to $1,000 for completion), meal provision, reminder calls, and allowed re-screening of newly eligible candidates ([59] pmc.ncbi.nlm.nih.gov) ([60] pmc.ncbi.nlm.nih.gov). As a result, dropout rate plummeted: before strategy changes, 45.2% of participants had dropped out; after, only 16.2% did ([18] pmc.ncbi.nlm.nih.gov). Importantly, the probability of completing the study climbed steeply with each additional day under the retention protocol,

reaching ~71% after ~90 days of engagement ([45] pmc.ncbi.nlm.nih.gov). This case highlights that even well into a trial, targeted retention efforts (tailored incentives, flexibility) can markedly salvage participation.

2. BC Healthy Connections Project (Catherine et al., 2020): In British Columbia, Canada, researchers ran an RCT of nurse home visits to support first-time mothers in socioeconomically disadvantaged communities. Their retention strategy was meticulously planned and multifaceted: they developed an a priori framework mapping retention activities across planning, recruitment, and maintenance phases, drew on literature, and tracked follow-up rates meticulously ([61] pmc.ncbi.nlm.nih.gov). Over four years of follow-up (during pregnancy and to age 2), they conducted 3,302 in-person or telephone interviews. Remarkably, completion rates were very high: 90% at late pregnancy, and 80–91% at successive postpartum follow-ups ([54] pmc.ncbi.nlm.nih.gov). Almost all participants (99%) consented to ongoing data linkage at study end ([54] pmc.ncbi.nlm.nih.gov). This was achieved despite the participants facing multiple disadvantages; the key was proactive retention planning, home visits (the trial involved the mother's home anyway), and strong relationships. The investigators conclude that *"retention is feasible"* even in hard-to-reach groups with the right methods ([54] pmc.ncbi.nlm.nih.gov) ([62] pmc.ncbi.nlm.nih.gov).

3. Decentralized Low Back Pain Trial (Sommer et al., 2018): This pilot study directly compared decentralized (telemedicine-based) vs conventional (clinic-based) trial conduct for patients with acute low back pain. Study technology included eConsent, e-diaries, and wearable sensors. In the decentralized arm (recruited via a telemedicine center), 89% of enrolled patients completed the study, whereas only 60% did in the traditional clinic arm ([16] pmc.ncbi.nlm.nih.gov). The decentralized arm also attracted a more rural and diverse population, implying better access. Participants in the telehealth arm reported uniformly high satisfaction with the eConsent, eDiary, and remote visits ([56] pmc.ncbi.nlm.nih.gov) (though some disliked the sensor). This case underlines that remote/virtual models, combined with digital tools, can **significantly improve retention** by eliminating travel and making participation more convenient.

4. Site-Specific Experience (Chaudhari et al., 2020): At one Indian clinical research center, over three years the observed drop-out rate across numerous trials was only **3–8%** ([32] pmc.ncbi.nlm.nih.gov). The investigators attribute this exceptionally low attrition to developing rapport with participants through compassionate communication and continuous availability of coordinators ([32] pmc.ncbi.nlm.nih.gov). They also mention use of approved recruitment materials (media, group sessions)and giving gifts like mosquito nets and glucometers in relevant trials ([63] pmc.ncbi.nlm.nih.gov) to keep participants invested. This anecdote underscores how intensive human factors (trust, respect, problem-solving support) at the site level can achieve very high retention.

These examples span diverse settings and populations, but common themes emerge: **tailoring strategies** to the participants and study context is essential, and layers of support (logistical, informational, and relational) can yield very high retention even in challenging scenarios.

Discussion and Future Directions

The research outlined above yields several conclusions and suggestions for future practice:

- **Comprehensive, Proactive Planning**: Retention cannot be an afterthought. As Catherine et al. note ([54] pmc.ncbi.nlm.nih.gov), designing a retention plan *before* recruitment and revisiting it regularly is critical. Protocols should include a retention workstream analogous to recruitment planning. Sponsors are beginning to recognize this: e.g. UK's NIHR and NIH have funded methodological initiatives (MRC START, Trial Forge) explicitly to find better retention methods ([9] pmc.ncbi.nlm.nih.gov).
- **Evidence Gaps**: It is clear from the Cochrane and other reviews ([24] pmc.ncbi.nlm.nih.gov) ([10] pmc.ncbi.nlm.nih.gov) that the evidence base needs strengthening. Many strategies are based on single studies or even expert opinion. More embedded *Study Within A Trial* (SWAT) evaluations of retention interventions are urgently needed, especially focusing on under-studied approaches like flexible scheduling, community engagement, or novel digital tools.

