TRANSFORMING THE CLINICAL TRIAL EXPERIENCE WITH PATIENT CENTRICITY

Proven Approaches to Improve Patient Retention, Compliance, and Engagement With Science-Based eCOA Solutions

Datacubed Health

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Despite the remarkable innovations of modern-day clinical research, many setbacks remain.

With an average patient attrition rate of 19 percent (and growing)[1] and ongoing struggles in adherence and engagement, meaningfully connecting with today's clinical trial participants is more challenging, and also more important, than ever.

Very often, these concerns stem from a lack of interaction and communication throughout the trial. While current eCOA solutions have advanced to support those needs, they have not made significant strides in patient engagement. Existing approaches like patient apps and telemedicine still feel stale in a decentralized trial environment that can and should do more.

"When you think about the impact of technology in engaging clinical trial participants, there has been monumental progress in the past 15 years or so," said Kyle Hogan, Executive Vice President of Strategy at Datacubed Health. **"But there's an opportunity to do better.** The apps and devices participants use are often confusing and disjointed—and the data gleaned from them is often reactive, rather than predictive to preempt participation barriers."

[1] https://www.centerwatch.com/articles/24543-recruitment-rates-rising-but-retention-rates-fall-according-to-new-study

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>
> Marina Acosta Enslen, Director of Clinical Management of Rho, Inc.

WHY PATIENT CENTRICITY?

The limitations of modern-day eCOA tools pose significant risks to commercialization: Patient disengagement and drop-offs can affect study costs, data collection, timelines, regulatory approval, and even time-to-market.

"The last thing you want is for subjects to drop out," said Marina Acosta Enslen, Director of Clinical Management of Rho, Inc., a contract research organization. "Not only does it push your timelines out and make it more expensive, but if you lose your participants, you lose the data which can damage the integrity of the study itself—and potentially even lead to an inability to reach desired endpoints."

Looking down the road, Enslen adds, these risks can also introduce profound clinical dangers.

"If your patient retention has faltered such that it impacts subject diversity—and you have a participant pool whose demographics are drastically different than the patient population for the particular disease state—there could be unanticipated adverse reactions that could impact patient safety and even lead to a drug receiving a black box warning or even getting removed from the market post-approval," she said.

So how can sponsors address the challenges? It requires a reimagining of clinical trial management toward a new eCOA model that prioritizes patient centricity. Manufacturers should put experience at the heart of their programs so that participants feel connected to and immersed in the protocol.

"The big advantage of patient-centric approaches is that you're removing the burden from the patient," Enslen said. "You want to make the experience of clinical trial participation easier on them, especially if it's a particularly debilitating or challenging disease. This can make participants more willing to participate, and ultimately more compliant, too."

WHY BEHAVIORAL SCIENCE?

Behavioral science and technology can together build a better eCOA framework for improved retention, compliance, and engagement.

For decades, industry leaders outside of healthcare have relied on principles of behavioral economics to track patterns of human conduct. Based on these insights, researchers have a better understanding of what motivates people to take action or not—and that work has touched nearly every aspect of our lives, from the products we use to the ads we see on TV. **Experts call this the "behavioral revolution."**

Many sponsors are already applying these evidence-based concepts to the clinical trial experience, particularly in the wake of COVID-19. By creating an interactive, patient-centric, and high-touch trial informed by behavioral science and powered by digital solutions, investigators can bolster more active and compliant participation.

This guide aims to help sponsors understand more about and optimize these insights. Inside, we'll explore the current landscape of patient engagement strategies, as well as the behavioral economics principles that stand to make a difference in today's clinical trials. We'll also discuss how to put those principles to action using a proven eCOA solution. Here's what sponsors, CROs, and investigators should know:

WHERE CURRENT ECOA SOLUTIONS FALL SHORT

The current eCOA landscape includes solutions such as telehealth and patient apps that have continued to make clinical trials more accessible for more people. And yet, those same solutions also impose technical and practical challenges that can negatively impact the patient experience and with it, the pathway to commercialization.

In this new era, decentralized models require more user-friendly, evidence-based innovation to improve patient engagement atop preexisting advancements.

