IQVIA TECHNOLOGIES

White Paper

The Case for Patient Diversity in Clinical Trials

A customer success story

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A customer success story

Two of America's greatest assets are its diverse demographics and its relentless pursuit of new medicines and treatments to improve patient lives worldwide. Unfortunately, it's a widely known challenge that the two do not go hand in hand. Minority participation in clinical trials is staggeringly deficient.

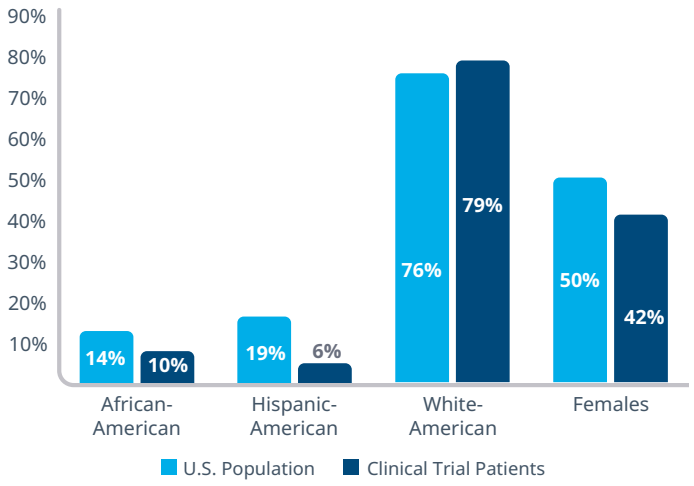
For example, while African Americans and Hispanic Americans make up 33% of the nation,[1] these groups account for only 16% of clinical trial patients.[2] The COVID-19 vaccine trials underscored these disparities. Despite Black individuals representing 21% of COVID-19 deaths, they comprised only 3% of major vaccine trial participants.[2] Other minority populations were similarly underrepresented.[4]

Unfortunately, this can sometimes mean that the populations in which a drug is tested are not the same as those that will use it once approved — and the FDA has noticed. In 2022, the FDA released a draft guidance to industry to provide recommendations to sponsors developing medical products on the approach for a Race and Ethnicity Diversity Plan to enroll representative numbers of participants from underrepresented racial and ethnic populations in the United States.[4]

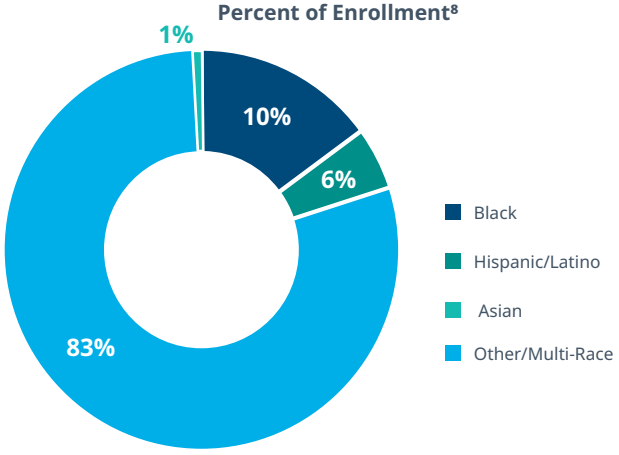
This is especially important in diseases where certain ethnic groups might be disproportionately affected, or where particular communities often respond poorly to established types of treatment. Pharmaceutical sponsors are now looking for innovative ways to monitor and impact the diversity of clinical trials and include it in their plans.[5] Enrolling a diverse and representative patient population is extremely important in ensuring that drugs work for the genuine target population.[6]

It's critical that the industry solves this challenge soon, as it is only going to intensify over time. By 2050, minorities will account for more than half of the American population with Hispanic populations representing more than 29% of the nation.[7]

U.S. POPULATION VS. CLINICAL TRIAL PATIENTS[1,2,3]



Percent of Enrollment[8]



Impacting diversity: A case study

In 2017, the FDA issued a challenge to to a large global pharmaceutical company, asking them to increase diversity for their latest Hepatitis trial by 15%. Achieving such a demographic would be difficult, but the Head of Global Operations at the company was up to the challenge.

To meet these goals, the team developed a multi-tiered approach combining several key tactics and technology solutions:

Education & Recruitment Materials

Dynamic, Real-Time Enrollment Tracking

Site Selection

Site Engagement

Educational patient materials

After speaking with community representatives and physicians across the nation, the sponsor understood that patients across many communities may have misconceptions regarding clinical trials. For instance, many populations don't understand why sponsors conduct clinical trials, what their rights are, and what they should expect in their trial.

As a result, the sponsor created minority-focused educational materials, translated into relevant languages, that focused on patient rights in a clinical trial and on the value they bring to other patients and families around the world. These materials were developed in several formats, distributed at sites and through other recruitment methods to reach as large an audience as possible.

