

WHITEPAPER

TRANSFORM PATIENT SAFETY AND DATA RELIABILITY IN DECENTRALIZED CLINICAL TRIALS

**with Remote Engagement, Self-Reported Outcome
Data and Improved Adherence**



spencer
health
solutions



INTRODUCTION

Uncertainty – around safely caring for patients and reliably collecting data – is the biggest barrier to the deployment of decentralized trials. While multiple articles and studies chronicled the concerns pre-COVID, the pandemic’s duration has forced the industry to accelerate adoption of remote, virtual and decentralized trials. Waiting out the novel coronavirus is simply not an option.

The stakes are high. More than half (56%) of patients indicated they were less willing to participate in trials due to COVID, and 80% were unwilling to visit the site for study appointments. As a result, trials enrollment has flagged. According to research from *GlobalData, Pharma Intelligence Center*¹ trials that had begun enrollment and secured sites and investigators are experiencing more trouble keeping enrolled subjects while trials that delayed launch are struggling to recruit. The research found that 7.2% of trials experiencing slow enrollment can’t find enough sites because of high COVID patient censuses or enough investigators because they have been reassigned to coronavirus activities.

NEXT-GENERATION DIGITAL HEALTH TECHNOLOGY

Strategic use of digital health tools may address concerns and makes new trial formats possible. But not just any tools. As mHealth has gained traction, we have learned three important lessons:

- 1. Connected care apps alone are not effective long-term.** According to *The Continued Use of Mobile Health Apps: Insights From a Longitudinal Study*, published in JMIR Mhealth & Uhealth in 2019: "... the use of mHealth tools has been limited, with reports suggesting that most individuals stop using them just before the fifth interaction, and a quarter of mHealth apps are used only once after installation. Although promising in its value, it is less likely that the intended benefits of mHealth app use, such as improved access and quality of care, are going to be realized through such short-lived uses of the apps."²
The takeaway: Apps may be a useful secondary support platform, but not primary. If you only use first-generation tools, you risk high drop-out levels which impacts study retention and relevance.
- 2. Patient portals in concert with digital tools have demonstrated value.** Writing in *Patient Engagement HIT*, Sara Heath noted that, "Providers like to use patient portals as a means to boost patient engagement because they serve both educational and communicative functions. This becomes incredibly useful as patients balance complicated treatment and medication regimens." Since we can't assume that all patients are comfortable with their cell phones, apps or even email, digital health tools must be simple to use and work for everyone. Effective portals feature uncluttered, simple interfaces that facilitate direct interaction with the solution or a care team member. Additionally, the mobile health study found, "Automatic data collection and simple data entry methods such as automatic food suggestions improve not only users' interactions with the app but also their satisfaction with the experience."
The takeaway: "Ultimately, when there is a good fit between users' needs and mHealth apps, continued use is likely to occur," Heath concludes, which enables a focus on patients with tools that simplify communication and support and boost patient engagement.

- 3. Patients have already integrated digital technology into their lives.** According to data from The Pew Research Center, most Americans (96%) own a mobile phone, 81% of them smartphones. They also own desktops or laptops (75%), tablets (50%)³ and e-reader devices (50%). Almost 75% of adults in the U.S. have broadband internet service at home⁴, including 63% of rural Americans.⁵
The takeaway: Engagement enables, empowers and supports the active involvement of patients and family members in their own care with the goal of improving patient-centricity, quality and safety. This includes interventions that increase activation and influence patient behavior.

Patients supplied with the spencer smart hub used the touch screen to answer health questions 75% of the time over a 36-month period. Tailored by disease, or personalized for individuals, the questions capture patient feedback with each medication dispense.

What does this mean for pharma?

Now is the time to integrate next-generation digital tech and devices into trials to boost the activation and engagement that yields serious return on investment:

- Increased patient safety and reduced drop-outs with personalized interventions prompted by real-time patient-reported and automated data-gathering
- Higher volume of more accurate real-world data and evidence
- Sustained participation and engagement via user-friendly interfaces, non-intrusive communications and highly relevant content



ENGAGEMENT IS THE LEVER THAT LIFTS PATIENT OUTCOMES

“The world of health information technology is continuing to grow, which has positive implications for both patient engagement and chronic disease management. As providers encounter new apps and devices, they will have to work them seamlessly into their workflows while maintaining the personal touch necessary for full patient engagement.”