One area of improvement is BYOD (bring your own device) integration—that is, consolidating ePRO tools into a single streamlined experience on a patient's own device. Whereas a typical approach might involve provisioned devices or separate apps to collect more data, that experience can add unnecessary burdens to participants while driving up costs for sponsors.[2]

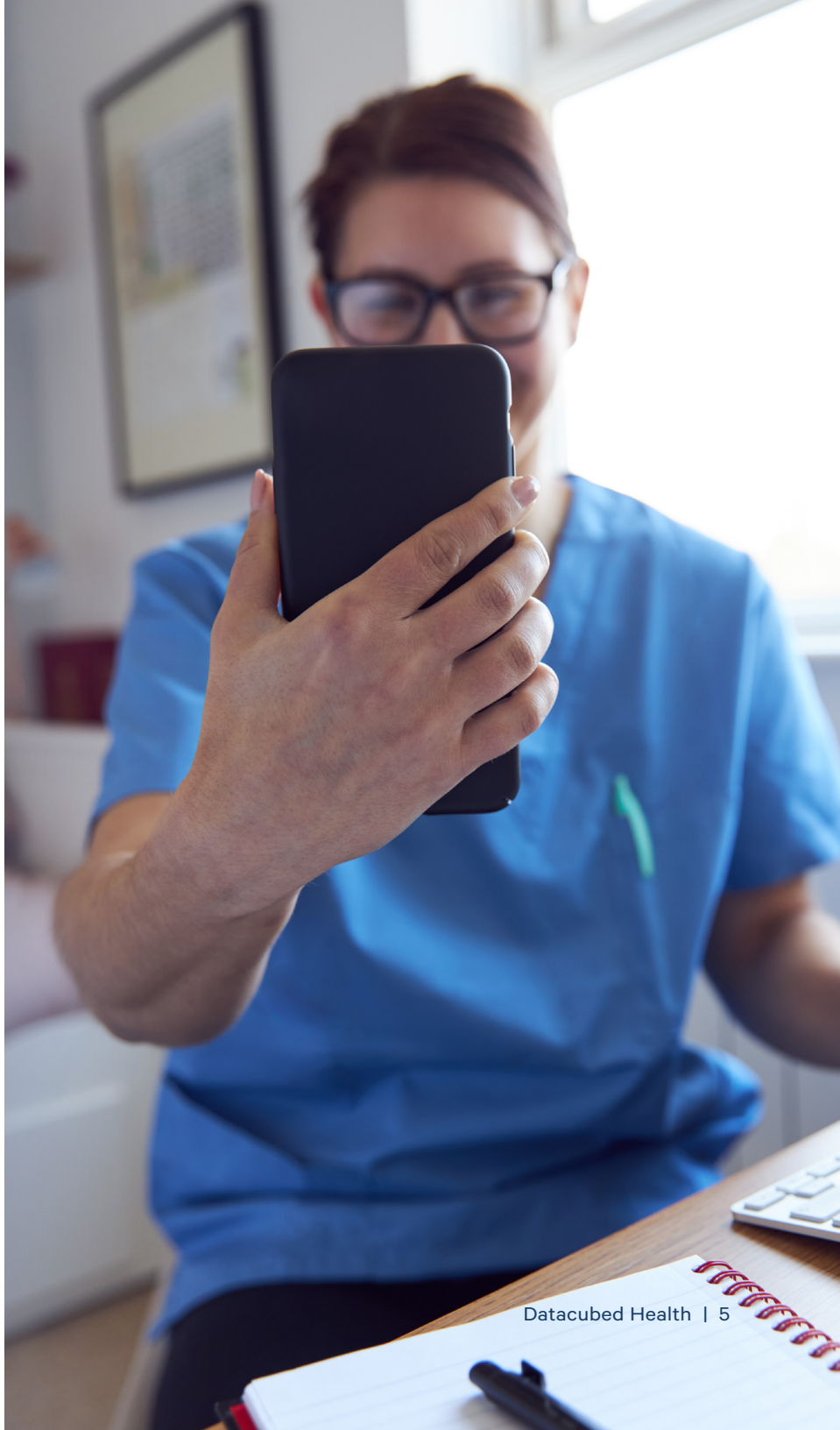
“Patient apps are really powerful in managing privacy and delivering information to trial participants, and sponsors are finding that they can use these tools not just to collect questionnaires, but also to facilitate clinician-to-patient encounters for true virtual care,” Hogan said. “But to achieve these goals, many studies require that participants toggle multiple apps and/or carry a separate phone. I can’t think of a less patient-centric solution than that.”

Hogan also points to the shortcomings in data collection seen in traditional eCOA solutions, which he says ties directly into patient engagement.

“A lot of sponsors are reassessing the data that they’re getting out of their eCOA tools as they consider how to drive new insights,” he said. “There’s a need for a more predictive approach to reporting so that sponsors can identify the participants at highest risk for drop-off and prioritize engagement efforts to retain them. Whether it’s an alert to the sponsor that they’re at risk or more targeted communications to the patient directly, the point is to preempt disengagement.”

With the help of new patient-centric approaches paired with what we know about human behavior, these and other challenges can all be channeled into actionable opportunities.

