

White Paper

# Patient-Defined Recruitment: The Movement Advanced by the Pandemic

*The pandemic forced the pharmaceutical industry to reimagine how we recruit patients to clinical trials – and it's delivering significant benefits to sponsors who embrace these changes.*

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# Executive summary

The growing role of patient voice in clinical trial planning, combined with the need to virtualize parts of former “traditional” trials, forced study teams to engage quite differently with patient populations during the early months of the COVID pandemic. Suddenly referrals from healthcare providers (HCPs) had stopped and in-person visits were replaced with computer-mediated encounters. As such, trial planners found themselves hurrying to re-engineer trial components and devise recruitment strategies that were focused on the patient, directly.



Using the core tools of data, technology, and well-established consumer marketing techniques, steeped in persona development and deployment, study teams committed to crafting custom messaging. It was a complex transformation to take recruitment communications directly to patients via a variety of mediums, but it paid off. Sponsors who bought into a more patient-centric recruiting process found that it led to faster recruiting, more diverse study populations, and more committed trial participants.

Over the past two years, IQVIA has been evaluating how the pandemic changed recruiting through patient surveys, comparison studies, and analyzing trial data. This white paper explores those learnings and offers best practices for sponsors and sites who want to make the most of the new recruiting environment and the growing consumer interest in clinical research participation. The challenge – and opportunity – today is how to keep that same intensity and focus, despite our society looking a bit more like pre-pandemic days.

#### **DIRECT-TO-PATIENT: A WIN FOR SPONSORS, A WIN FOR PATIENTS**

In March 2020, business came to a near grinding halt in many service industries. However, it was simply not feasible to stop clinical research activities. Not only were participants in the process of receiving trial therapies, but the severity of COVID necessitated new trials for diagnostics, vaccines, and treatments.

Understanding all that was at risk and needing to act with urgency, stakeholders like site teams, sponsors, and regulators rapidly embraced decentralized clinical trial (DCT) technologies. Though there had long been interest in virtual trial aspects for direct-to-patient (DTP) offerings, COVID accelerated the adoption of telemedicine visits, wearables, online patient portals, and electronic consent (eConsent) tools, as well as smart chatbots to answer participants' questions in a timely manner.

With consumers more tech-savvy than ever before, these tools were embraced. An IQVIA survey conducted in 2020 had found that roughly 40% of respondents from the US and EU were “extremely interested” or “very interested” in participating in clinical trials. Nearly half of the US respondents interested in trial participation said they trusted clinical research more now than before COVID and that awareness of COVID trials, positive perception of vaccines, and positive coverage on social media were the biggest influencers of that trust.

For sponsors seeking to capitalize on these trends, the use of enabling technologies in a concerted, holistic manner helps deliver measurable benefit tied to recruitment – even when more targeted. A 2022 IQVIA study comparing DCTs to traditional studies revealed that DCTs were associated with an average 78% reduction in time to first-patient-in, a 39% reduction in screen failure rates, and a 26% reduction of non-enrolling trial sites

## GETTING STARTED: UNDERSTANDING THE JOURNEY

The growing interest and trust in clinical research are a boon for pharmaceutical manufacturers that, at times, have struggled to win over skeptical consumers. Potential participants are signaling that they are available and convinced of the value of clinical research – but there is work to be done. This is where the patient voice construct can contribute salient insights that illuminate important nuances based on demographics, disease state, gender, age and more. Having a solid understanding here means better targeting up front and less change needed down the line.

By scouring healthcare databases and analyzing real world data to identify trends and themes, along with patient-generated insights gathered via interviews and surveys in the patient community, journeys start to take shape. These enable the definition of the patient's experience with a disease and determine how that experience differs across different sub-populations.

