



WHITE PAPER

YOU CAN'T HAVE PRECISION MEDICINE IF YOU STILL HAVE DISPARITIES

How to address disparities in clinical research to accelerate cures for *all* patients

By Kathy Giusti and Richard Hamermesh, co-chairs of the HBS Kraft Accelerator Leadership Forum



OVERVIEW

The promise of precision medicine is developing precise treatments for all patients. But that promise is not realized if registries and clinical trials are not representative of the populations affected by a disease—which is often the case today. That means treatments are not being tested with all patients who need them.

Through our work co-leading the HBS Kraft Accelerator Leadership Forum, we have held meetings bringing together CEOs of leading disease foundations and have heard in-depth case studies of how organizations are working to address disparities. We have also conducted dozens of interviews with leaders throughout the healthcare ecosystem to understand strategies and approaches in addressing disparities.

Through these meetings, case studies, and interviews, we have gained valuable perspective on which ideas and strategies can be reapplied and have developed a framework to help guide disease foundations in accelerating the development of cures for all patients.

Among the key ideas in this framework are that:

1. **Addressing disparities requires a strategy.** The most successful efforts don't jump to tactics; they are grounded in a clear organizational strategy.
2. **There is no one-size-fits-all solution.** The right strategy and plan will vary based for each disease and the specific patients affected by the disease.
3. **Engage patients by going *beyond* AMCs.** Historically, clinical trials have recruited patients mainly through academic medical centers. But this approach is limited. We have heard success stories of working with health systems and community networks, and even going directly to consumers.

Provided below is background about the HBS Kraft Accelerator and the Leadership Forum and an explanation of the framework we have developed, including several mini-case studies, to help organizations think about and address disparities.

BACKGROUND

HBS Kraft Accelerator

In 2016, the Kraft family made a donation to Harvard Business School focused on precision medicine. As a result, Kathy Giusti and Richard Hamermesh became co-leaders of the HBS Kraft Precision Medicine Accelerator. Over the next four years they brought to HBS over 300 of the most innovative leaders from across the precision medicine ecosystem to share insights and best practices. Giusti and Hamermesh disseminated key findings through the *Harvard Business Review* and other leading publications and have curated a collection of tools and resources in the HBS Kraft Accelerator [Playbook for Cures](#).

HBS Kraft Accelerator Leadership Forum

Early on in the COVID-19 pandemic—as many nonprofits were experiencing revenue declines of 80% or more¹—and in anticipation of the post-COVID world, Giusti and Hamermesh created the HBS Kraft Accelerator Leadership Forum.

Regular Leadership Forum meetings bring together C-level nonprofit leaders to focus on the most significant challenges they are facing and to share solutions, best practices, new business models, and partnership opportunities.

In the second half of 2020, Leadership Forum members agreed that addressing disparities had quickly become a top priority for their disease-focused organizations. They each agreed to develop and share case studies describing how their organizations are working to address disparities.

Together, through a series of meetings and presentations, Leadership Forum members have shared and are continuing to share relevant strategies and programs their organizations are pursuing to address the problem. Through these discussions, along with interviews of more than 40 direct-to-consumer experts and experts on disparities at academic medical centers and health systems and within communities, a series of ideas has emerged for how disease foundations can activate the right strategies to find cures for all patients.

The Idea in Brief

We have heard three major themes:



Define the representative population for your disease and set intentional goals. The starting point is to determine what is the “representative” population for a disease, with knowledge that every disease is different. This picture of representative then guides an organization in its efforts to create representative data.



Develop a channel and engagement strategy to enroll representative patient populations in registries. The channel strategy will vary based on the demographics of a disease. It may involve a combination of channels including AMCs, health systems, community networks, and direct-to-consumer activities. It can also entail working with partners who are trusted by and have access to your patient population.



Once you have aggregated representative data, **leverage this data to generate insights** about disparities, treatment and care gaps, and opportunities.