Cultural tips for sites

The sponsor also created a series of materials that provided cultural pointers and tips while explaining that certain cultures should be seen as part of a healthcare team, instead of as strictly patients. They also provided live and on-demand information sessions for sites, background materials, and implementation guides to sites. Finally, they employed the "teach-back" method to let sites test how they would use this information in practice. This allowed sites to better address patients' concerns during the enrollment process.

Site selection

The sponsor selected sites using a rigorous screening process. Sites had to be motivated and prove that they could meet the sponsor's diversity goals. In addition, they had to outline their enrollment strategy that would ensure they would meet the diversity targets while meeting the accelerated enrollment timeline of eight weeks.

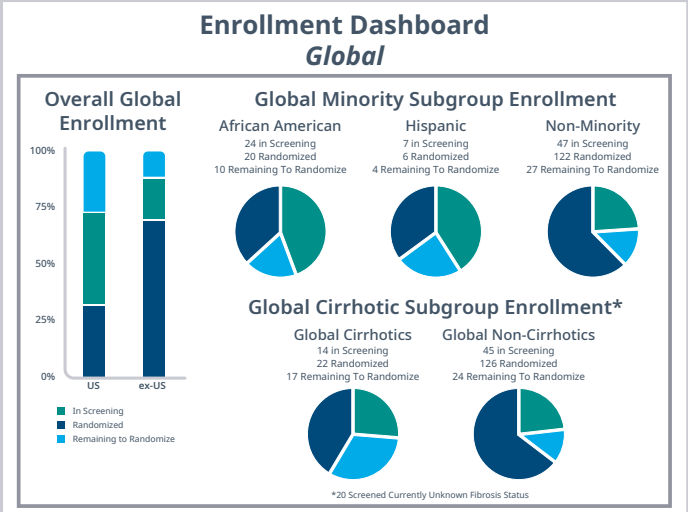
"We needed to find a way to manage enrollment on a global basis that was more than the traditional pathways. We couldn't afford to have emails stuck in spam folders and a lack of shared information. We needed to ensure everyone got it, from site teams to regional headquarters."

– Head of Global Operations

Dynamic real-time enrollment tracking

The sponsor implemented the IQVIA Investigator Site Portal to provide sites with a dynamic real-time enrollment tracker and to keep them engaged and focused on diversity from startup through closeout.

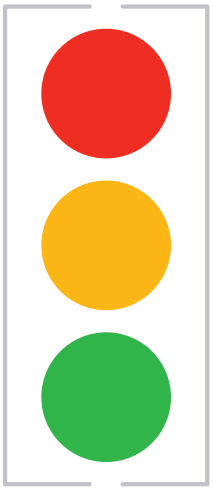
This technology platform also provided sites with real time genotype enrollment status based on current diversity metrics, and ensured transparency for study teams managing the process.



	Total Subjects Screened	Screen Failed	In Screening	Target to Randomize	Total Randomized	Remaining to Randomize
Minority Distribution						
African American	52	5	24	30	20	10
Hispanic	15	2	7	10	6	4
Non-Minority	192	22	47	160	123	27
Cirrhotic Distribution						
Cirrhotic	41	4	14	40	23	17
Non-cirrhotic	197	23	45	160	126	24
Unknown	20	4	16	No Target	0	No Target
Study Totals	**255**	**21**	**75**	**200**	**148**	**51**

Every day, the sponsor guided sites to log in to the study dashboard. There, sites could check enrollment status at a glance while receiving real-time notifications from the company.

Using twice-daily IRT feeds to update the portal with current diversity enrollment numbers, the tracker acted as a virtual traffic light for the screening and randomization of various genotypes at each site. While no patient was denied entry to the trial, the dashboard provided a way to let sites know which groups were still lacking in enrollment and allowed sites to focus their efforts on enrolling these types of populations.



STOP
enrolling this genotype

ENROLL
but stop new screening

SCREEN & ENROLL
this genotype

Based on current demographic statistics, sites were instructed either to stop enrolling, enroll but stop new screening, or screen and enroll each particular genotype. This ensured minority populations were actively being recruited at all times, across all sites, with a simple technology solution that reduced site burden and effectively changed behavior.

Meanwhile, the dashboard provided the sponsor with full transparency of the efforts of sites and enrollment numbers, which was used to generate management reports. This enabled monitors to target their follow-up with sites appropriately and senior management to make strategic decisions and realistic projections based not on conjecture but accurate real-time metrics.

Keeping sites engaged

Sites are typically highly enthusiastic and engaged after the investigator meeting — but it's much more difficult to keep them engaged three weeks, three months or three years later. As a long-term customer of the Investigator Site Portal, the sponsor understood the power of site engagement technology and used IQVIA Technologies to ensure their Hep-C study was top of mind at global sites.

