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Foreword

COVID-19 itself is an indiscriminate virus, but the health outcomes of individuals affected and the impact of the pandemic on diverse communities has bluntly demonstrated how deeply inequalities are tied to social determinants of health (SDoH) and at play in public life.

The report included in this e-Book – *Assessing eHealth Initiative's Guiding Principles for Ethical Use of SDoH Data During COVID-19* – outlines powerful examples of business, state and community-based initiatives to tackle the problems of SDoH. While we know true equity is some way off, it is encouraging to see progress.

The eHealth Initiative's principles point toward solutions, especially in providing a benchmark for communication and information sharing that will help us tackle wider health concerns, whether pandemic-related or not.

I am inspired to see data and purpose combining in an effort to combat some of the problems of this pandemic, but also to witness ethical use of people's private details and information to improve their health and lives as we navigate this challenge. From the US payer that used SDoH data to identify those in need of food support and provide 900,000 meals, to the health care provider that evaluated patient needs versus local ability to meet those needs at the precision of 200 meters, we have triumphs to share and build on. Building on that work with a view toward the clinical trial enrolment process, we stand a greater chance of attracting members of diverse communities, which will help us create medicines that are truly universal.

The COVID-19 pandemic has provided a benchmark for communication and disclosure around health and wellbeing that could prove invaluable to the clinical trial stage of health care development and delivery. If we utilize that insight responsibly and with care, we can create a lasting legacy to be proud of.

The insights we gathered in collaboration with eHealth Initiative and Informa Pharma Intelligence and present here could even be regarded as a blueprint for a healthier world – a world in which demographic, economic, geographic and historic barriers to inclusion in clinical trials disintegrate, taking a key step toward achieving health equity.

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Emily Mortimer is Director of Market Planning with responsibilities for strategy and development activities for the LexisNexis Social Determinants of Health solutions. In over 8 years at LexisNexis, Ms. Mortimer has served as subject matter expert for MarketView, our medical claims and analytic solutions, serving in several capacities including leading client services and implementation, managing analytics and statistical modeling resources, and contributing to product management and strategy. Ms. Mortimer has a background in public health and epidemiology, holding an MPH from Drexel University School of Public Health.

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Reducing Clinical Trial Burdens Brings Greater Participant Diversity – PhRMA

BY SUE SUTTER

EXECUTIVE SUMMARY

Industry principles for enhancing diversity in clinical trials call for use of digital data collection tools and flexible scheduling of study site visits to reduce barriers to enrollment, as well as greater involvement of under-represented communities in the trial design planning process and recruitment of investigators with diverse ethnic and racial backgrounds.

Making clinical trial participation less burdensome through the use of digital data collection tools and flexible scheduling is part of the Pharmaceutical Research and Manufacturers of America's strategy for enhancing study diversity.

The industry group also recommends recruitment of clinical trial personnel with diverse racial and ethnic backgrounds, and getting patients, advocates and caregivers from under-represented groups more involved in the trial design process.

PHRMA'S CORE PRINCIPLES FOR STUDY DIVERSITY

- Building trust and acknowledging the historic mistrust of clinical trials within Black and Brown communities
- Reducing barriers to clinical trial access
- Using real-world data to enhance information on diverse populations beyond product approval
- Enhancing information about diversity and inclusion in clinical trial participation

The Pharmaceutical Research and Manufacturers of America (PhRMA) principles for enhancing diversity in clinical trial participation, released on 17 November, focus on four main areas.

"The industry's new clinical trial diversity principles are an important step toward greater health equity," PhRMA president and CEO Stephen Ubl said. "We are addressing issues of mistrust and working to reduce systemic issues that deter communities of color from participating in clinical trials, so that those patients who want to participate, can."

Many of the PhRMA strategies align with recommendations in the US Food and Drug Administration's recent guidance document on enhancing the diversity of clinical trial populations. The guidance, released 9 November, discusses recruitment strategies, eligibility criteria and other study design considerations for improving the diversity of participants.