- **Personalization and Risk Profiling**: Emerging work suggests it may be possible to use baseline data to predict high-risk dropouts ([64] pmc.ncbi.nlm.nih.gov). Machine learning models trained on historical trial data could flag participants who might disengage, allowing targeted interventions (for example, assigning a retention "champion" or additional follow-ups to those individuals).
- **Technology Integration**: The trend toward e-health and mobile health (mHealth) is likely to accelerate. As the scoping review notes ([52] pmc.ncbi.nlm.nih.gov), the challenge will be to design technologies that support *intrinsic* motivation (e.g. fostering autonomy and relatedness) rather than just adding digital burden. For example, user-friendly apps that gamify assignment completion or create virtual communities could provide intrinsic rewards. Virtual reality or AI chatbots might eventually play roles in participant engagement.
- **Decentralized Clinical Trials**: The COVID-19 pandemic fast-tracked adoption of decentralized trial methods. Future hybrid or fully decentralized trials can make participation easier (home visits, local labs, remote device monitoring). Experience from pilot studies (like Sommer et al.) is promising, but larger trials should test whether such models reliably raise retention across diseases and demographics.
- **Patient-Centered Culture**: Ultimately, retention reflects the trial's alignment with participant needs and values. As more sponsors adopt patient-engagement frameworks (PCORI, FDA's patient-focused guidance, etc.), retention strategies will become more standardized. The example of using patient advisory panels to refine the recruitment message and schedule, as in Trials (2018) ([12] trialsjournal.biomedcentral.com), is likely to be emulated widely.
- **Policy and Oversight**: Regulatory guidelines could further incentivize robust retention planning. For instance, Institutional Review Boards (IRBs) could require a retention plan as part of protocol approval. Trial registries might start asking for retention targets or strategies, akin to reporting recruitment plans.

In summary, we recommend that trialists adopt a **participant-centric approach**: listen to potential volunteers' concerns, minimize burdens, engage communities, and continually treat participants as valued partners. Combining human elements (rapport, respect) with smart use of technology appears to be the future of retention-enhancement.

Conclusion

Patient retention is a **make-or-break** aspect of clinical trials. High attrition not only jeopardizes trial validity, but also translates into wasted resources and ethical pitfalls. As documented by numerous studies and as we have analyzed, retention depends on a spectrum of factors from the personal (participants' beliefs and circumstances) to the procedural (trial design, site management). Addressing retention requires an **integrated strategy**: build trust through communication and participant involvement, reduce burdens via flexible and decentralized approaches, and provide incentives and support as appropriate. No single tactic suffices; rather, deploying a *portfolio* of tailored interventions is key.

This report, drawing on systematic reviews, case studies, and expert recommendations, highlights both what is proven and what is promising in the field of retention. While some traditional methods (e.g. follow-up calls, reimbursements) remain staples, new innovations (text messaging platforms, AI screening, mobile apps) offer fresh opportunities. Crucially, retention must be considered at every stage of trial planning and execution. Investigators should create retention plans akin to recruitment plans, continuously monitor dropout rates, and be prepared to adapt if problems arise.

Finally, robust evaluation of retention strategies is needed. The relative lack of high-certainty evidence ([24] pmc.ncbi.nlm.nih.gov) ([10] pmc.ncbi.nlm.nih.gov) means we must continue researching "what works" in diverse settings. Surveillance of real-world retention efforts, combined with embedding SWATs, will help build best practices.

In conclusion, keeping participants from dropping out is both a science and an art. Trials that excel in retention invest time and creativity in understanding and meeting participants' needs. By doing so, they ensure better

data, faster answers, and ultimately more ethical and efficient research that honors the commitment of trial volunteers.

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