The Case for Patient Diversity in Clinical Trials

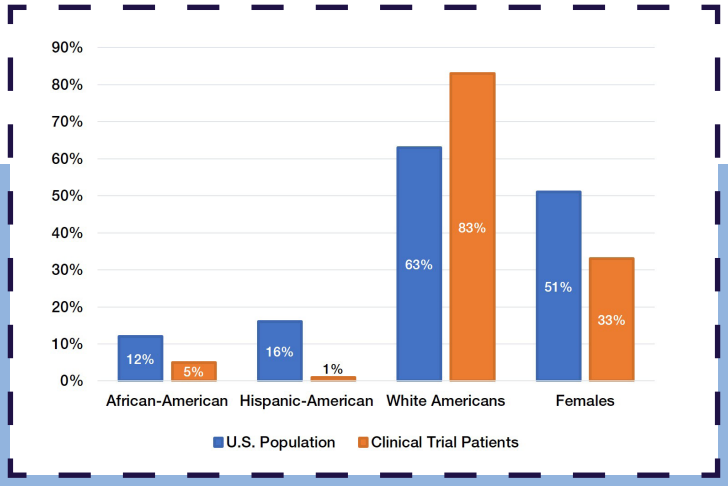
Two of America's greatest assets are its diverse demographics and its relentless pursuit of new medicines and treatments to improve patient lives worldwide. Unfortunately, it's a widely-known (but little discussed) challenge that the two do not go hand in hand. Minority participation in clinical trials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

For example, America contains over 39 million African-Americans and 52 million Hispanic-Americans. While these groups represent 28% of the nation, they only account for 6% of clinical trial patients.

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.

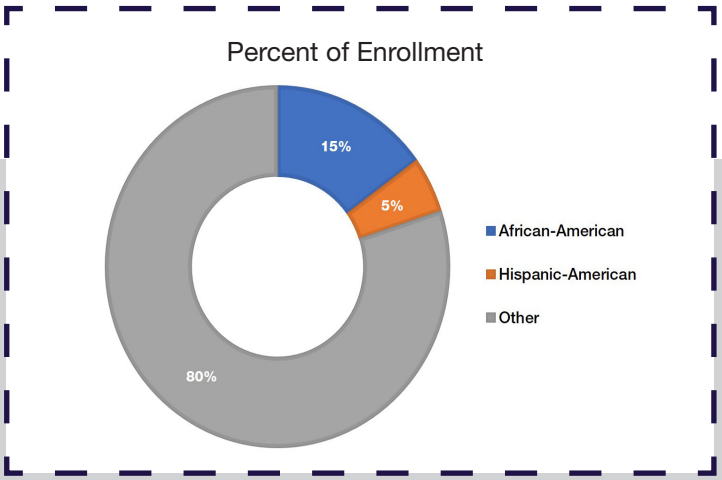
As the industry continues to struggle with enrollment overall, diversity has seemingly been placed on the back-burner. Unfortunately, this can sometimes mean that the populations who test a drug candidate are not the same populations who will use it once it's approved - and the FDA has noticed. In 2016, Robert Chaff, Commissioner of the FDA stated that one of their greatest challenges is "ensuring that research participants are representative of the patients who will use the medical product."[3]

This is especially true in diseases where certain ethnic groups might be disproportionately affected, or where particular communities often respond poorly to established types of treatment. For example, studies have shown the poor effect of ACE inhibitors in African-American patients[1]. Thus, enrolling a diverse and representative patient population is extremely important in ensuring that drugs work for the genuine target population.



Taking the First Step

Often in business, as in life, one of the biggest steps is the first one: identifying a problem and resolving to solve it. How a business defines success determines who they are as a company. The simple act of creating a goal and a mission statement can put into action new approaches and policies that drive results.



In 2017, the FDA issued a challenge to the sponsor, asking them to increase diversity for their latest hepatitis trial by 15%. Achieving such a demographic would mean a significant increase over the sponsor's previous study 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. They may also not understand what their rights are and what they should expect throughout 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 on several formats and distributed at sites and other recruiment 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, and provided background materials and implementation guides for 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***