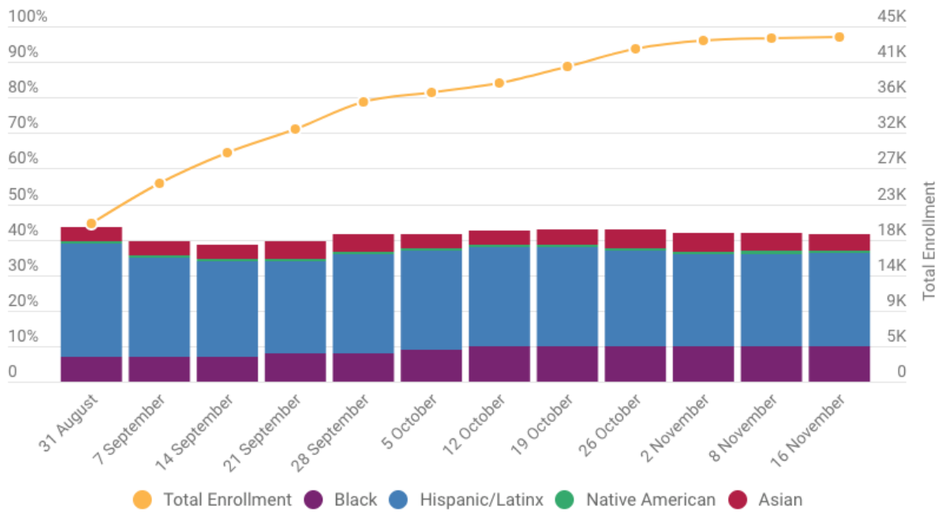
COVID'S DISPROPORTIONATE IMPACTS

Although there had been a growing focus on the need to increase clinical trial diversity, this effort has become top of mind in recent months given the civil unrest over racial inequality and injustice in the US and the disproportionate impact that the COVID-19 pandemic has had on communities of color.

Pfizer Inc. and Moderna, Inc. have been posting weekly updates on enrollment of minority populations in their US Phase III trials for their mRNA vaccine candidates against COVID-19.

Diversity In Pfizer's COVID-19 Vaccine Trial Slipped Again After A Rebound...

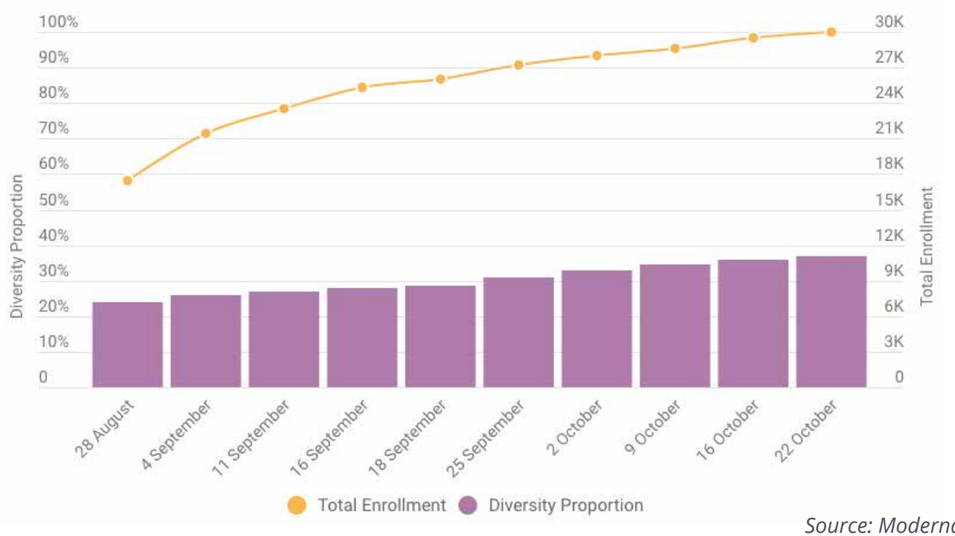
Enrollment of Blacks increased, but the percent of Hispanics moved lower in recent weeks, which caused overall trial diversity to drop.



