

# ***Patient Centricity***

IN THE ERA OF DECENTRALIZED TRIALS

*Did you know?*

60% OF INDIVIDUALS  
TURN TO THE INTERNET  
FOR HEALTH INFORMATION!

PEW Research Center

55% OF ACTIVE TRIALS  
MOVED TO REMOTE +  
VIRTUAL MODELS IN 2020!

Tufts Center for the Study of  
Drug Development

ONLY 9 OUT OF 100  
ELIGIBLE PATIENTS WILL  
ENROLL INTO YOUR TRIAL!

*...all this, and more, inside!*

# Introduction:

## How patient voices can guide rapid change



IT WAS A  
RATHER  
HARSH  
WAKEUP  
CALL.

In the course of just a few short weeks, the outbreak of SARS-CoV-2 disrupted the traditional operations of the entire healthcare sector. The old ways could no longer suffice in the face of the pandemic. The time had come, suddenly and without much warning, for every team in the industry to reinvent the wheels that, for years, they'd taken for granted.

This tectonic shift in medical services was perhaps most evident in the field of clinical trials. Strategies that once required months and years of approvals, testing, and regulatory review, are now being rolled out into the field by study teams motivated to whatever it took to keep recruitment and research timelines on track.

This makes sense. It's common knowledge, after all, that delays in patient recruitment and retention are one of the main barriers that prevent treatments from gaining FDA approval and reaching patients and their communities.

**More than 85% of clinical trials fail to complete enrollment within their forecasted timeframe,** and **dropout rates upwards of 30%** are not uncommon. These preexisting challenges only grew evermore challenging in the face of the pandemic.

Study sites are operating at limited capacity; site visits, already a challenge for many patients in the days before COVID, are more difficult than ever before; traditional recruitment through clinics, billboards, support groups, and the like are rendered ineffective; the list of newly magnified challenges goes on.

According to a recent analysis by the Tufts Center for the Study of Development, **55% of active, ongoing trials transitioned to remote and virtual execution models since spring 2020.**

That figure perhaps would be higher if the teams in the field had relevant experience with these ideas and tools. However, the same analysis by Tufts discovered that **60% of investigative sites reported having no prior experience** with remote processes and solutions before the pandemic. This gap in expertise surely led to some slowness in the adoption of virtual and remote tactics.

With such high need for these new methods, the clinical trial space likely has no choice but to grow more adapted for this new reality.

This is a moment of great opportunity; it's also a moment that could lead to inefficiency and deteriorated patient experiences due to the poor implementation of new ideas. In our experience, the best way to mitigate the risk of introducing poorly-designed solutions to a study is simple: **Listen to patients.**

This opinion comes from a well of hard-won experience: At Clara Health, we specialize in building and using decentralized and virtual trial enrollment experiences that **recentralize the study around the patient.** By listening to and working directly with patient and caregiver communities, we've accelerated recruitment, helped improve management of budgets, and improved retention for our partner study sponsors.

As such, we felt it'd be appropriate to start our analysis with a patient story.

### AN UNEXPECTED PIVOT

*The clinical trials industry found itself adapting to the new normal rapidly, even if teams were generally unexperienced with virtual and remote solutions.*

**55%**

*of active, ongoing trials transitioned to remote + virtual models in 2020*

**60%**

*of investigative sites reported having no prior experience with remote solutions*





## A Trying Experience

Vickie depended on a clinical trial to receive treatment. So why were so many hurdles placed in her way?

Vickie had lived with psoriasis for 17 years when a change in insurance switched her over to Medicaid coverage. In Louisiana, where she lives, this meant her treatment options were **suddenly much more limited**. Not only were her choices curtailed, the treatment she did have immediate access to did nothing in the way of providing resources or support. **Overnight, managing her psoriasis became even more challenging.**

Fortunately, a friend of hers – who also lives with psoriasis but had coverage through more comprehensive insurance – learned about a clinical trial, and relayed the information to Vickie.

As soon as she heard about it, Vickie took up the opportunity to apply to the study in a heartbeat. She did so even though the study would require a 3-hour drive, one way, for every single study

visit, and even though she had to pay for the travel costs out of pocket. It would be uncomfortable, sure, and the logistics of traveling regularly for such long durations of time would be a challenge to schedule around; even so, Vickie remained undeterred. For her – and for so many patients just like her – the promise of potential treatment outweighed any other concern.

Vickie participated in the trial and received treatment through it. But after completing the study – again, with those six-hour roundtrip visits to the study site – she never heard back about the study results. Years after her participation, she doesn't know if the medication made it to Phase 3, if she could have participated in the Phase 3 trial, or if the therapy itself received FDA approval.

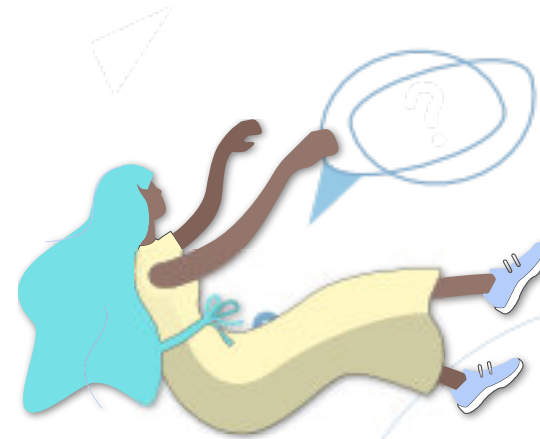
It wasn't altogether surprising, then, that she's yet to try to join another study. It turns out that, even for the most motivated patients, there are limits to anyone's patience and flexibility.

Vickie's story resembles thousands of other patient journeys. More often than not, patients are left to shoulder an outsized proportion of the work as they jump through the numerous hoops between them and enrollment into an appropriate trial.



## WHAT WE DEMAND OF PATIENTS

Four core challenges made participating in the trial more demanding than it could have been. Unfortunately, this is a common trait of so many clinical studies.