This white paper goes into more detail about each of these themes.

¹ The Impact of COVID-19 on Large and Mid-Sized Nonprofits, Independent Sector, Survey during May and June 2020. [Link](#)

HBS KRAFT ACCELERATOR LEADERSHIP FORUM FRAMEWORK FOR ADDRESSING DISPARITIES

Step 1: Define the representative population for your disease and set intentional goals.

What is a “representative” patient population is different for every disease, since the demographics and genomics are different for every disease. The representative patient population for prostate cancer is very different from the representative patient population for breast cancer. And what is representative for sickle cell disease, which mainly affects Black individuals, is very different from multiple sclerosis, which is most common among Caucasians.

Thus, the starting point for every foundation is to define “representative” in terms of factors such as gender, race, age, and ethnicity and then, once there is a clear definition of representative, to set very intentional goals for the diversity of the population in a registry or clinical trial. (While this now sounds somewhat obvious based on the current context, historically, disease foundations and pharmaceutical companies have not known what is representative and have not set intentional diversity goals.)

Two examples :

1. **Multiple Myeloma Research Foundation (MMRF).** As part of MMRF’s CoMMpass studies, which began in 2011, long before addressing disparities was a priority, MMRF did not set intentional patient recruitment targets. However, because participating enrollment sites included AMCs (such as Mount Sinai in New York City and Emory) and health systems (like CarolinaEast and the VA) with a large number of Black patients, a diverse patient population was recruited, almost by accident. Among participants in CoMMpass, 77% were Caucasian, 16% Black, 2% Asian, and 5% other.

Knowing that minorities are a significant and important part of the multiple myeloma patient population, MMRF is now intentional. For current and future studies, MMRF wants 20% of participating patients to be Black.



2. **Follicular Lymphoma Foundation (FLF).** FLF is a relatively new organization, founded in 2019. In sprinting to create the organization, build an infrastructure, use social media to access FL patients, and initiate research, the topic of diversity had not been on FLF’s radar.

In early 2021, IQVIA assisted FLF in gathering data from sources such as the SEER Incidence Database (SEER is the National Cancer Institute’s Surveillance, Epidemiology, and End Results Program). For the first time, FLF had a sense of its representative population (at least in the US): 85% of patients with follicular lymphoma are white, 6% are Black, and 4% are Asian.

When looking at previous FL clinical trials, FLF discovered that 19% of patients were Asian while only 1% were Black, meaning that Asian patients were dramatically overrepresented while Black patients were underrepresented. FLF is using this understanding of what is representative to set intentional goals about engaging more Black patients.



Step 2: Develop a channel and patient engagement strategy to enroll a representative patient population.

Once an organization has determined what representative is for a disease, the charge becomes to create a strategy that produces a representative patient dataset. Members of the HBS Kraft Accelerator Leadership Forum are using various strategies and channels to engage the right patients for their registries and trials.

A) Academic medical centers

Historically, researchers have relied on AMCs as the primary source of patients for clinical trials. While academic medical centers have clinical trial experience and expertise, minority populations tend to be underrepresented in trials because AMCs have not been particularly effective at enrolling minority patients.

But this doesn't have to be the case. At a recent Leadership Forum, HBS Professor Robert Huckman, who is on the board of Brigham & Women's Hospital—an AMC in Boston—said that AMCs are aware of the issue and need to do better. He noted that many AMCs are located in areas where they have access to diverse trial participants, including Black patients and uninsured patients. He believes there is potential for AMCs to do more to address disparities. The challenge is making this a priority for AMCs, which don't always face incentives to recruit diverse populations.

The Pancreatic Cancer Action Network (PanCAN) is making diversity a factor in choosing AMCs for research sites in the organization's Precision Promise clinical trial. This trial started with 15 sites, but PanCAN is adding five more sites and included diversity as a selection criteria. Being chosen as a site is a competitive process, requiring completion of an extensive RFP.