An initial review may suggest that most treatment journeys are similar, but the deeper, multi-factor analysis will illuminate where patient needs, and experiences have varied. A patient's demographics, life experiences, access to healthcare, diagnosis (and misdiagnosis), treatment options, quality of life, pre- and post-treatment, and myriad other factors all affect the journey and whether they are likely to respond to trial participation through various sources. All these details should inform the recruiting strategy

## FINDING AND AMPLIFYING PATIENT VOICE

Once variations of the disease journey are mapped, “voice of the consumer” marketing principles can help transform these insights into a compelling recruiting strategy. Just as companies like Amazon and Netflix use detailed data about past customer preferences to make targeted recommendations, technology and patient journey data inform the patient experience and associated recruiting campaigns that capture attention.

To define the voice of the patient, potential participants are ideally engaged prior to trial planning to capture their feedback on protocol design, support services, recruiting materials, study branding and messaging, recruitment strategies, and other choices that will impact their interest in study participation. Journey data and patient feedback are combined to create unique patient personas, which are composite descriptions of potential patients and caregivers.

Each persona includes descriptions of their behaviors, disease experience, health and wellness goals, risk profile, and likely response to outreach. Combining the persona data and patient journey insights results in the creation of empathy maps, which provide insights into stages of the disease, what a persona may encounter, and how they may feel about these interactions. An empathy map can reveal fears, pain points, bottlenecks, and motivators, so that the final recruiting strategy is as targeted as possible.

These detailed maps inform current and future recruiting strategies, ensuring all interactions are relevant and intriguing and leave patients wanting to learn more.

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## Recruiting best practices: Lessons from the pandemic

Taking the time to understand patient needs helps sponsors hone their protocol, site selection, technology use, and outreach strategies to streamline recruiting and attract the patients they are intending to serve.

Throughout the pandemic -- and beyond -- IQVIA worked with recruiters across clinical trials to leverage these techniques for more robust recruiting results. Through these trials and ongoing research about clinical trial trends, best practices were identified that helped recruitment teams accelerate results and attract more diverse participants to their studies.

Here's how it was done:

### **DIRECT OUTREACH TO PATIENTS**

Direct engagement with patients in the community became a necessary practice during the pandemic, helping sites successfully recruit subjects to the fast-paced, high-volume, ever-changing trial landscape.

This DTP approach was essential to meeting recruiting goals for COVID vaccine trials. Vaccine developers had to attract thousands of healthy participants from diverse communities to these studies as quickly as possible. Instead of relying solely on physicians to recommend trial opportunities to their patients, pharma companies embraced DTP outreach campaigns and state-of-the-art technology to bring consumer-level ease of use to the entire recruiting process.

With a strategy for DTP in place prior to the pandemic, IQVIA was poised to meet the moment as this approach became a necessity. IQVIA supported recruiting efforts for several DTP trials during the pandemic. In these projects, our DTP outreach experts worked with consumers, sponsors, and sites to create ads designed to attract specific populations by adapting language, imagery, and content for each community. We tested versions of each ad with targeted populations to identify

the messaging and format that resonated the best with these communities. Then they posted those across relevant channels inviting interested consumers to learn more about trial participation with one click.

Patients who responded were instantly connected to a study website with trial-related information and pre-screening questionnaires to determine if they qualified. Those who did were linked to a nearby site to sign-up for in-person or virtual appointments. They were also connected to a patient portal where they could learn more about the study and review eConsent information. Through this experience, patients also had access to chatbot scheduling assistants to ensure an easy-to-use, personalized trial experience.

On the back end, once participants were enrolled, their data was seamlessly captured and populated in all relevant trial documents (while adhering to data privacy regulations). This eased tracking for sponsors and sites eliminated the need for participants to fill out multiple forms, further supporting a positive consumer-level engagement experience.

### **IQVIA'S APPROACH**

IQVIA's Direct-to-Patient (DTP) approach has become an integrated component of our overarching recruitment projections and assuming contribution from both site-based and community-based populations has become the standard approach to deliver certain therapeutic areas, such as Infectious Disease & Vaccine trials. Such a hybrid approach attracts patients from high-performing sites and directly from the community to accelerate results and meet study goals. Further, our site partners have come to expect broad community recruitment support and we see this consistently reported in the top needs expressed by sites when asked what they need to be successful in recruiting interested participants.