### Inaccessible information:

There was no information source to learn about this trial. Only patients who had access to certain clinics and physicians were able to find this study. By centralizing and gating information from curious, motivated patients, the study slowed its own ability to recruit – and retain – participants.

### No option for remote visits:

Patients were required to come to the study center for every visit, making it difficult for any patient that did not live close by to participate. Within the design of any study, there are visits that cannot be done outside of a study site. However, it's commonplace for studies that do not adapt to patient needs and require site visits for simple procedures such as blood draws that could have been more easily (and cheaply) done remotely, via in-home nurse visits or by leveraging clinics local to study participants.

### No travel support:

Vickie was on her own getting to and from the study site closest to her. This added up to 6 hours of driving on the days she had study visits. Not only did she have to sacrifice a significant amount of time, but she also had to pay for the additional costs of travel out of pocket.

### No follow up:

Vickie never heard back from the study team. This lack of appreciation for her sacrifices and critical involvement in the study is yet another symptom of healthcare's tendency to make information inaccessible. Simply following up could have led to Vickie enthusiastically joining the next phase of the study, or may have motivated her to participate in other research. Instead, the clinical trial world saw yet another patient leave unsatisfied and unmotivated to contribute to further research.

# De/Recentralizing Clinical Trials

If only **9 out of 100** potential participants will actually enroll into a trial, how can clinical trials decentralize themselves in order to provide **a more accessible experience, recentralized around the patients?**

## Push and pull recruitment



100

interested patients

31

pre-screened

13

consented

12

Screened

9

enrolled

→ 7 complete

2

dropout

**The industry average recruitment funnel**

To understand how best to leverage these kinds of patient stories in pivoting a study's design, we need to first take a step back to appreciate that patient expectations had already changed, well before COVID's disruptive entrance into the industry.

After all, the digital age has led to a fundamental paradigm shift in trial recruitment. The Pew Research Center found that **nearly 60% of individuals turn to the internet for health information**. And it's not just patients: When asked about who they were searching for, **39% of respondents said they were searching for themselves**, but **another 39% said they were looking to help someone else**. This means that significant numbers of patients and caregivers alike feel comfortable in searching for answers on their own terms, and on their own time, even if the answers they find are not specifically created with patients in mind.

But the experience is severely lacking. Most everyone in the 21<sup>st</sup> century is accustomed to hailing a ride, ordering food, or even finding or selling a prized antique lamp from some far-flung corner of the world, with just a few taps on a phone screen. Compared to these wonders, the process of finding of a trial, enrolling into a study, or simply getting in touch with a research team feels stubbornly rooted in

a near-forgotten past.

In working directly with patients across numerous studies in disease indications ranging from neurodegenerative to gastrointestinal, we heard about the same friction points over and over again.

Patients inform us **that information about studies is hard to find**; that, even after finding a study that seems like a match, **it's difficult to get in touch with the study team**; and that the process to clear every hurdle before **enrolling is taxing, confusing, and overwhelming**.

These are some of the reasons why, on average, **only 9 out of 100 potential participants will actually enroll into a clinical trial**.

Given how difficult it is for patients to get involved with research, we spoke with pharma partners, patient advocate allies, and study sites to distill the dozens of new patient engagement strategies into three best practices. By focusing our decentralization efforts around these three key goals has helped us **increase recruitment speeds for our partner studies by 3-4x**.

In the face of ongoing pandemic-related operational challenges and ever-changing expectations from the patient community, these principles are proving to be ever more relevant.



## DECENTRALIZE INFORMATION

*Decentralized information should be easily understood and discoverable, by any patient or caregiver,* without requiring the support of a medical professional or study coordinator. To accomplish this, we work with sponsor teams, their IRBs, and with patients to transform information that once only existed as dense blocks of jargon-heavy text in less-than-inviting spaces like ClinicalTrials.gov and corporate landing pages.

Our patient-facing content – videos, podcasts, blog posts, and our own Clara study pages – speak to their needs directly, in the language that they find most engaging and welcoming. And we use our own Clara blog, network of patient advocates and organizations, and digital channels such as Google, Facebook, and Twitter to make the content as easy to find as possible.




## DECENTRALIZE ACCESS

In 2020, taking the initial steps in accessing a trial can be, and should be, easy and immediate, and not require lengthy processes around centralized resources like study sites or site coordinator schedules. Once you've done the hard work of winning a patient or caregiver's attention, your content – be it a blog post or a patient-friendly study page – should link to **clear and frictionless next steps**. That might mean a digital screener or just a simple intake form, but regardless of that, study teams should avoid putting the ball in the patient's court. Wherever possible, make their part of the action as easy as possible while challenging your team to be as responsive as possible in kind.

## DECENTRALIZE SUPPORT

Once they find information about a study that could be a fit, patients get highly motivated to take next steps. If the study has offered easy and quick next steps, patients will be excited to speak with the study team about their questions and concerns. Unfortunately, next steps can often be onerous or slow. Studies often ask for patients to fax in documents, consolidate medical records, or to call between the hours of 9–5 (Mondays through Wednesdays, thank you very much!). Even if a patient has yet to visit a study site or randomize into the study, there's no need to gate general patient support behind centralized resources. **A simple support line or email address, and communications that set concrete and timely expectations,** can do wonders in keeping a patient engaged through the enrollment journey.





# Decentralizing information

We know that a majority of people will leverage internet searches to find information about treatment options. When patients look for trial options online, they're often curious about four high-level questions:

1. *Can this trial potentially help me?*
2. *Does it look like I can participate?*
3. *Is it feasible (financially and logistically) for me to participate?*
4. *What is the next step to see if I can join the study?*

However, it's still relatively uncommon to find clinical trial information created specifically for patient and caregiver audiences. Linking to a ClinicalTrials.Gov listing or dense scientific journal blurbs do a poor job of encouraging engagement with a given study. This means that answers to these simple questions are often buried in complicated language, foreign to the average reader. Simply understanding a study

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listing itself is burdensome to the patient or caregiver. Eligibility criteria is often unclear, misleading, or even outdated and incorrect.