Based on PanCAN's increased focus on disparities, the organization has added several measures related to diversity to its site-selection criteria. These include the demographics of the patient population served by a site and whether the site has minority outreach programs. All of the recently selected sites have minority outreach programs and/or significant African American, Native American, or Latino patient populations. A real-world challenge that PanCAN faced was how to balance selection criteria associated with diversity along with geographic diversity, patient volume, and operational capabilities required to execute on the study.

"WHEN LOOKING AT SITES TO FUEL A PROGRAM LIKE THIS, WE AIM TO BALANCE THE NEED FOR INCREASED DIVERSITY IN PARTICIPANTS WITH THE SITE EXPERTISE AND OPERATIONS REQUIRED TO EXECUTE A STUDY AS COMPLEX AS PRECISION PROMISE."

SUDHEER DOSS, PHD, CHIEF DATA OFFICER & HEAD OF BUSINESS DEVELOPMENT, PANCAN

While AMCs will remain an important source for patients for registries and trials, a central theme from the Leadership Forum is the need to go beyond AMCs in engaging patients.

Professor Huckman pointed out that in some Black communities there may be distrust of what people see as a predominantly white medical delivery enterprise. As a result, many people in Black communities don't seek a relationship with a primary care provider or a healthcare institution. Instead, they want episodic treatment at a moment of need, which could be provided through urgent care centers or retail clinics. Researchers need to understand this mindset and work through channels that provide them with access to a wide and representative population of patients.

B) Health systems

As the MMRF's experience with the CoMMpass study showed, health systems that are embedded in communities often have success in recruiting diverse patient populations.

Ochsner Health, the largest health system in Louisiana, is an example of a health system with the ability to help recruit a diverse patient population. Ochsner has about 40 hospitals and clinics that provide care to roughly one million individuals; Ochsner also has an independent academic medical center with a clinical research arm and a data science research arm. For years Ochsner has been working to improve African American participation in clinical trials. Lessons from Ochsner's experience include:

- **Build trust in the community.** Ochsner has formed a diverse Community Research Advisory Board, recruited diverse public advocates as spokespeople, invested to build 10 community health centers in disadvantaged neighborhoods, and is launching the Institute for Health Equity.
- **Form partnerships.** Ochsner partnered with Xavier University, a local HBCU, to start a joint physician assistant program. Ochsner's actions have provided "street cred" in the community.
- **Secure additional resources.** For studies on COVID-19 vaccines, Ochsner was selected as a site, based on its history of minority recruitment for studies. But for these COVID studies, the large pharma companies didn't provide any additional resources to assist with recruitment, and the recruitment materials were inappropriate. Ochsner had to do everything on its own, which involved going into communities, partnering with the local HBCUs, and enlisting local influencers. Lack of additional resources is frustrating and highlights the need for adequate resources to do what it takes for minority recruitment.



“WHEN YOU’RE DEALING WITH RECRUITING MINORITIES, IT’S GOING TO REQUIRE EXTRA RESOURCES. YOU CAN’T TREAT THEM THE SAME AS YOU WOULD TREAT A SITE TO RECRUIT UPPER-CLASS WHITE PATIENTS.”

LEONARDO SEOANE, SVP & CHIEF ACADEMIC OFFICER, OCHSNER HEALTH

An example of a foundation partnering with a health system is the Prostate Cancer Foundation’s (PCF) work with the VA.

As background, 57% of prostate cancers are due to familial inheritance, and the genetics of West African ancestry confer a 2 to 11 times higher increased risk of prostate cancer, depending on the genetic profile of the individual. African Americans are twice as likely to get prostate cancer and to die from it.

PCF is working on a new type of polygenic risk score with a high predictive accuracy that is based on reading a set of inherited genes for men of West African ancestry.