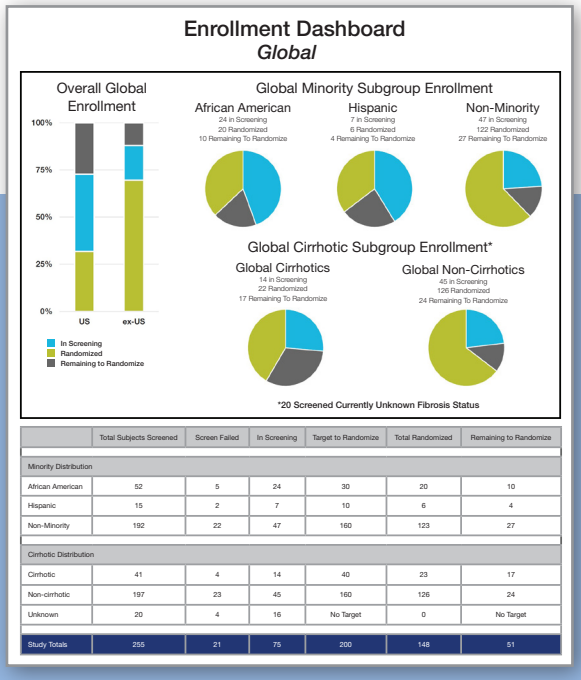
Technology Tools

In addition, the sponsor implemented the **DrugDev Spark™** clinical operations suite to provide sites with a dynamic real-time enrollment tracker and to keep them engaged (and focused on diversity) from startup through closeout.

Dynamic Real-time Enrollment Tracking

When the sponsor needed a way to provide sites with real-time genotype enrollment statuses based on current diversity metrics, and to ensure transparency for study teams managing the process, the company partnered with DrugDev to develop a dynamic enrollment tracker.

Every day, the sponsor guided sites to login to the study dashboard. There on the first page of the DrugDev Spark network, sites could check enrollment statuses at a glance while receiving real-time notifications from the company.



	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

Using twice-daily IVR 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 into the efforts of sites while allowing them to drill-down into enrollment numbers and generate management reports. This enabled monitors to target their follow-up with sites appropriately, and for senior management to make strategic decisions and realistic projections based not on conjecture but accurate real-time metrics.

> **"In total, we uploaded over 491 enrollment reports over the course of the study with fantastic response rates from sites. On average, more than 50% sites viewed and downloaded the new enrollment reports within four hours of an update."**
>
> ***– Head of Global Operations***

Keeping Sites Engaged

The industry knows that it's easy to keep sites engaged three days after the IM – but much more difficult to keep them engaged three weeks, three months or three years later. As a long-term customer, the sponsor understood the power of site engagement technology and used DrugDev Spark to ensure their Hep-C study was top of mind at global sites.

The platform served as a trusted source of information used by sites to understand enrollment goals, communicate among themselves, and outreach to the sponsor directly. This approach was successful in ensuring that the site engagement tool was continually used by sites throughout the trial as DrugDev Spark proved to be one of the primary drivers in meeting the sponsor's diversity goals. The Site Engagement 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
- Trial conduct support (visit guides and support tools)

> **"We established a clinical trials community. It was not just a share point application or a website, we engaged sites with communication that they could respond to."**
>
> ***– 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.

Educational Videos, Awareness and Team Building

The site engagement 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.

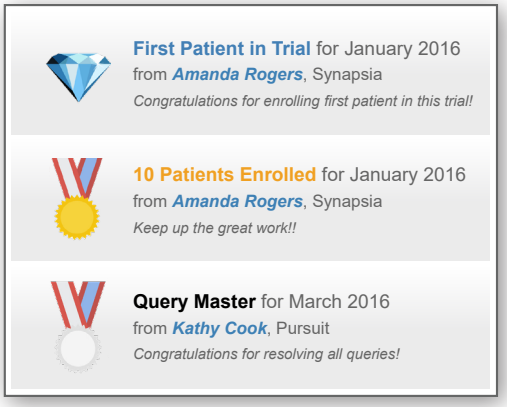
In addition, the sponsor used the site engagement platform to promote awareness, and foster a sense of greater community with team photos. They encouraged sites to post pictures to the platform that showed them spreading awareness through colorful dress and activities. In addition, they created fund-raising incentives that donated to hepatitis foundations on behalf of sites. These features coalesced to preserve morale while keeping sites focused on the trials.

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 platform's communication newsfeed for everyone in the network which allowed them to like, comment, and share.

The theory behind badging is that such a visible level of recognition within the system makes sites feel proud of their accomplishments and inspires them to earn more badges. It also enables sponsors to develop a secure virtual community of sites within a team-based and results-oriented environment. DrugDev 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

DrugDev's Site Engagement platform 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 studies allowing sites to download, upload, track, and manage documents efficiently.