Source: Pfizer statistics

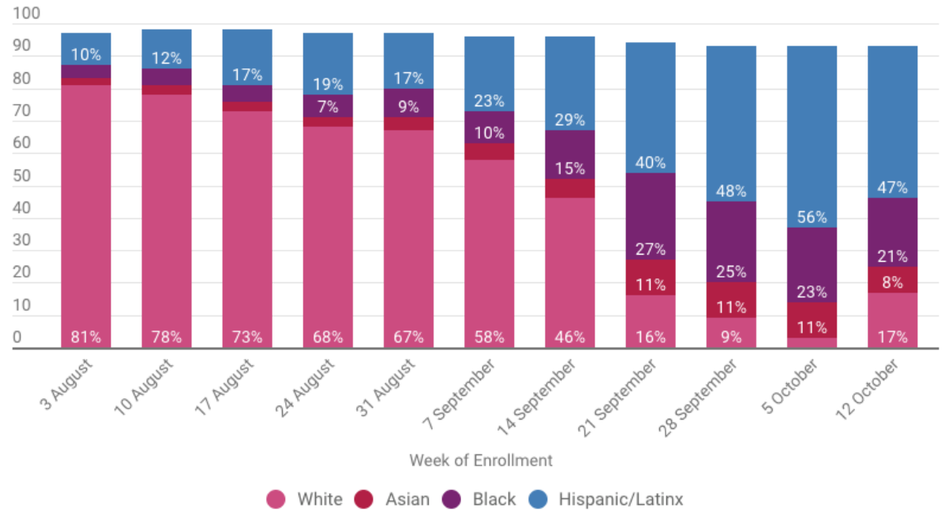
... While Moderna Maintained Upward Trajectory

The diversity percentage is less than Pfizer, but minority enrollment increased as the trial progressed until enrollment ended in late October.



Source: Moderna statistics

Diversity Advances In Weekly Moderna Enrollment



Source: Moderna statistics

However, it is widely recognized that a big educational push will be needed if communities of color and other traditionally underserved populations are to have confidence in any COVID-19 vaccine ultimately authorized or approved by the Food and Drug Administration (FDA). (Also see "Patient Warehousing Emerges As Another COVID-19 Vaccine Confidence Problem" - *Pink Sheet*, 22 Oct, 2020.)

The Biotechnology Innovation Organization has been working with developers of COVID-19 vaccines and therapeutics to try to diversify their clinical trial populations by connecting industry sponsors with organizations that represent minority communities. (Also see "BIO Is Helping Companies Boost Minority Participation In Clinical Trials" - *Pink Sheet*, 9 Oct, 2020.)

REPRESENTATION, ACCESS AND FAIRNESS

PhRMA said its document represents the first-ever, industry-wide principles on clinical trial diversity.

"Enhancing meaningful representation of diverse participants in clinical trials would help provide information about drug response and measures of safety and efficacy in populations that have been historically under-represented and under-studied, in particular Black and Brown people," the document states.

"Additionally, lack of participation of patients from diverse backgrounds may limit early access to potential therapies through clinical trials, especially in the setting of unmet medical need," the principles state.

PhRMA also cited the need to take into account a "fundamental issue of fairness and justice," as well as the ethical consideration that clinical development of drugs and biologics should serve the needs of those who are affected by the disease or condition.

ACKNOWLEDGING PAST WRONGS, BUILDING TRUST

The PhRMA document discusses the need to address minority communities' distrust of the medical research establishment that has resulted from historical mistreatment of study participants, such as in the case of the Tuskegee syphilis study.

The principles call for conducting outreach to the medical community in underserved areas and supporting trial sites with comprehensive education on medical product development. "We will do so in a manner that is culturally competent and developed in partnership with the communities we are seeking to serve," the principles state.

A pool of investigators with diverse ethnic and racial backgrounds "can serve as a trusted and knowledgeable source of information for under-represented diverse populations."
– PhRMA Principles

Biopharma companies that voluntarily adopt the principles also commit to encourage the recruitment and retention of clinical trial personnel with diverse racial and ethnic backgrounds. This pool of investigators "can serve as a trusted and knowledgeable source of information for under-represented diverse populations."

The principles call for educational efforts aimed at increasing clinical trial access and reducing barriers for under-represented and diverse populations using approaches that address all health literacy backgrounds and different levels of clinical trial awareness.

"We commit to conduct community outreach such as partnering with health and community advocacy groups that are working with the communities we aim to reach to increase clinical trial awareness and potential opportunities for participation."