## Feedback drives messaging for Alzheimer's study

A top pharma company came to IQVIA for assistance in finding participants with prodromal Alzheimer's dementia. They wanted to capture insights about the targeted patient population and their caregivers to help them refine recruitment materials and messaging.

IQVIA's recruiting experts created a focused online survey and shared it with a predefined engaged population of patients and caregivers dealing with Alzheimer's dementia. The survey included two concepts for recruitment ads with different visuals and text and asked respondents to rate them on overall preference.

The survey garnered over 275 responses and showed a strong positive response to both ad concepts but the patient voice panel "clearly preferred one concept over the other due to its relatability." The feedback helped the sponsor hone the outreach materials. Ultimately, they used Version B for primary ads, while Version A was used in the study guide to support the patient/caregiver decision to join the trial, and new Concept C for the pre-randomization outreach.

### REAL-TIME TRACKING INFORMED OUTREACH

Because every recruiting interaction is tracked, IQVIA's outreach coordinators can deliver a high level of transparency around DTP spending and performance via established KPIs and standardized reporting. Weekly or even daily reports can be shared with sponsors and site teams to ensure alignment and success across recruiting efforts.

During the pandemic, these technological innovations

sped recruiting, reduced leakage in the recruiting funnel, and freed recruiters and sites to focus on engaging, one-on-one, with the patients who were likely to become study participants. It also allows for targeted re-engagement, where recruiters are prompted to reach out to a patient who has stagnated in the recruitment process. The purpose is to contact these individuals, renew interest in participating in the study, and ultimately contribute to randomizations supporting a positive consumer-level engagement experience.

## Direct-to-patient in action for IDV

IQVIA's Global Patient and Site Solutions team successfully supported multiple vaccine trials including a variant booster trial after initial COVID vaccines were approved and Respiratory Syncytial Virus (RSV) trial.

IQVIA's team created a DTP multichannel outreach campaign and deployed site support solutions that complemented trial recruitment efforts, allowing sites to focus on high-quality patient care, maximizing patient flow for increased efficiency and accelerate enrollment. Delivering randomizations 80% over target while enabling the study to meet enrollment goals and timelines.

96% of participating sites opted-in to the DTP campaigns, demonstrating that sites see the benefits of this outreach strategy and appreciate support to engage the community.



**Achieved 80% over target randomizations and meeting enrollment goals and timelines**

## DIVERSITY BECOMES A PRIORITY

In April 2022, the US Food and Drug Administration (FDA) released [draft guidance](#) on achieving diversity in clinical trials. The document provides recommendations to sponsors for developing a race and ethnicity diversity plan for trial enrollment.

The growing expectation for diversity in trial populations spurred pharma companies to develop formal diversity strategies, hire diversity recruiting experts, and set specific diversity criteria for new studies. Today, nearly every trial IQVIA supports now has diversity requirements, and our teams have honed specific strategies for engaging diverse communities in our outreach efforts, which include:

- **Work with trial sites in communities of interest.**

Diversity and inclusion have become key components of the site selection process. Choosing sites in communities of interest reduces the travel burden and demonstrates the sponsor's commitment to supporting the communities they say they want to serve.

- **Make sure site staff represent patients.** It's not enough to locate a site in diverse communities. The staff must reflect that community's race, culture, language, and other defining factors. Patients want to see themselves reflected in the study team. It creates a sense of connectivity for participants and instills confidence that the staff understands their needs.
- **Customize outreach for target populations.** Our DTP recruiting teams create multiple ads featuring people and content that reflect community preferences. The messaging is informed by research defining what makes a trial appealing to different demographics. For example, our 2020 survey found that African American populations are more likely to say their interest in trial participation is a desire for "people like me" to be represented in clinical research. In contrast, white respondents were more likely to join a trial because their physician recommended it, or the study offers access to new treatments. These insights help DTP teams create messages that resonate.