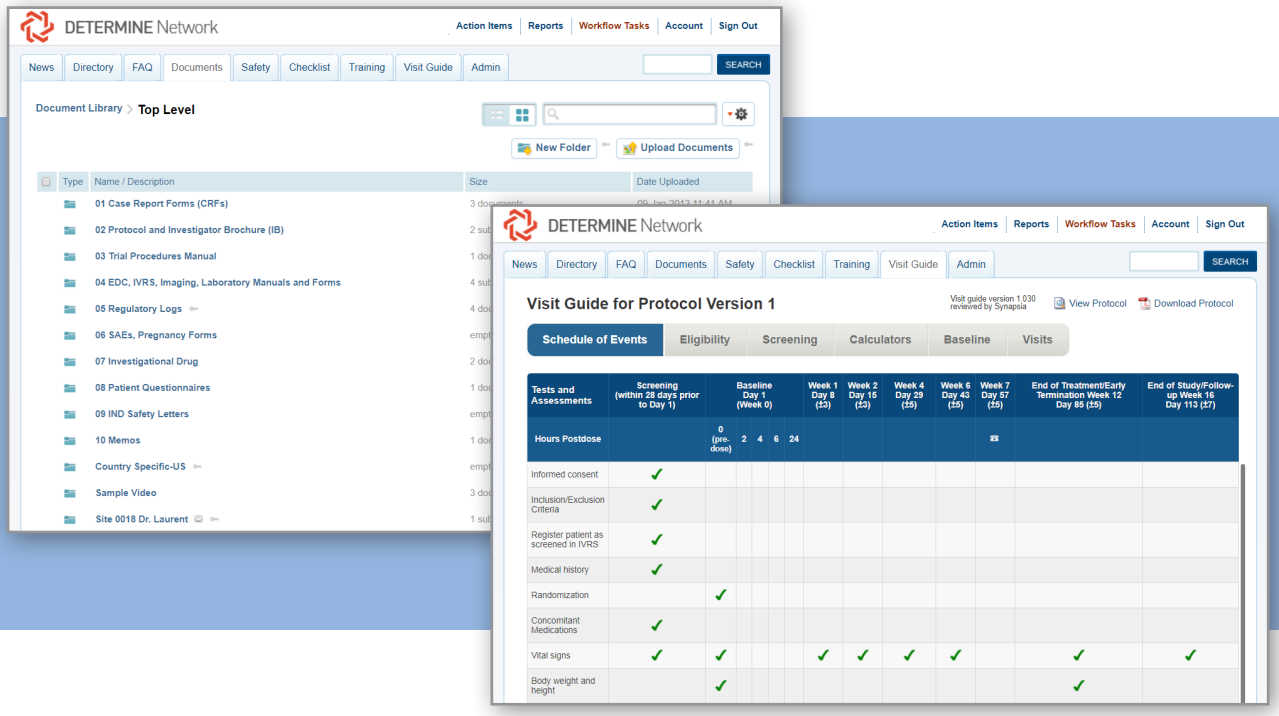
As a result, the sponsor met their eight-week site activation goal because sites didn't have to worry about tracking different documents, managing versions, or document storage.

Trial Conduct Support - Visit Guides and Support Tools

The Site Engagement platform allowed the sponsor to ease the burden of sites enrollment challenges. Tools such as the visitation guide allow sites to walk patients through enrollment protocol while minimizing deviations from standard protocol. The platform also provides an enrollment calculator which allows investigators to automatically schedule all future patient visits based on their availability.

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 through the combination of its commitment, targeted educational materials, and DrugDev Spark for dynamic real-time enrollment tracking and ongoing site engagement. This was an increase far greater than in any previous study by the sponsor.

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…

- ✓ Establishing a clinical trial community that became a trusted source of information for study news
- ✓ Engaged sites who responded to updates in study news and commented on updates
- ✓ 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.

DrugDev Spark™

DrugDev helps the world do more trials through **industry-wide collaboration**, **standardization** and a **beautiful technology experience**. DrugDev Spark™, the unified clinical operations suite, is comprised of proven solutions used by 85 sponsors and CROs on over 1,800 clinical trials to transform the quality and efficiency of clinical trials from startup through closeout. DrugDev Spark is powered by the DrugDev Golden Number, the award-winning universal identifier for global site facilities and investigators used by TransCelerate and the Investigator Databank.

To learn more how DrugDev can help improve your next trial, from study startup to closeout, request a personal demo at **www.drugdev.com**.

References

1. *Page, Michael R., RPh. The JNC 8 Hypertension Guidelines: An In-Depth Guide - See More At: http://www.ajmc.com/journals/evidence-based-diabetes-management/2014/january-2014/the-jnc-8-hypertension-guidelines-an-in-depth-guide#sthash.oDnst92R.dpuf. AJMC, 2017. Web. 20 June 2017.*
2. *Incidence Reference: Successful Strategies for Engaging Women and Minorities in Clinical Trials; The Society for Women's Health Research United States Food and Drug Administration Office of Women's Health; September 22 23, 2011 Trends Reference: PhRMA Diversity in Clinical Trials Roundtable Meeting Summary, May 2014*
3. *Califf, Robert M., M.D. 2016: The Year of Diversity in Clinical Trials https://blogs.fda.gov/fdavoice/index.php/2016/01/2016-the-year-of-diversity-in-clinical-trials/. Web 2016*