This is why we work directly with patient and caregivers to craft messaging and content for a study's target audience. We find that working with these stakeholders offers our team insights that we would not have gleaned, and improves outreach efforts considerably, thanks to the strength of the messaging. Creating language to speak to patients who have just received a diagnosis is a very different process from creating language that speaks to experienced caregivers adding to their existing knowledge about the disease and its treatments.

So, be they a caregiver, daughter, or a newly-diagnosed patient, we make sure to speak to each individual audience, our goal is to always meet our audience where they are in their healthcare journey, and speaking to their most immediate concerns. This tailored language encourages higher levels of engagement, and motivates patients to move further down the enrollment funnel.

Furthermore, every trial has its own unique advantages for potential participants comparing it with other trials and existing treatment options. These can be uncovered through discussions with the patient community and competitive analysis of the industry. Each dimension of the trial – from the number of visits required to travel compensation provided – can and should be highlighted in study materials. Because different types of individuals care more or less about different aspects of the trial, leading to customized trial websites with language emphasizing their primary topics of interest.

The Clara Platform can support unlimited numbers of webpages for a study, each with tailored

messaging for a subset of the target patient audience, and automatically detect which version of the trial page to show each visitor. But even without the Clara Platform, any study team should look to ***spin up supplemental pages or sections on their study pages that, at least, address specific concerns from key subgroups of their target patient community.***

No matter the sophistication of the digital tools they have on hand, a study team should always ask themselves whether the messaging offered to patients is specific, easy to find, and easy to understand. After all, it's through the consistently showing understanding for the individual that invites prospective participants to feel understood – that is, recentralizing messaging around a patient's expectations and lived experience – that can motivate them to action.

*What patients want to know:*

*Can this trial potentially help me?*

*Does it look like I can participate?*

*Is it feasible (financially and logistically) for me to participate?*

*What is the next step to see if I can join the study?*



## SELECT ACTION ITEMS FROM A RECENT VIRTUAL FOCUS GROUP

- ☐ Topics for educational material development
- ☐ Changes in placebo control group model
- ☐ Requests for scientific reasoning behind I/E criteria
- ☐ Concerns RE: placebo group treatment option
- ☐ Provision of full travel + retention support

## DECENTRALIZED FOCUS GROUPS

Virtualization can help recruitment, even before the study opens for enrollment. For example, our team used the Clara platform to create virtual patient focus groups — an easy, digital (and, of course, socially-distanced) — to better collect feedback from our patient and caregiver groups.

These HIPAA-compliant, easy-to-access virtual groups allow our core audience the opportunity to make their voices heard at a time that works best for them, and from the comfort of their own homes.

Participants walk through a study protocol, broken into a series of easy-to-understand questions. As the patients and caregivers provide answers, they shine a light on the components of a trial – for example, the number of visits, the language used in the ICF, or even the lack of context around the scientific basis of each of the exclusion criteria – that present challenges to them.

All this information helps us to, in turn, work with the sponsor of a study to bake patient-friendly and patient-supportive features into the design of the trial that will lead to improvements in both patient recruitment and retention.

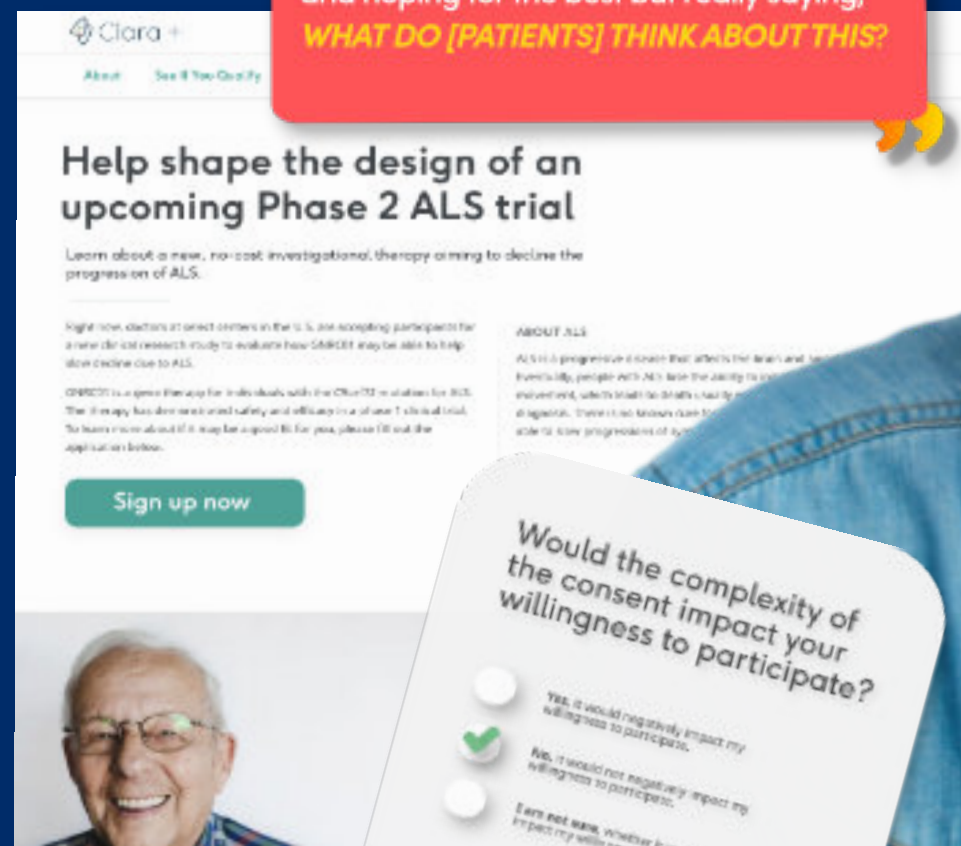
This approach is important in any indication, but even more so in rare, complex, and progressive conditions.

# Feedback from an ALS VIRTUAL FOCUS GROUP

This to us, to me, is **GROUNDBREAKING**.  
So, kudos to them and to you.

I JUST WANT TO APPLAUD YOU AND THE **COMPANY** for recognizing that [the] patient voice is an important part of this process and just thank them for me.