PROACTIVELY REDUCING BARRIERS TO PARTICIPATION

The strategies aimed at reducing barriers to, and burdens of, participation in company-sponsored trials start at the design stage and follow a patient-centric approach.

"We commit to prospectively plan and design medical product development programs that promote inclusion of diverse populations in clinical trials and aim to understand the needs of those who are affected by the disease or condition being investigated," the principles state. This includes identifying sites where diverse patients with a particular disease under study may be located, identifying health care providers that treat under-represented populations, and working with investigators to address the goals of enrolling a diverse study population.

When designing a trial, sponsors should consider recruitment challenges and barriers to enrollment that may result from aspects of the study design, such as planned visit schedules, location and financial implications, and how these factors could be addressed.

"For example, flexible scheduling and utilizing digital technologies (e.g., mobile tools and wearable technologies to gather data from participants, decentralized or virtual trials) may help to encourage greater participation from diverse patient populations who do not have easy access to a clinical research site," the principles state.

The FDA's guidance, "Enhancing the Diversity of Clinical Trials Populations – Eligibility Criteria, Enrollment Practices and Trial Designs," similarly urges sponsors to consider recruitment challenges that may result from the planned visit schedule, as well as difficulties with accessibility.

The FDA urges sponsors to consider the use of mobile medical professionals, such as nurses and phlebotomists, to visit participants at their locations instead of requiring that participants visit distant clinical trial sites.

Sponsors should reduce the frequency of study visits to those needed to appropriately monitor safety and efficacy, the guidance states. Sponsors also should consider if flexibility in visit windows is possible, and whether electronic communication or digital health technology tools can be used to replace site visits and provide investigators with adequate real-time data.

"Consider the use of mobile medical professionals, such as nurses and phlebotomists, to visit participants at their locations instead of requiring participants to visit distant clinical trial sites," the guidance states.

The FDA guidance also suggests sponsors consider using electronic informed consent so that participants do not have to travel to a clinical site.

However, under-represented populations with limited or no internet access may benefit from personal interactions with investigators to better understand the risks and benefits of study participation, the agency said. "For these populations, consider holding consenting processes and interventions in locations that are more accessible to the participant."

Furthermore, sponsors should consider providing trial resources and documents in multiple languages, and having multilingual research staff or interpreters on hand, to encourage participation and retention of individuals with limited English comprehension, the agency said.

BROADER ELIGIBILITY CRITERIA

During the trial design phase, sponsors and investigators should take into account the incidence, prevalence and severity of the condition in various populations, as well as other prognostic factors that may influence response to an investigational drug or outcome variable, PhRMA's principles state.

"We should design appropriately inclusive study protocols that address the circumstantial needs of patients by more closely involving patients,

patient advocates, and caregivers from Black and Brown and other under-represented groups in the trial design process," the principles state.

PhRMA also called for broadening trial eligibility criteria, when scientifically and clinically appropriate, to increase diversity. This can be accomplished by leveraging information on the populations at risk for a particular disease, data from earlier trials, the drug's mechanism of action and any available post-approval data or real-world evidence to better understand the treatment effect for selected subgroups.

ROLE FOR REAL-WORLD DATA

PhRMA's strategies for learning more about how drugs work in diverse populations extend beyond product approval.

"During the post-approval phase, collecting clinical real-world data/real-world evidence may be an important method of supplementing trial data, in compliance with all applicable local laws and regulations, serving as an effective and efficient means to enhancing understanding of drug effects in diverse patient populations," the principles state.

The FDA's guidance sees a role for real-world data in promoting more efficient recruitment of a diverse population. This could be accomplished by using claims data and electronic health records to identify potential sites and participants, the agency said. However, the guidance highlights the need to maintain patient privacy and ensure patient consent for the sharing of identifiable data from electronic health records is obtained and maintained.

The PhRMA principles also call for biopharma sponsors to post their policies or practices aimed at enhancing the diversity of clinical trials on their corporate website.

UNCONSCIOUS BIAS TRAINING

The issue of unconscious bias is addressed in a Q&A section of the PhRMA document.