Sara Heath, senior editor, *Patient Patient Engagement HIT*⁶

The landmark study, *What The Evidence Shows About Patient Activation: Better Health Outcomes And Care Experiences; Fewer Data On Costs*⁷, established the power of a person’s willingness and ability to independently manage their health. The research shows that highly engaged patients are more likely to make healthy life decisions and take advantage of regular check-ups, screenings and immunizations. Similarly, highly activated patients with chronic conditions are more apt to adhere to treatment and participate in self-monitoring at home. By contrast, less activated patients are three times as likely to have unmet medical needs and twice as likely to delay medical care than activated patients.

“Only about 15 to 20% of health-related outcomes are because of medical interventions” noted Dr. Wayne Jonas, MD, executive director, Integrative Health Programs, Samueli Foundation, in a *Psychology Today* article.⁸

The rest are related to health behaviors – like diet, physical activity, smoking status — and the physical, social, and economic environment that impact patients’ abilities to make healthy choices and access medical care.

“Behavior and lifestyle can impact up to 70 percent of chronic illnesses; therefore, healthy behaviors are essential for creating health,” Jonas continued. “But behavior change must be connected to what is meaningful for the person, or it cannot be sustained.”

SIMPLIFY THE COMPLEX TO ENGAGE IN A WAY PATIENTS WELCOME

To decrease frustration and increase continued participation, we must connect with patients in ways that aren't intrusive, occur when they are thinking about their health, and deliver content that is personalized and relevant to them and their condition. This strategy rewards patients for engaging so they take medications as prescribed and continue providing automated and direct data-gathering. Here are four examples:

1. **Deploy custom surveys to gather multiple levels of qualitative patient and quantitative group data.** For example, Catalyst Healthcare has taken thousands of readings from spencer in-home units. During the COVID-19 crisis, using the spencerCare™ dashboard, pharmacists were able to gain clear visibility into medicines taken, patient responses to health status and added symptom questions. The data could then be aggregated for population health analysis. Their data showed that 153 people answered yes to having one or more of the respiratory symptom questions over a 3-month period and pharmacists followed up with direct outreach.
2. **Passively collect real-word data (RWD).** Passive biometrics and digital tracking data can be added to EHRs, product and disease registries, and patient-reported and mobile-enabled health status. This more complete set of RWD enables you to report real-world evidence (RWE) of usage, benefits and risk.
3. **Deliver content that motivates healthy behaviors and improves outcomes.** A study published in the *Journal of Medical Internet Research* shows the value of delivering relevant content via a patient portal to promote and nurture healthy habits. Automated messaging reminded patients to eat healthier and get more exercise, producing a 0.53% decrease in hBA1c levels, which reduces likelihood of myocardial infarctions and microvascular complications.⁹
4. **Improve safety.** Patients don't suddenly stop taking meds in a trial unless there is a problem or a safety event. Tracking daily adherence levels in near-real time allows the medical monitoring team or site coordinator to use data trends to mitigate potential problems and keep patients safe.

ADHERENCE IMPACTS PATIENT OUTCOMES

Adherence to prescribed medication is a coveted but rarely achieved goal of clinicians in research and everyday health and medication management.

Sadly, the average is about 50-55% adherence to protocol¹⁰, which impacts investigational drug studies in hidden ways, such as increasing variance, lowering study power and reducing the magnitude of treatment effects.¹¹ If [40% of trial participants](#)¹² stop taking the study drug properly within 5 months, trial sponsors must increase the sample size 200% to maintain the same statistical power.

“That’s why adherence data is mission-critical,” notes Alan Menius, chief scientific officer at Spencer Health Solutions. “When you’re trying to prove effectiveness, patients who were supposed to be taking the investigational drug but aren’t become a member of the comparative group. Unfortunately, without accurate adherence data, researchers don’t have visibility to that. The result? The effect of the drug looks smaller or the variability of the results prevents making a conclusion.”

The pandemic is another challenge to adherence. According to the PPD Decentralized Clinical Trials Survey Report¹³, patients’ ability to visit investigator site(s) is the area most impacted by the pandemic (57%). Remote site visits and monitoring are the most important clinical trials pandemic mitigation strategies; 69% of trial managers have already implemented them. Source: *PPD Decentralized Clinical Trials Survey Report*¹³

The challenge now, given patients’ apprehension to travel, is tracking medication adherence and patient compliance and support from the home.