PCF concluded that the VA, where prostate cancer is the leading type of cancer, is an ideal partner for developing this risk score, for collaborating to improve the standard of care in treating prostate cancer, and for solving issues of health equity in cancer research and care. The VA has one of the best longitudinal electronic medical records in the US and has records for 500,000 patients with prostate cancer, 90,000 of whom (18%) are African American. Also, the VA offers the best US model for health outcomes research in cancer as the health system offers all veterans equal access and complete health equity.

In partnership with the VA, PCF is working to provide patients the same level of care as the chair of a hedge fund would receive at a top AMC. This includes genomic testing, sequencing, and biomarker evaluation. PCF is working toward a standard of care where no decision is made without precision, which means that no decision is made without genomics and without exploiting the power of big data. It also means that every veteran with prostate cancer, regardless of race, should get equal access to promising clinical trials.

“IT IS POSSIBLE TO CHANGE A CULTURE WHEN BREAKTHROUGHS KEEP COMING TO IMPROVE THE STANDARD OF CARE. SO IF YOU CHANGE THE STANDARD OF CARE, AS OUR FOUNDATION HAS REPEATEDLY DONE OVER THE PAST 10 YEARS, IT BECOMES A LOT EASIER TO GUIDE AND INCENTIVIZE OTHERS TO DELIVER THE STATE OF SCIENCE OF PRECISION ONCOLOGY CARE.”

DR. JONATHAN SIMONS, CEO, PCF

In building this relationship with the VA, PCF has invested considerable time and substantial capital, and has gained an extensive and granular understanding of the VA’s current model of cancer care. There is now alignment within the VA and the VA is looking for other partners to replicate for other diseases what PCF has catalyzed.

Dr. Simons suggested that disease foundation leaders look for partnership opportunities with the VA and with other integrated health systems such as Geisinger and Kaiser.

C) Community networks

An important way to engage patients is to go outside of the traditional healthcare system and reach patients in their communities. While some organizations try to go into communities on their own, this can be a challenge if the organization lacks awareness and trust within the community. An effective approach is to identify and partner with the right community network “trust brokers,” which is a way to reach into communities at scale.

Silas Buchanan, CEO of the Institute for eHealth Equity, works with underserved communities of color, raising their literacy around adopting and utilizing technology to improve their health outcomes. Buchanan has worked with the AME Church, the largest mainline historically Black denomination in the world, with 2,000 congregations and about two million members. The idea has been for these congregations to have dedicated health ministers, often retired doctors or nurses, who are embedded in the congregation. Almost 40% of AME congregations now have health ministries. This provides a culturally appropriate platform to connect with and gather data about patients with specific diseases and then provide

information and assistance to patients. “The messenger can be as important as the message,” said Buchanan. “Faith-based organizations can be important messengers.”

Buchanan is now working on both a secular and a non-secular social network consisting of faith-based organizations along with barber shops, nail salons, and corner stores. The intent is to find ways to strengthen communities on an ongoing basis, not just when there is an urgent need, and to share data with communities to improve health outcomes. The goal is to form partnerships that become clinical trial resource centers and have these centers become embedded as part of the clinical trial process.

“IF YOU’RE NOT WORKING AS HARD AND WITH INTENTION WITH CULTURALLY APPROPRIATE FAITH AND COMMUNITY-BASED ORGANIZATIONS AS YOU ARE WITH ACADEMIC CENTERS, YOU’RE NOT GOING TO GET WHERE YOU WANT TO GO AS QUICKLY.”

SILAS BUCHANAN, CEO, INSTITUTE FOR HEALTH EQUITY

D) Direct-to-consumer (DTC)

Another way to reach and engage patients is by using traditional consumer marketing techniques. As part of the HBS Kraft Accelerator, an entire workstream was dedicated to direct-to-consumer marketing approaches that nonprofits can use to engage patients. The principles from this workstream also apply to addressing disparities.

As a new organization, the Follicular Lymphoma Foundation has built an online community largely through Facebook. Upon learning that this community lacked representative participation by Black individuals, FLF began actively recruiting more Black patients and influencers into its Patient Superusers Group on Facebook.