I love that we're working with a company that's not just throwing this trial together and hoping for the best but really saying, **WHAT DO [PATIENTS] THINK ABOUT THIS?**





# Decentralizing access

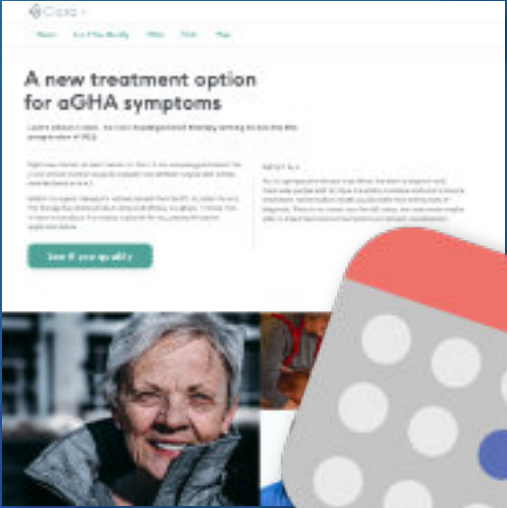
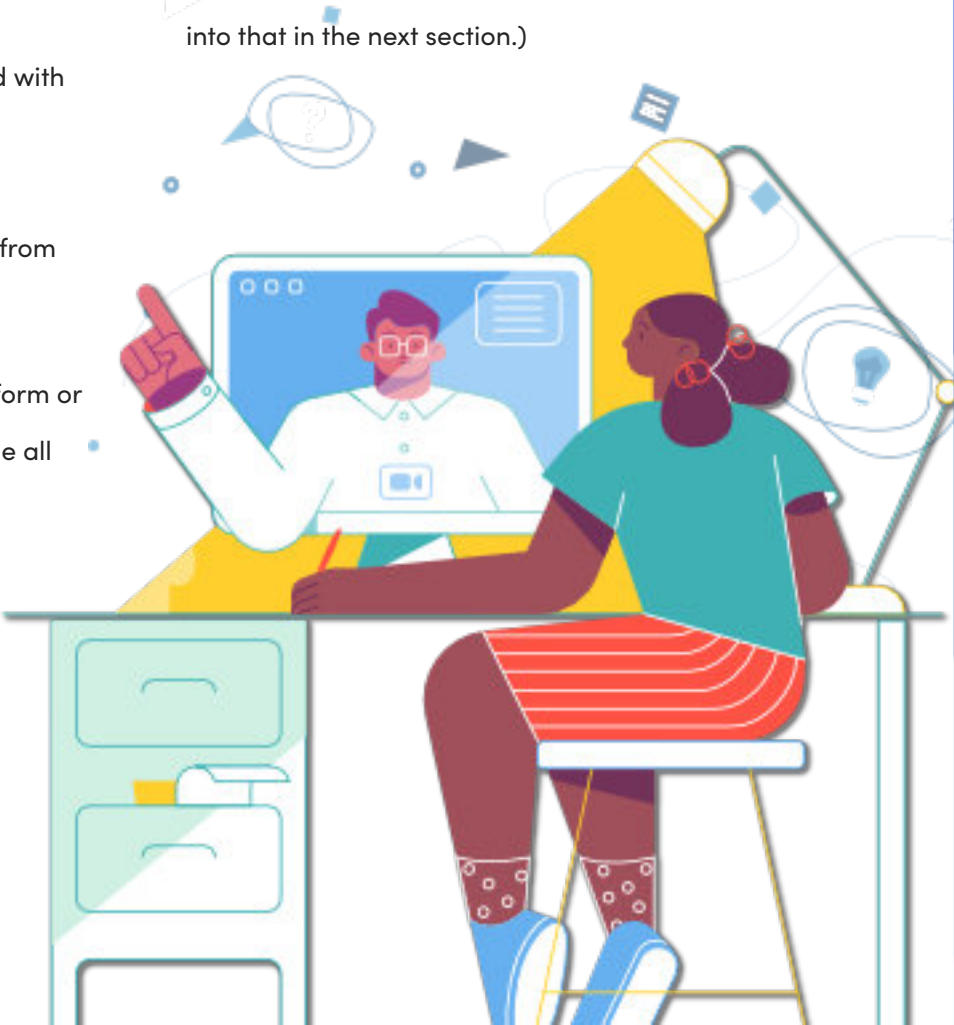
Even if awareness of a study is high in the patient community, it is too often the case that the road to trial enrollment remains opaque, slow, and unresponsive; it's a process that places much of the burden on the shoulders of the patients.

Think of recruitment as a funnel. At each step of the enrollment process, there is a potential for leakage within the funnel. These leaks could be caused by slowness in response times, ambiguity in next steps, or simply the number of steps required for a patient to get all the way through to randomization. Providing patients immediately accessible next steps paired with immediate communication responses and clear expectation setting can do wonders for providing access points to the study that are decentralized from your study team.

So, whether it's just a contact information intake form or a full-fledged digital prescreen, be sure to provide all

interested patients with a big, obvious next step button that walks them through a clear and concise initial experience

Digital tools can provide all applicants with a smoother, faster enrollment experience that responds to them in minutes, instead of days to weeks. After the initial vcontact capture or digital prescreen, think through what other steps your team could help a patient complete remotely. In our experience, the tools that helped to decentralize access most materially were: **Digital preConsentscreening, eConsentconsent, and digital appointment scheduling**, as well as **decentralized support systems** such as patient help lines and EMR consolidation assistance (but we'll get into that in the next section.)



## SCHEDULING FOR IMMEDIATE IMPACT

It seemed like a small detail.

The Clara Platform already featured live support, digital screening, and immediate email confirmations, sent to applicants seconds after they completed their intake forms. But we noticed that only 45% of applicants were responsive to sites after we made the referral, even if these referrals were made within a day or two of the initial application.

As a response to this low response rate, we built a scheduling tool that immediately guides a patient through an easy online flow to schedule a call with our patient support team after they complete their prescreeners. The tool automatically sends out calendar invites once a call is scheduled, and programs outreach so that patients are texted, emailed,

or called to be reminded of an upcoming visit or call, through their preferred communication channel.