“We have to satisfy [patient expectations of increased remote care](#) and encourage their willingness to engage with technologies that help keep them distanced if we want to get real-time longitudinal data access and adherence information from the safety of their homes,” Rhoads says.

For example, research shows an in-home electronic medication dispensing system (MDS) consistently deliver high adherence among chronically-ill patients.

“The average medication adherence recorded by the MDS over the six-month study duration was 98.35%,” noted the authors of *Mitigating the Effects of Nonadherence in Clinical Trials*.¹⁴ “The high adherence was reported in two existing studies related to medication dispensing technology; their participants’ average adherence over six months of data collection varied from 97–98%.” The study also noted that, “Older adults find the devices acceptable, easy to use, and supportive of their daily activities. Users further report a perceived improvement of medication adherence and health outcomes.”

“No matter what you throw at spencer, patients remain adherent,” Menius says. “I haven’t found a comorbidity or demographic where patients using spencer are non-adherent.”



“MDS can be an effective, long-term solution to medication non-adherence in older adults experiencing chronic conditions and taking multiple medications. The technology induces better consistency and improvement in medication taking behaviour than simple, non-technological intervention.”

SOURCE: Mitigating the Effects of Nonadherence in Clinical Trials

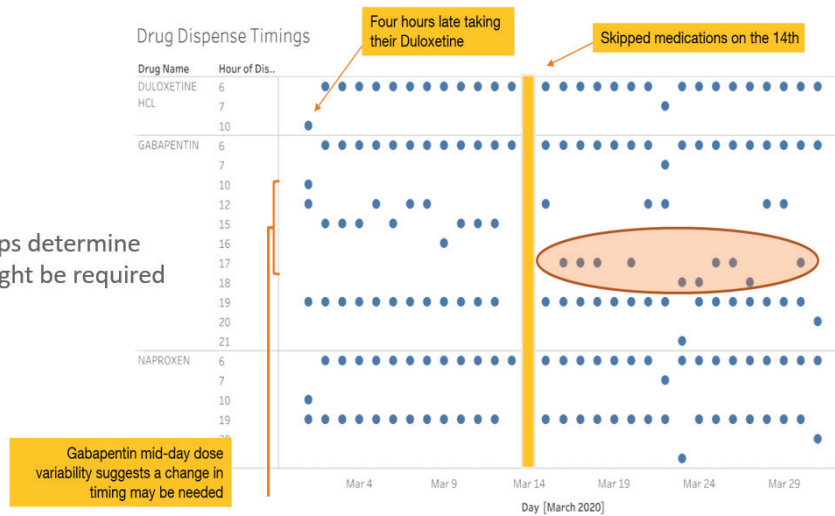
ADHERENCE IS MORE THAN A SINGLE DATA POINT

It's not enough to know simply that patients took their meds. Truly relevant real-world adherence data includes multiple points:

- 1. Are patients taking the medication? Reminders and alerts help patients stay on schedule and allow dose monitoring, but it's a tiny piece of the adherence puzzle.** Data shows that adherence is higher when patients have a fully connected healthcare experience with clinical team, which is made possible via the portal.
- 2. Are they taking it as prescribed?** Protocol compliance and patient engagement keep patients on therapy so data can be collected and used. Non-compliance may cause the patient to be removed from the study, which costs time and money. From a safety perspective, double-dosing can put patients in danger. Medications taken within 2 hours of each other may result in toxicity. Real-time alerts enable you to deliver timely patient outreach and immediate intervention.

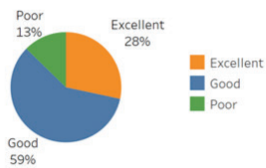
Real-Time Data

Near real-time data helps determine where interventions might be required

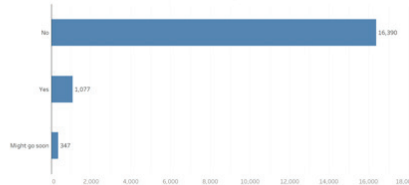


- 3. Do they have concerns or issues?** Patients don't usually stop medication on a trial because they forget to take the drug. Drop-outs are driven by multiple factors including side effects and serious adverse events. Clinical trials already have a high degree of accountability and engagement with paper or eDiaries and site interactions on routine levels dictated by a protocol's schedule of events. Automated engagement surveys provide even more context, empowering patients to proactively ask for outreach or alerting the clinician to follow data that indicates a need for intervention. If post-medication survey questions were being asked, the clinician would see how patients are feeling and responding which could mitigate any potential health issues or changes in how the patient is taking their medication. Real time data enables you to watch for trends that may signal an issue with the drug or health crisis.