Clinical investigators and trial site personnel may be unaware of unconscious bias impacting recruitment decision-making when managing trial enrollment, the document states. Unconscious bias training for those involved in conducting and reviewing clinical trials may improve health care disparities through increased understanding and use of inclusive approaches to increase enrollment and retention of diverse populations.

Such training should be considered not just for clinical investigators and site staff, but also for sponsor clinical trial staff, contract research organizations and institutional review boards, as appropriate, PhRMA said.

Clinical Trial Diversity Requires Community-Based Research Infrastructure, US FDA's Woodcock Says

BY SUE SUTTER

EXECUTIVE SUMMARY

COVID-19 trials could have reached underserved populations better if research infrastructure was in place where people routinely get their health care, acting commissioner Janet Woodcock says; PhRMA is looking to establish a public-private partnership that would build a sustainable community-based infrastructure for clinical research.

The COVID-19 pandemic has highlighted the need to build clinical research infrastructure in community settings to ensure speedy trial enrollment and adequate representation of diverse populations.

Expansion of the research enterprise beyond academic medical centers could get a big boost from the creation of a public-private partnership focused on this objective and by designing simple, pragmatic trials that can be readily conducted in communities, government and industry representatives said during a 10 March webinar sponsored by the Milken Institute.

Reflecting on lessons learned from the pandemic, leaders from the US Food and Drug Administration, National Institutes of Health, biopharma industry and advocacy community recounted the push to try to enroll diverse populations in trials for COVID-19 vaccines and therapeutics, reasons why those efforts were not always successful in the current clinical research structure, and how to head off such problems in advance of the next public health crisis.

"If we don't have research infrastructure in the community where people get their health care, where they are used to going, then we're not going to reach those communities in an emergency because you cannot just build up infrastructure capacity in the middle of a pandemic."
– FDA's Janet Woodcock

"If we don't have research infrastructure in the community where people get their health care, where they are used to going, then we're not going to reach those communities in an emergency because you cannot just build up infrastructure capacity in the middle of a pandemic," FDA acting commissioner Janet Woodcock said.

"One of the reasons we could not reach those populations as well as everyone desired is they didn't have the clinical trials infrastructure support, the research personnel. The investigators didn't have training. They hadn't been doing research because they hadn't been supported in doing research," Woodcock said. "We have to move clinical research out into the community, and we have to support that if we're going to be successful in any way in enrolling populations who reflect this country."

'GALVANIZED' INDUSTRY EYES PUBLIC-PRIVATE PARTNERSHIP

While the notion of bringing clinical trials to patients – rather than the other way around – is not new, it has taken on a new urgency with COVID-19, which has had a disproportionate impact on morbidity and mortality in traditionally under-represented communities.

Biopharma companies are re-examining their inclusion and exclusion criteria with an eye toward boosting study diversity, and have increased the attention paid to recruiting more representative populations.
(Also see "Clinical Trial Diversity: We Must 'Turn This Moment Into A Movement'" - *Pink Sheet*, 18 Feb, 2021.)

Nevertheless, it became apparent early in the pandemic that even with industry efforts over many years to diversify clinical trial enrollment, reaching those in underserved communities was still a struggle, said Richard Moscicki, chief medical officer and executive VP-science and regulatory advocacy at the Pharmaceutical Research and Manufacturers of America.

"I think on that front industry itself has really been galvanized in a way that it never had before in this past year," Moscicki said.

"We're quite committed this year to trying to find the right way to launch a public-private partnership that will … build a sustainable community-based infrastructure for clinical research."
– PhRMA's Richard Moscicki

He noted that all PhRMA member companies have signed on to the trade association's new principles for enhancing diversity in clinical trial participation.

Those principles, released in November, call for making clinical trial participation less burdensome through the use of digital data collection tools, recruiting clinical trial personnel with diverse backgrounds, and getting patients, caregivers and investigators from underserved communities more involved in the trial design process. (Also see "Reducing Clinical Trial Burdens Brings Greater Participant Diversity – PhRMA" - *Pink Sheet*, 17 Nov, 2020.)

However, PhRMA is looking to do more.

"We're quite committed this year to trying to find the right way to launch a public-private partnership that will … build a sustainable community-based infrastructure for clinical research," Moscicki said.