The Joy Collective’s experience is a powerful example of DTC in action. The Joy Collective is a Black and women-owned agency that works with brands to create movements that impact lives. The Joy Collective was engaged by the Ad Council to engage the Black community on Covid-19 vaccination. This agency developed deep understanding and insights about vaccine hesitation in the Black community and used these insights in creating a campaign titled “Let’s Get Back To.” The campaign has authentic multi-platform creative that educates Black individuals to make an informed choice. Messaging leads with empathy and respect, acknowledges personal choice, and empowers individuals.

This messaging was delivered through community-based programs and partnerships, including virtual town halls in partnership with organizations such as the NAACP, BET, Black sororities and fraternities, and faith-based organizations. Messages were delivered by trusted messengers and ambassadors, featuring respected actors, athletes, and pastors. And targeted communication included email campaigns and provision of tool kits.

The results have been impressive and have moved the needle in the Black community by increasing the percentage of the population that has received a Covid-19 vaccine. The Joy Collective’s work shows that well-orchestrated health-focused DTC efforts in minority communities can be successful in reaching the intended audience and motivating action.

Step 3: Leverage this representative data to generate insights about disparities, treatment and care gaps, and opportunities.

The reason to aggregate representative patient data is to analyze this data to determine how well treatments work among all patients.

An example is the Cystic Fibrosis Foundation (CFF). CFF has a registry, started in the early 1970s, that contains data, including demographic data, on 90% of CF patients in the US. However, despite having this extensive longitudinal data, CFF hadn’t looked at this data in-depth to better understand disparities. That changed in 2020 as CFF looked more rigorously at the data in its registry.

Through this analysis, CFF found:

- A 14% participation rate in clinical trials among all patients with CF
- But only a 3% participation rate among African Americans and Hispanics
- 2X higher mortality rates among African Americans and Hispanics over age 18

CFF was disappointed to find that despite previous efforts to enlist minorities in trials, only 3% of African Americans and Hispanics participate in trials. The reason: CF is perceived as a white person’s disease and CFF is perceived as focused on the white community. To address this, CFF is working to build a cycle of trust by identifying brand partners and giving a greater voice to people of color.

Most importantly, the finding about higher mortality rates among African Americans and Hispanics has led CFF to want to understand the basis for these disparities. The prevailing assumption had been that differences in outcomes



were due to socioeconomic differences. As background, 90% of people with CF can benefit from drugs that have been developed for CF. But among the 10% who don't respond to these drugs, 40% are African American or Hispanic. The reason for this difference isn't just socioeconomic; it's also genetic.

Since conducting this analysis, CFF has been transparent in calling attention to this data at its international CF meetings, which has lit a fire in the scientific and care community.

“ONE OF THE LESSONS FOR US WAS THAT WE ARE COLLECTING THE RIGHT DATA, BUT LET’S REALLY LOOK AT THIS DATA TO UNDERSTAND AND QUANTIFY SOME OF THE DISPARITIES TO GIVE US A TARGET. IN-DEPTH UNDERSTANDING IS ESSENTIAL IF WE ARE TO DEVELOP THE RIGHT STRATEGY TO DELIVER ON OUR MISSION TO SERVE ALL PEOPLE WITH CF.”

MIKE BOYLE, CEO, CYSTIC FIBROSIS FOUNDATION

CONCLUSION

The key to accelerating cures for all patients is having representative patient data. Developing this data requires defining “representative” for a disease, setting intentional recruitment goals, and taking a strategic approach to determine the most appropriate channels for recruiting patients. Since representative is different for every disease, there is no one-size-fits-all approach; a different engagement and recruitment strategy is needed for every disease.

Once representative data is generated, it must be analyzed to identify if disparities exist and to understand whether the disparities are socioeconomic or genetic, and the reasons for the disparities.

Accumulating representative data and the subsequent analysis is the path to accelerating cures for all patients.