After this feature launched, we found that **85% of patients** scheduled a followup screening phone call with our patient support team; these patients were more responsive, more engaged, and were more likely to successfully followthrough with connecting to the relevant study site.

The lesson learned: **Patients thrive when expectations are clear and next steps are immediate.**

Scheduling, by itself, isn't a world-changing feature. However, by making scheduling an immediate next step after prescreening for a patient to engage with and complete, we provided yet another point in the process in which patients could feel catered to through a small and actionable request. This gave patients more agency, without offloading the responsibility completely onto them; it also further deepened the trust between our support team and the patients, making it more likely for the applicants to be responsive and more preemptive in asking us for help through the long enrollment process.

**85% OF PATIENTS SCHEDULED FOLLOWUP PHONE SCREENS WITH OUR PATIENT SUPPORT TEAM WHEN IMMEDIATE DIGITAL SCHEDULING BECAME AVAILABLE.**



# PROVIDING ACCESS, EVEN FOR PAUSED OR DELAYED TRIALS

During the early weeks of pandemic-related shelter-in-place orders, our team had been working with a number of partner trials that found themselves having to pause recruitment and operations. As they worked to determine what lay ahead, we saw many more trials enter a freeze state, and realized that a stop-and-go, stuttering cadence could be the reality for many months to come.

To help sponsors plan through this unpredictable period of time, we built a version of our platform called **Clara Registry**, allowing trials to continue recruitment efforts even if the trials are paused or delayed.

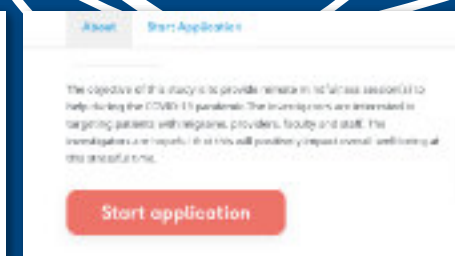
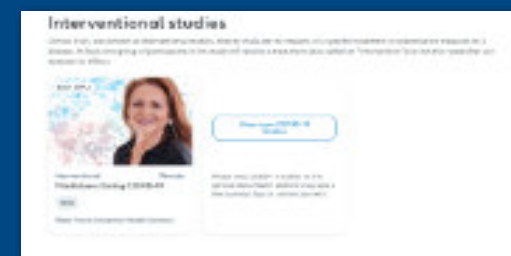
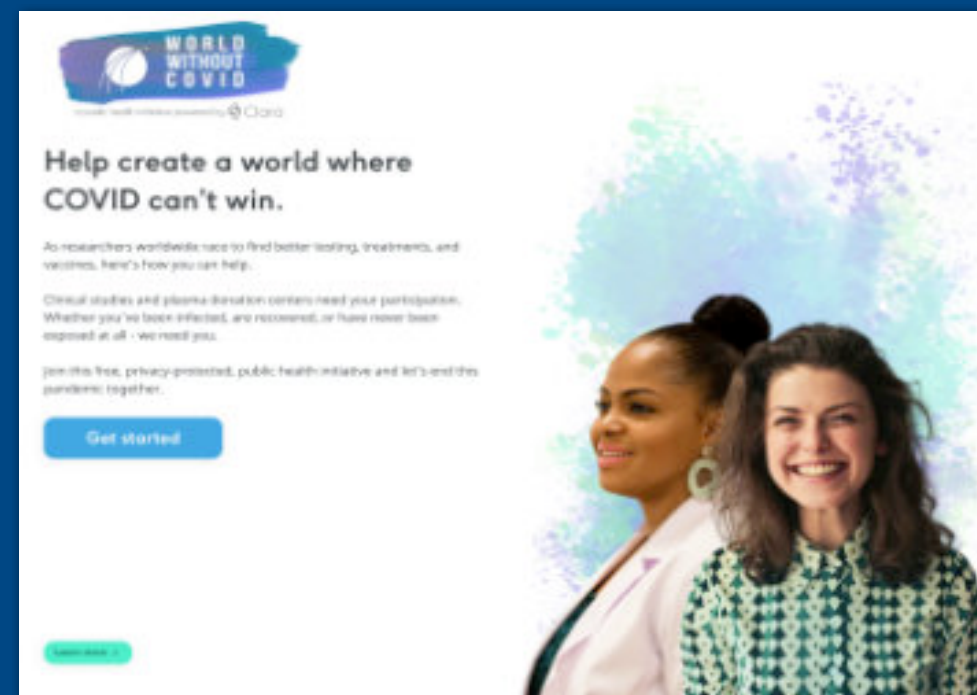
The Clara Registry allows study teams to enable patients to apply to their study, be screen, and remain engaged via regular, programmed touch points during the period of time that the trial may be paused or otherwise not operational. As clinical operations come back online, Clara Registry *automatically reengages all prequalified registrants and provides easy and*

*supported on-ramps to enrolling.* This is yet another way for patients to have access to decentralized and immediate next steps, even if the study itself is paused or slow in response for the foreseeable future.