The Investigator Site Portal served as a trusted source of information used by sites to understand enrollment goals, communicate among themselves, and reach out to the sponsor directly. The Site Engagement module of the platform used an integrated approach to help sites and the sponsor accomplish their enrollment and diversity goals, including:

- Relevant and timely study news
- Educational videos, awareness and team building
- Inspiring leaderboards and recognition badges
- Document exchange
- Visit guides and support tools

"In total, we uploaded nearly 500 enrollment reports over the course of the study with fantastic response rates from sites. On average, more than 50% of sites viewed and downloaded the new enrollment reports within four hours of an update."

– Head of Global Operations

Relevant and timely study news

Study news and community updates were critical to keeping site teams engaged. The sponsor pushed relevant study news such as enrollment numbers, important updates, and video tips to sites. They also ensured that these updates were sent using custom distribution lists so that only those who needed to know would receive the information. This tactic, along with ensuring that no update was ever emailed to teams, caused the platform to become the single source of trusted study information.

"We established a clinical trials community. It was not just a Sharepoint application or a website; we engaged sites with communication that they could respond to."

– Head of Global Operations

Educational videos, awareness and team building

The Site Engagement module solution was key in reinforcing the training methods used by the sponsor at the outset of the trial. Sites could view additional training videos along with tips and tricks from other investigators and leaders in Hepatitis care.

In addition, the sponsor used the Site Engagement module of the platform to promote awarenessand foster a sense of greater community with team photos. They encouraged sites to post pictures to the platform that showed them spreading awareness. They also created friendly competitions that awarded donations to charities.

AWARENESS AND TEAM BUILDING

Encourage sites to post pictures to the network that show them supporting awareness (e.g., wearing orange for a melanoma study).

Inspiring leaderboards and recognition badges

"Gamification" is an emerging social strategy used in numerous industries to promote system adoption and motivation. One aspect of gamification is to reward users for positive behavior and to acknowledge their achievements with a token similar to a video game — for example, attaching a virtual badge to their profile.

The sponsor employed this idea with great success throughout their Hep-C trials by recognizing and rewarding site accomplishments that were significant in meeting their diversity goals. Awards were announced through the module's communication newsfeed."

First Patient in Trial for January 2016 from *Amanda Rogers,* Synapsia

Congratulations for enrolling first patient in this trial!

10 Patients Enrolled for January 2016 from *Amanda Rogers,* Synapsia

Keep up the great work!!

Query Master for March 2016 from *Kathy Cook,* Pursuit

Congratulations for resolving all queries!

The theory behind badging is that such a visible level of recognition makes sites feel proud and inspired to earn more badges. It enables sponsors to develop a secure community of sites that are team-based and results-oriented. IQVIA Technologies believes strongly in this concept having seen badges posted throughout sites and observed the result of encouraging and congratulating site staff in front of their peers.

"We received feedback from sites that they were printing out their badges and hanging them around the office. This made us ecstatic and let us know that the badges were working."

– Head of Global Operations

Document exchange

The IQVIA Investigator Site Portal provides sites and sponsors with a secure repository of all study documents that is fully searchable with built-in metric tracking and flexible access permissions. The sponsor employed this tool with great success throughout the Hep-C study, allowing sites to download, upload, track, and manage documents efficiently.