- **Partner with local organizations and leaders.** Much of the DTP recruiting success occurs on the ground. Our teams work with local religious leaders and community influencers to promote education about trials and study opportunities at schools, churches, community events, and other places of interest. These partnerships help us get the word out and create connections between the study and the community.
- **Conduct Data Informed Protocol Assessment (DIPA) to understand variations in perceived burden.** Different populations have different concerns about the burden of trial participation and what it might involve. This can affect their decision to participate in a trial. For example, invasive procedures like a lumbar puncture may deter some patients, whereas others may balk at excessive travel or the idea of home health visits. Conducting a DIPA assessment as part of the protocol development process can help sponsors understand these concerns and factor them into protocol designs.

## Direct-to-patient testing draws diverse populations

IQVIA worked with a large pharma company to recruit more than 40,000 healthy participants to a vaccine trial while adhering to strict diversity demographics – at least 10% Black/African American, 23% Hispanic/ Latino, and 23% over the age of 65.

IQVIA used analytics technology and its DTP experts to test hundreds of ads designed to attract specific populations. They placed ads in the market and monitored the number of views, number of links clicked, and how response rates broke down by age, gender, and ethnicity.

In one example, the tested two versions of an ad designed to attract participants from the Black/African American communities. One ad featured an image of an older Black couple riding bicycles, a “slice of life” ad. The other ad featured an older Black couple in a doctor’s office speaking with a Black doctor.

The ad with the doctor generated 42% more referrals as compared to the version with the couple riding the bicycles. It was one of hundreds of multi-variants tests the team conducted during the recruiting phase of this trial. Each comparison helped them meet diversity quotas while managing recruiting volumes at sites.



***42% more referrals generated using the ad with the doctor as compared to “slice of life” ad***

## Conclusion

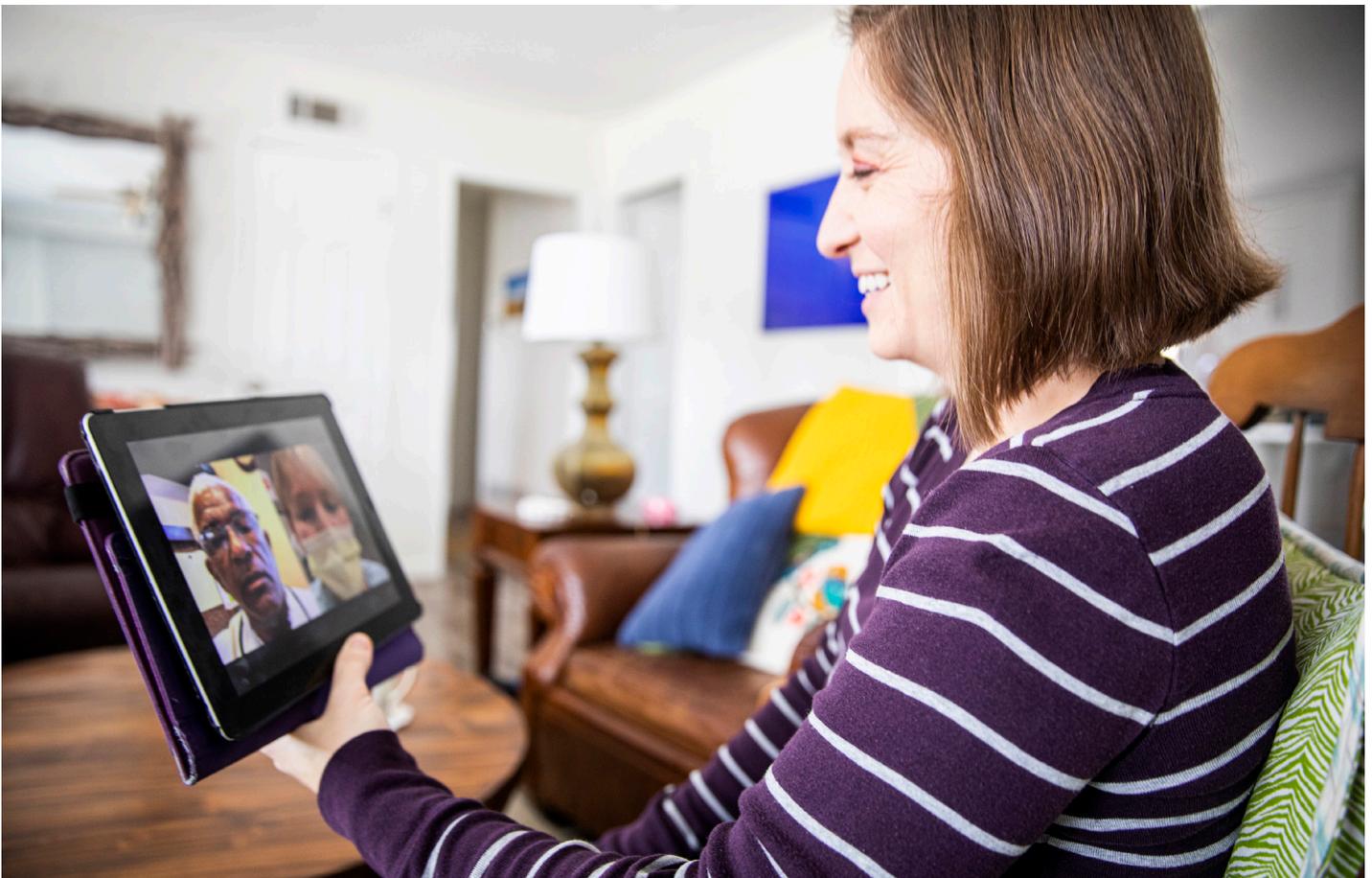
Ongoing patient engagement during the pandemic proved personalization's value to trial recruiting. By understanding the patient journey and leveraging technology as well as data to create a more personalized experience, sponsors can engage communities in clinical research in new ways.