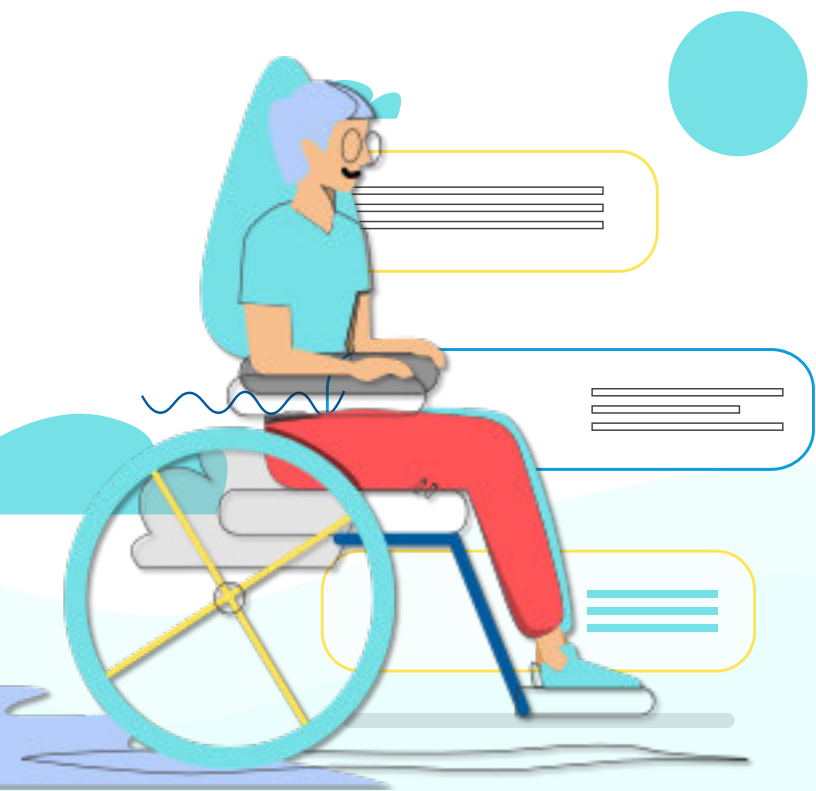
To provide a live test for this new platform, we built and launched World Without COVID, a registry that anyone, healthy or sick, could use to apply to all the COVID-related studies for which they are a fit.

Within the first three days of launching the registry, we saw more than **1,000 people sign up** on the platform. And thanks to the easy, oneConsentclick next steps provided for them, **more than half of these signups applied to at least one study.** Since its launch in late April, we've continued to work with academic institutions, industry sponsors, and advocacy organizations to engage the registrants with the latest opportunities in COVID research, helping generate hundreds more applications to ongoing studies.

This registry platform now powers a number of different initiatives for our partners and patient communities, with **registries in conditions from Parkinson's to ALS to c.Diff and beyond.** These registries help hundreds of patients engage and connect to studies across the world, and prove that COVID doesn't necessarily mean that a trial cannot recruit; it simply means that recruitment must evolve to meet this strange and historic moment.



**EVEN IN THE FACE OF THE COVID PANDEMIC, PROVIDING AN EASY, INTUITIVE, AND FAST REGISTRY EXPERIENCE HELPED MORE THAN 50% OF REGISTRANTS IMMEDIATELY APPLY TO RELEVANT TRIALS.**



## Decentralizing patient support

### Providing immediate patient support

Even if a patient has an easy time applying to a clinical trial, the maze of steps after the initial first steps can be overwhelming, and lack sufficient patient support. Patients report to our team that the most and common frustration involved in enrolling into a trial had to do with **slow response rates, inconsistent communication and information, and resultant anxiety from ambiguity.**

To help address this industry tendency to put the onus of action on the patients, we developed a **live, HIPAA-compliant patient support platform that we call ClaraCare.** Through ClaraCare, every patient is

given an experience free of confusion, hold times, and frustration. The service is maintained by full-time, in-house, Clara Health team members, who listen to each unique participant's needs in order to maintain their engagement and enthusiasm through the entire enrollment process.

We also took care to ensure patients could connect to the 24/7 live support through whichever channel they find most accessible, be that through **email, SMS text messages, phone calls, or live chats on the study page.** This approach to accessibility is especially pronounced for people who live with conditions like ALS, where the symptoms of the disease absolutely influence each patient's preferred mode of communication.

This focus on providing as many avenues of support as possible expands the way any patient can enroll into a trial; in action, we've seen **ClaraCare increase enrollment rates by 4x**, simply by helping patients who would have dropped out of the convoluted process without the added support.

While a support system that is as comprehensive as ClaraCare can be difficult to for every study to erect on their own, the best practices of providing multiple outreach channels and being prompt (if not immediate) in confirming that a patient's message has been received can help every trial applicant feel heard and supported.

## The impact of providing wraparound support

“

**EVERY SINGLE OBSTACLE WAS BEING THROWN OUR WAY**, and my child was suffering. My hands were tied. I happen to be online later that day looking for the possibility of a clinical trial for a biologic for pediatric asthma patients.

I went online to Clara and on the front page was a pediatric study, 20 miles away for asthmatic patients. It was like a beacon of light!

I inquired about getting some more info and was contacted immediately. The process was easy. He was screened. And now we are on the way to a path of possible relief for [my son].

Working with Clara Health was a godsend. It was like the sky opened up for us

**Brooke Abbott**

Patient advocate and mother of a son with chronic illness





## Providing site support

Another way in which decentralized support can help improve a patient experience is by offering **decentralized support systems for sites**. One major hurdle, across many (if not most) trials is the immense burden placed on study sites, staffed by under-resourced teams who typically only reach out during traditional business hours. The process of transferring a patient to a site can be difficult for both parties.

To accommodate these circumstances, ClaraCare began to work closely with the site coordinators and PIs to bridge the gap between them and potential participants. Our team is able to assist patients who were interested in the trial, empathize with their unique healthcare journey, and guide them through the next steps to enroll without increasing study site burden, ultimately driving up conversion rates from preConsentscreening to enrollment.

Offering decentralized support for individual sites paid dividends in accelerating screening visits for **Amylyx’s CENTAUR study**. As part of this work, our team carried out over **875 emails, live chats, texts, and calls** for the study to provide comprehensive support. Offloading the initial logistical work from sites led us to deliver full accrual in just **3.5 months**, and **two-fold increase** from the rate of enrollment prior to Clara’s involvement in the project’s final month. Supporting both patients and site teams **offers 360 degree views of the various challenges** that emerge within any study’s recruitment operations. By leveraging that visibility and resolving issues from both sides of the equation, a study team can accelerate recruitment, and recentralize support around those in the process who require it most.

*When my husband received his ALS diagnosis*, our family had researched online and spoken to physicians about our options, but Clara explained the process and answered our questions much more clearly than other sources. We can’t tell them how much we appreciate their excellent information, great search engine, and amazing ability to follow up on all the challenging questions they get from patients. I have a gut feeling from speaking with the Clara team that they understand what it’s like for patients in such a difficult position.