[2] https://c-path.org/wp-content/uploads/2021/04/BestPractices5.pdf



BEHAVIORAL SCIENCE MEETS ECOA: BUILDING A BETTER PATIENT EXPERIENCE

As more sponsors encounter the difficulties and costs associated with patient disengagement, there's a growing movement for more patient centricity in clinical trials through more effective eCOA tools. **Enslen says she's seen indications of that movement first-hand.**

"In the past ePRO was an afterthought for sponsors who wanted to conduct a more traditional clinical trial," she said. "Now, more and more clients are coming to us who actively want to use these tools for the benefit of patient experience. COVID-19 certainly accelerated those trends because it forced sponsors to explore what's possible in digital patient engagement."

With trial success so deeply reliant on participant behaviors, it would make sense that studying those behaviors would be vital. For years, various industries have seen the success of behavioral economics for social media apps and targeted ads that drive desired behaviors of everyday life. That science extends to clinical trials.

"Providers and sponsors have been applying behavioral insights to clinical trials for years, even if they haven't realized it," said Marie Onakomaiya, Ph.D., MPH, Chief Scientific Officer at Datacubed Health. "For example, telling a patient that they might expect a 30-minute wait when it's more likely to be 15 minutes sets a reference point that leads to a positive experience. Similarly, helping trial participants feel like they are contributing to the greater good creates a sense of identity that feels more rewarding."

Those are both examples of principles in behavioral economics—and just as these and other principles are used in traditional clinical trials, they can also be translated to eCOA solutions to improve patient engagement.

"Certain stimuli can have a real biological impact on a participant's likelihood of engaging with the trial," Dr. Onakomaiya said. "For example, when confetti pops up after a participant completes each instrument on our app, it can trigger the release of dopamine so that the user feels reflexively reinforced."

But a behavior-informed approach doesn't just improve the patient experience—it can also optimize data integrity, she adds.

"Participants will subconsciously adjust their answers to even basic questions depending on who is administering the questionnaire, similar to how you'd speak differently to a close friend compared to your boss," Dr. Onakomaiya said. "So when you can have a neutral robot ask those questions, instead of a clinical research coordinator, it can help solicit more reliable answers."

7 PRINCIPLES TO CONSIDER

Dr. Onakomaiya points out seven principles based on behavioral science research to consider in an eCOA product—which are all incorporated in the Linkt platform by Datacubed Health:

1. Respect participants' time. Aim to save time with patient apps—such as prefilling forms or implementing a passcode or biometric login so that participants don't have to type in a username and password every time.

2. Respect participants' money. Structure participation such that participants don't miss work to participate or only miss work minimally.

3. Promote trust. Design instruments and other trial components with user experience in mind so that participants can trust that the tool won't create added stress.

4. Bind identity with participation. "Identity-lock" the trial experience to the patient's identity with customizable digital avatars.

5. Create motivational intervals. Create milestone-based motivation at the beginning (instant rewards for patient action), middle (intermittent rewards throughout the trial), and finish line (rewards for finishing).

6. Embed meaningful goals. Create goals that happen sooner and more often than overall study milestones to make progress trackable. Offer digital rewards for every completed goal that can be exchangeable for real-world rewards, such as a donation to a selected charity.

7. Make participation fun. Make trial instruments more interactive with engaging activities and find ways to incorporate positive surprises throughout the trial.

SOLVING THE ECOA PROBLEM

Translating the science of human behavior into eCOA is just another step on the historical pathway of solving problem after problem to improve patient engagement. Back when paper diaries were the only option, compliance rates were poor and data went underreported, Hogan says.

"People would wait until right before the visit and fill out their diaries in the parking lot," he said. "And because of that, the data just wasn't good."

As an example, one systematic literature search of 11 diabetes studies found that roughly half of all paper data was inaccurate.[3] But when eCOA technologies came around, they had the distinct advantage of timestamping entries to better monitor compliance and data integrity. After that, sponsors saw a measurable impact on their engagement rates—to as high as 80 percent, which inevitably became the standard, Hogan added.

But while 80 percent compliance is good, it's not great. Through fundamental eCOA enhancements such as motivational design, customizable avatars, progress maps, and instant rewards, behavioral science can help push those goalposts even farther.

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Kyle Hogan, Executive Vice President of Strategy at Datacubed Health

“Leveraging these insights on human behavior in a patient engagement strategy has become the new baseline,”

Hogan said, adding that Datacubed has achieved an average of 90 percent compliance for questionnaire completion. “In addition, the impacts on patient retention are equally important and directly related to that experience piece of it.”

Enslen adds that these concepts are evident in how many sponsors are managing their trials in the wake of COVID-19. Now that the pandemic has accelerated an already-trending decentralized model, researchers who work to troubleshoot patient barriers and promote positive experiences stand to see the most success—particularly given the heightened awareness of clinical research after 2020.