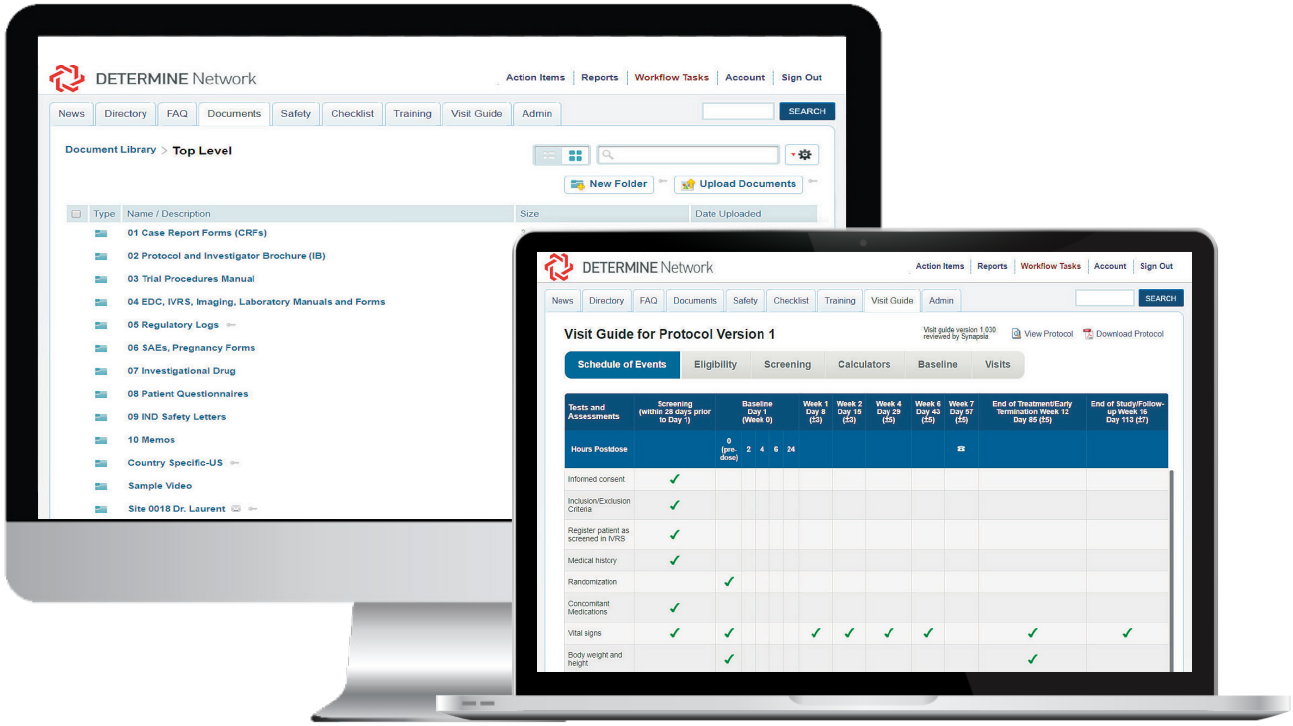
As a result, the sponsor met their eight-week site activation goal.

Visit guides and support tools

The Site Engagement module allowed the sponsor to ease the burden of sites' enrollment challenges. The platform provides a visit calculator that allows investigators to automatically schedule all future patient visits based on their availability, minimizing the protocol deviations.

Additionally, the platform provides an interactive directory of all relevant study contacts, third-party educational materials, links to other systems, and a searchable FAQ.

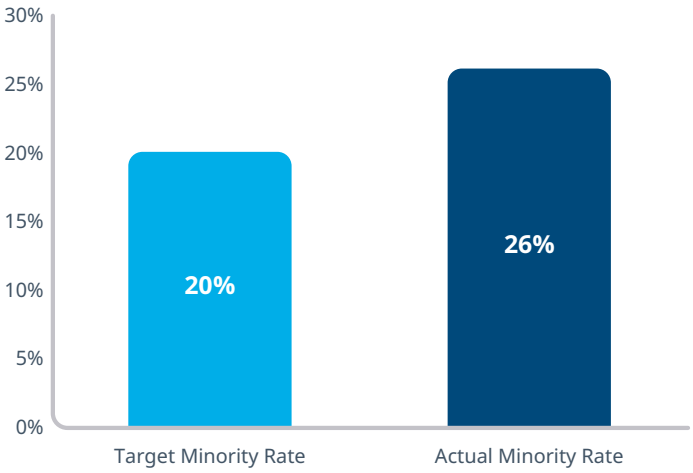
These tools coalesce in a way that caters to sites' needs while reinforcing the platform as a single-source of trusted information.



The results

With an outstanding 26% actual minority participation rate, the sponsor surpassed the diversity goals set by the FDA.

In addition, they activated all study sites throughout the Hep-C trial program within eight weeks and completed all enrollment activities within an additional eight weeks, a remarkably short activation time.



In addition to the diversity goals, the sponsor celebrated other successes such as:

- An established clinical trial community that responded to posted content and engaged with each other
- Well-educated sites and patients who understood each other, their roles, and how they were helping better the world
- Very high patient retention and adherence rates

"The combination of educational information along with technology tools allowed us to far surpass our goal. It was something that my team and I took pride in and something we think is worth sharing with the industry."

– Head of Global Operations

SUMMARY

The sponsor's efforts in achieving diversity were a success. Through careful research, outreach, technology, and education, they surpassed the diversity goals recommended by the FDA for the Hepatitis-C study.

IQVIA Technologies develops purpose-built solutions on a future-state architecture to enable connected intelligence across the entire life sciences product life cycle. Under our Orchestrated Clinical Trials (OCT) platform, we're driving smarter, faster trials for sponsors, sites and patients with more than 20 market-leading, cloud-based products, and tech-enabled services. These best-of-breed technologies are grouped as Digital Suites and are available independently of our CRO services, with support models customized to meet your specific business needs.

To learn more how IQVIA Technologies can help improve your next trial, from study startup to closeout, request a personal demo at

www.IQVIA.com/InvestigatorSitePortal

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