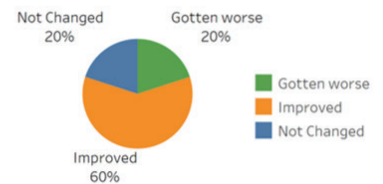
How do you feel?



Recent hospital, ER or Urgent care visit?



Since starting my antidepressant my depression has:



HEALTHCARE INNOVATION ENABLES DECENTRALIZED TRIALS

- **Real-time analytics and insights** support analysis and intervention so you can force multiply your clinic site teams with proactive outreach and content.
- **Telehealth** capabilities make possible virtual check-ins that keep patients engaged, safe, compliant and enrolled.
- **Automation** makes it more efficient to send questions, schedule follow-up, and deploy triage-level surveys. Automated communication creates a habit that ensures engagement.
- **Mobile apps** are complementary tools that make it more convenient for patients to participate in trials, improve engagement and allow data-gathering when patients are away from home

Remote engagement, patient-reported outcome data and improved adherence are transformative for decentralized clinical trials. Patient portals that combine the best of mobile apps with more advanced easy-to-use technology are fundamental tools in continuing clinical trials, gathering accurate data and ensuring patient safety during the pandemic and beyond.

THE PATIENT EXPERIENCE

Spencer Health Solutions provides a singular, simple platform to coordinate care, improve safety and enhance patient experience.

ABOUT SPENCER HEALTH SOLUTIONS

Advancing research and healthcare from the home. Bring new treatments to market faster and at a lower cost with the spencer® Direct-to-Patient platform. Spencer Health Solutions, Inc.'s award-winning spencer® technology combines medication dispensing, telehealth and engagement so patients, their health care providers, and clinical research teams stay connected.

For more information, visit www.spencerhealthsolutions.com. Follow us on Twitter [@spencerhealth](https://twitter.com/spencerhealth)

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¹ <https://www.clinicaltrialsarena.com/comment/clinical-trials-disruptions-growing>

² Vaghefi I, Tulu B. The Continued Use of Mobile Health Apps: Insights From a Longitudinal Study. JMIR Mhealth Uhealth. 2019;7(8):e12983. Published 2019 Aug 29. doi:10.2196/12983 **TERMS OF USE:** <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6740166/>

³ <https://www.pewresearch.org/internet/fact-sheet/mobile/>

⁴ <https://www.pewresearch.org/internet/fact-sheet/internet-broadband/>

⁵ <https://www.pewresearch.org/fact-tank/2019/05/31/digital-gap-between-rural-and-nonrural-america-persists/>

⁶ "How Patient Engagement Supports Chronic Disease Management" by Sara Heath, Patient Engagement HIT <https://patientengagementhit.com/features/how-patient-engagement-supports-chronic-disease-management>

⁷ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2012.1061>

⁸ <https://www.psychologytoday.com/us/blog/how-healing-works/201909/patient-engagement-is-the-blockbuster-drug-the-century>

⁹ Arambepola C, Ricci-Cabello I, Manikavasagam P, Roberts N, French DP, Farmer A. The Impact of Automated Brief Messages Promoting Lifestyle Changes Delivered Via Mobile Devices to People with Type 2 Diabetes: A Systematic Literature Review and Meta-Analysis of Controlled Trials. J Med Internet Res 2016;18(4):e86 URL: <https://www.jmir.org/2016/4/e86>

DOI: 10.2196/jmir.5425

PMID: 27095386

PMCID: 4873307

<https://www.jmir.org/2016/4/e86/>

¹⁰ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2012.1061>

¹¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5066799/>

¹² (<https://blog.spencerhealthsolutions.com/medication-non-adherence-costs-causes-and-clinical-trial-implications>), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5066799/>

¹³ PPD Decentralized Clinical Trials Survey Report; provided by Spencer

¹⁴ Shiovitz TM, Bain EE, McCann DJ, et al. Mitigating the Effects of Nonadherence in Clinical Trials. J Clin Pharmacol. 2016;56(9):1151-1164. doi:10.1002/jcph.689