Patients have shown a new interest in study participation – but the caveat, here, is that their interest can be fleeting. If sponsors want to make the most of these trends, they must embed patient perspectives and supportive technology into every trial and embrace a more collaborative, patient-centric approach to attract desired patients to their studies.

The sponsors who observe the methods that evolved during the pandemic will experience easier recruiting, higher retention rates, and the ongoing support of study participants as future advocates for clinical research.

It's a virtuous cycle that, when done correctly, benefits patients, sponsors, and public health, at large.

To learn more about IQVIA Patient Recruitment and Enablement solutions visit [IQVIA.com/patientrecruitment](https://www.iqvia.com/patientrecruitment).



# About the authors



## **SHANA HULL**

Director, Patient Recruitment Strategy

As Director of Patient Recruitment at IQVIA, Shana Hull is responsible for developing global patient recruitment, engagement, and retention strategies for pharmaceutical sponsors' phase I-IV clinical trials. This includes understanding potential barriers and motivators for sites and patients, and recommending solutions, technologies, and tactics in support of our sponsor's goals. Shana has more than 15 years' experience working in human and animal health industries with seven years of experience at IQVIA.



## **JENNIFER CROWLEY**

Associate Director, Patient Centric Solutions

As a seasoned healthcare and technology marketer, Jennifer Crowley's role at IQVIA is to ensure that patient-facing applications are effective for engagement over the course of disparate trial journeys. On top of her 20 years working in high tech, Jennifer is a rare disease mom with firsthand experience as a caregiver and clinical research advocate.



## **GAIL LONG**

Director, Head of Marketing Patient Recruitment

As Head of Marketing for Patient Recruitment and Enablement at IQVIA, Gail Long is responsible for connecting potential patients to clinical trials. Her team identifies potential patients through precision targeting and utilizes a wide range of outreach channels to reach these potential patients. Gail has over 9 years of experience in patient recruitment and over 30 years of marketing experience.



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