*The Wife of an ALS patient*



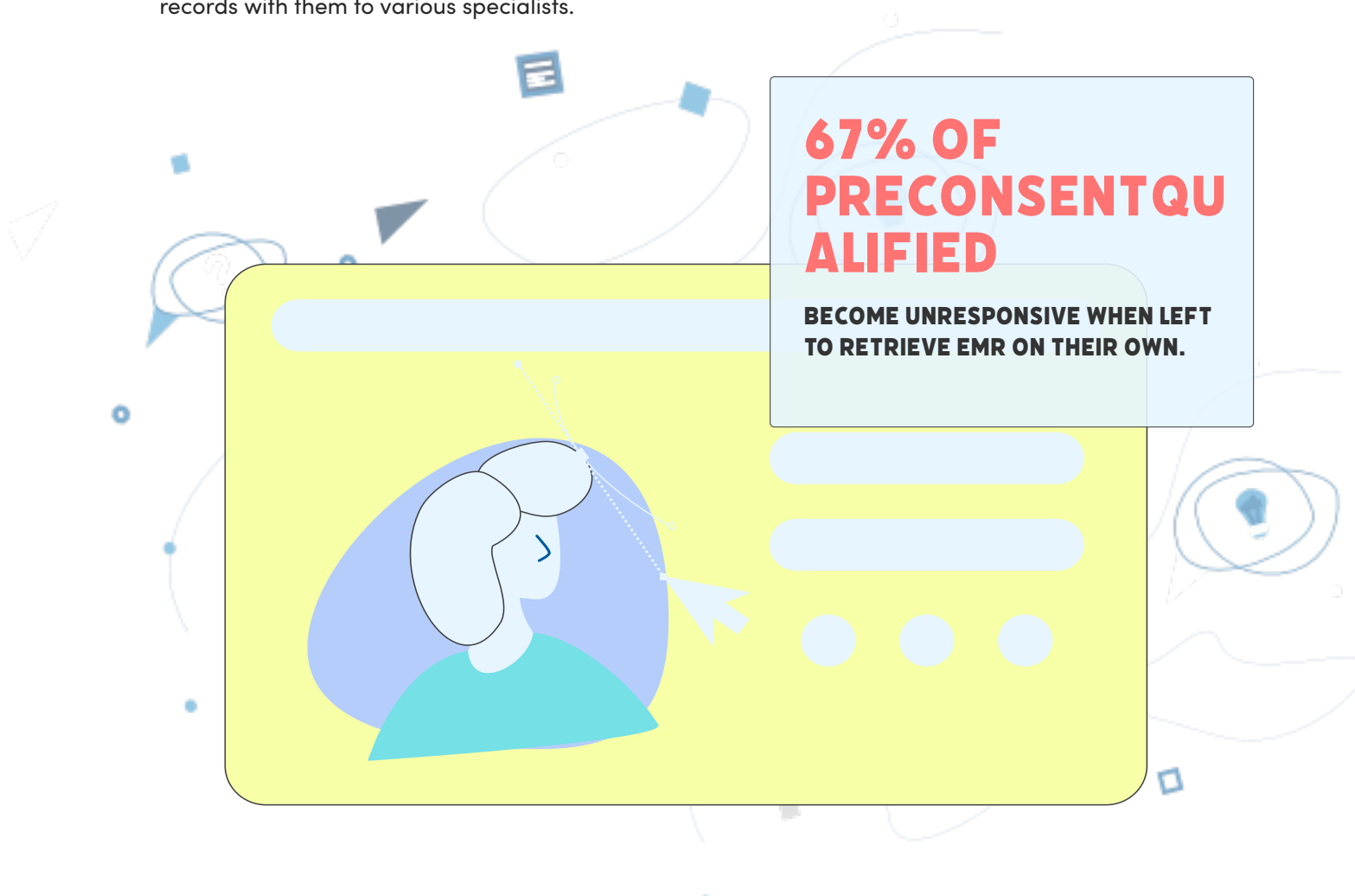
## Assisting EMR consolidation

Offentimes, a study will request that a patient locate, collect, and send their electronic medical records (EMR) to the study site after passing initial screening. This is not always a simple task.

A study by Health and Human Services found that, in 2017 alone, **only 28% of patients viewed their own medical record**. Gaining access to medical records is tedious, challenging, time consuming and an immense barrier for patients to enroll in clinical trials. The added logistical requirements of tracking down phone numbers, making phone calls, requesting the records (and, inevitably, following up on the requests), and so on represent a significant tax upon a patient or caregiver’s energy, time, and resources.

This difficulty is why we added EMR consolidation and screening into our ClaraCare capabilities. Because of our patient support team’s experience, time, and technological resources, we’ve seen our **additional support decrease the time this process normally takes by 40%**.

When assisting patients with medical record aggregation and transfer at Clara, we’ve seen the support service be especially helpful for patients with debilitating conditions, older populations, as well as patients with acute medical conditions who have not yet grown accustomed to bringing their medical records with them to various specialists.



# Participant retention

The average dropout rate across all clinical trials is an astonishing 30%. Simply enrolling patients isn't sufficient; a study team must also focus on recentralizing support around those participants who have joined a trial and are working through the many logistics involved in their participation.

Many reasons patients choose to leave a study early can be prevented through collaborating with them on developing protocol design centralized around their needs; however, providing special attention to the patient experience during the study timeline and providing support and solutions to common issues can also make a significant impact.

Anyone who ever had to work while very sick may understand some of a patient's burden. Even during periods of remission or wellness, participants in a trial – and patients in general – still wear many hats on a daily basis. They **project manage** their own medical conditions; they may be **parenting or caregiving**, or otherwise trying, like anyone else, to **maintain a social life**; they're **working for a paycheck**; all this, while also trying to participate in a trial.