“You’re seeing more active participation in terms of subjects seeking out clinical trials than you did previously,” she said. “In turn, that creates this scenario where you have a deeper pool of subjects who are advocating for themselves more than we’ve historically had. Sponsors certainly have a lot of opportunities to make the most of these trends.”

[3] https://pubmed.ncbi.nlm.nih.gov/23324062/

MEETING THE MODERN-DAY NEEDS OF MODERN-DAY PARTICIPANTS

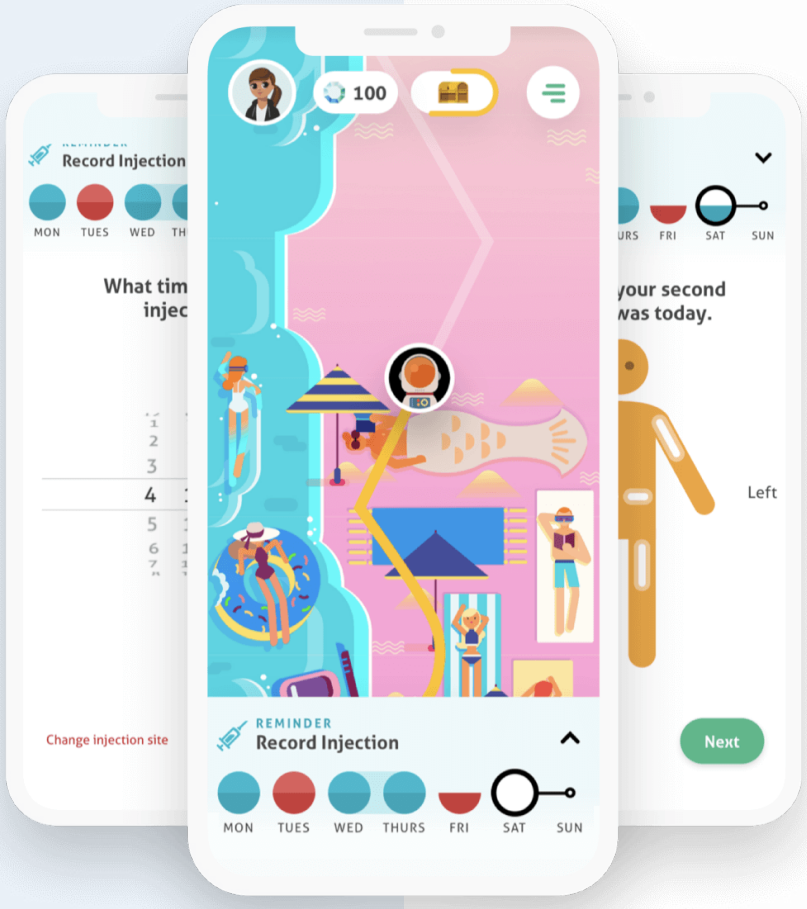
Participants have never been more connected to the ecosystem of clinical research than they are today. While eCOA tools have made strides in fostering engagement, adherence, and retention, they've also created new strains and barriers on participants from technical overload and outreach that misses the mark.

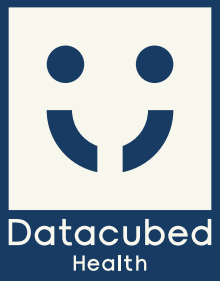
By simplifying and getting back to the basics of human nature, sponsors can adapt their approach for the modern-day needs of today's participants. An integrated eCOA platform informed by behavioral science principles—including reducing friction and increasing motivation—makes the clinical trial experience more memorable and meaningful. This then generates more comprehensive and predictive data that preempts patient drop-offs and can help get lifesaving therapies to participants faster.

That's why we created Linkt. As a next-generation eCOA tool designed by behavioral scientists, our solution works to remove patient barriers for a more enriching trial experience. Request a demo to learn more: https://www.datacubed.com/request-a-demo/

ABOUT LINKT

Linkt is the industry's most innovative approach to clinical outcomes and patient-reported outcomes data. This powerful, consumer-grade app helps sponsors and CROs manage patient-centric clinical trials with minimal administration. By combining proven behavioral science concepts including personal identity, motivational intervals, and meaningful goals, Linkt consistently delivers retention rates of 80 percent, and compliance rates of 90 percent.





ABOUT DATACUBED HEALTH

Datacubed Health is a pioneering technology company making better science and healthier communities a reality. Datacubed applies individualized solutions for the capture of active and passive data for engagement with patients in in-person, hybrid or fully virtual clinical studies. Focusing on healthcare and life sciences, Datacubed offers software and services driven by behavioral science to improve patient retention and compliance, resulting in better data and positive health outcomes. Visit datacubed.com.

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