The facets of retention support that we've seen measurably improve a participant's willingness to remain enrolled in a trial are three things:

***Live 24/7 travel concierge***

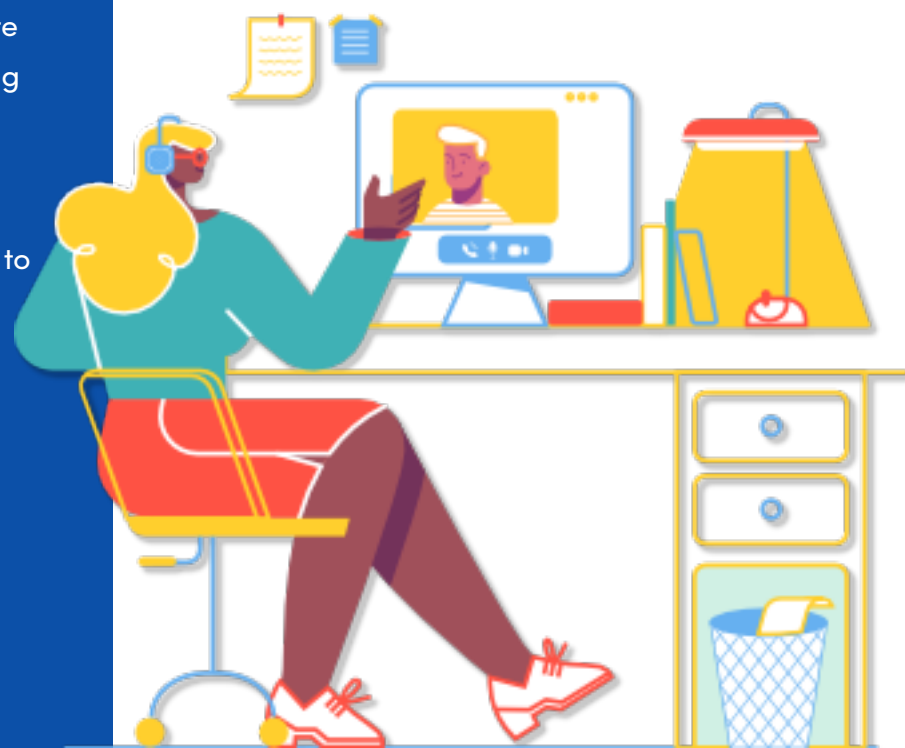
***Compensation support***

***TeleConsenthealth study visits***

## **Travel Concierge**

Travel costs and time associated with going to and from a study site are common reasons that result in patients discontinuing their participation. To solve this problem we've built a white glove concierge travel support service – ClaraCare Travel – that takes care of all the burden of getting to and from a study site away.

Our in-house travel support team is available 24/7 for patients, caregivers, and site coordinators to resolve any points of friction that may come up during travel for a study visit. They create fully personalized itineraries which include bookings from plane tickets, to overnight lodging, to private car services for individuals who are at high-risk during the current COVID-19 pandemic, our team takes every measure to create a safe and worry free experience for patients and their caregivers.



## **Compensation Support**

Federal guidelines allow sponsors to provide compensation to participants for taking part in clinical trials as long as the amount given does not cause undue influence. However, they leave the review of payment amounts and timelines up to a trials Internal Review Board (IRB).

Needless to say, travel in 2020 has become quite a bit more challenging than it once was in the past. Now more than ever, it's important to consider the needs of patients and their care team when calculating compensation support.

At Clara, we work closely with the IRB, our patients and clients to find the right amount of compensation for participating in a trial. Once determined, our platform is able to provide compensation directly to the patients in the form they prefer. The time spent is extremely valuable for patients who are often dealing with many other responsibilities on top of managing their disease and now spending additional hours every month and sometimes every week to participate in a trial.

## **Telehealth and Remote Visits**

But it may be the case that an in-person visit is not necessarily required for some aspects of a trial. With digital tools like Zoom video conferencing and Dropbox file sharing offering HIPAA-compliant versions of their products, some visits that would have had a patient come into a site for a simple check-in or to sign or transfer documents can now be done entirely remotely.

Even more complex visits for blood draws or sample collection can be done remotely via in-home nurse visits or leveraging local labs to handle the procedures.

The new COVID-related normal means that travel has become, and will remain more difficult or inaccessible for patients. On the other side, site staffing and capacity will remain constrained. As such, now is the time for every study team to review its protocol (perhaps with a few of patients) to determine which components of their trial can be made virtual or be remotely rendered.

***The Clara team so thoughtfully planned my trips!***

They so totally exceeded my expectations with the process and precision of executing travel plans, pick up and delivery of myself to and from each study visit. Plus, they were always able to answer my questions, listen to my concerns (and even speak with the site on my behalf), and arrange accommodations nearby the site that deConsentstressed my travels immensely!

***ClaraCare Travel-supported trial participant***



# Conclusion

Even as COVID forces every research team to decentralize their trial design and operations, maintaining a focus on recentralizing the study around patient and caregiver experience offers the ability to accelerate recruitment and improve retention.

This could not happen through technology or the human touch alone. But, as we walked through in the examples above, co-designing a combination of both with patients and caregivers can offer the key to unlocking your trials enrollment. This recentralized approach empowers any study team to account for and address potential issues proactively, and provide every applicant and participant a smoother, more supported experience.

This is the moment to reflect on your study's design, and to think creatively about where the patient experience can be **improved**, not just mitigated. Are there visits that can be virtualized? Is your decentralized recruitment effort still reliant on old, traditional channels such as bus stop signs or flyers? Whatever the problem may be, you can be confident that there is a digital and human solution waiting to solve it.

## ***P.S. If you want any assistance...***

Clara Health is the product of thousands of experiences of patients, caregivers, clinicians, sponsors, study coordinators, and researchers. We built this solution to create a funnel that transforms clinical trials into truly patient-centric experiences. In fact, we're building more solutions everyday!

So, if you'd like to chat about how best to decentralize your trial and recentralize it around the patient experience, please get in touch with our team at [team@clarahealth.com](mailto:team@clarahealth.com). We'd love to consult with you on the opportunities that exist for your study, and to help implement solutions in the most patient-centered way possible.





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