"Our goal with this public-private partnership is to create a community-based network of centers focused on enhancing diversity in clinical trials," PhRMA told the *Pink Sheet*. "This is something we are absolutely committed to tackling this year along with other interested stakeholders, including members of our industry, key government entities and community partners."

Woodcock welcomed the idea of a public-private partnership. "I believe both government and industry need to ban together, and maybe a PPP is the way to do it and provide sustainable trial personnel and training to investigators who are in the community," she said.

In the current pandemic, the lack of trained investigators in community settings has not just been a problem for those communities that have been historically underserved, she said.

"We had tens of thousands of people dying from COVID and we couldn't get patients enrolled because we didn't have enough sites, and even if the major medical center had a site going their network sites out in the community didn't have trained personnel," Woodcock said. "This is not something … you can do on a dime. You have to build a sustainable infrastructure."

SIMPLIFYING STUDIES …

In addition to building infrastructure, designing trials that can be readily conducted in community settings is critical to expanding the reach of clinical research.

"Simplifying trials would really help," Woodcock said.

Pragmatic community-based trials are ideal for answering questions about provision of health care and what kind of treatment policy should be used for a given disease, she said. "They could be used also for a pivotal trial, or a portion of the pivotal trials, for investigational drugs and devices, but they have to be simple enough."

"Not that I'm saying the community researchers are going to be simplistic," Woodcock continued. "They just won't have time and they won't have the extensive laboratory backup and all that sort of stuff that people at the medical centers do."

The FDA is working with a variety of partners to try to run studies off of information routinely entered in electronic health records, rather than having separate case report forms, she said. "This simplifies and enables other parties involved mainly in clinical care to participate. But these trials have to be more pragmatic. We can't have dozens of researchy-type of activities associated with them."

Yet, even these simpler studies require a certain amount of infrastructure and training. Consequently, the goal is to set up pragmatic trials and infrastructure support to enable the participation of community practitioners, Woodcock said. "The question is where can the funding come from that would support this kind of ongoing activity?"

… AND ENGAGING WITH THE COMMUNITY

National Institutes of Health (NIH) director Francis Collins highlighted the need for community engagement in the trial design and recruitment process, pointing to the large Phase III studies of the COVID-19 vaccine candidates as a useful case study.

The FDA's June 2020 guidance on COVID-19 vaccine development strongly encouraged enrollment of populations most affected by the disease, specifically racial and ethnic minorities. The FDA also said evaluation of vaccine safety and efficacy in late-stage trials should include adequate representation of elderly individuals and individuals with medical comorbidities.

Vaccine sponsors were vocal about their commitment to enroll diverse populations in the Phase III studies, and Pfizer Inc. and Moderna, Inc. even posted regular updates on the diversity of their subjects while the trials were enrolling. (Also see "Pfizer COVID-19 Vaccine Trial Diversity Slips As Enrollment Rises, Unlike Moderna" - Pink Sheet, 18 Sep, 2020.) Pfizer expanded its Phase II/III trial target enrollment from 30,000 to 44,000 in a bid to increase diversity and include adolescents and immunocompromised individuals.

"I can't tell you how many Saturday mornings I spent … meeting with the leadership of the companies that were running those trials, trying to do what we could to boost up the participation of diverse individuals, because it was not going well at the beginning for most of these."
– NIH's Francis Collins

Among the first four fully enrolled Phase III vaccine studies designed to support emergency authorization in the US, enrollment of Black and Hispanic participants ranged from 10%-19% and 11%-45%, respectively, with approximately one-quarter to more than one-third of participants falling into the older age groups. (Also see "COVID Trial Diversity: What Participants In The Vaccine Phase III Studies Look Like" - *Pink Sheet*, 8 Feb, 2021.)

Collins said the diversity achieved in the Phase III studies was the result of a lot of hard work and community engagement.

"I can't tell you how many Saturday mornings I spent – probably at least 15 or 16 of them – meeting with the leadership of the companies that were running those trials, trying to do what we could to boost up the participation of diverse individuals, because it was not going well at the beginning for most of these," Collins said.

"It took a very specific commitment at the top level of all those organizations, and a willingness to spend more money and perhaps even slow down a little bit in terms of the … timetables that we were trying to meet, in order to end up with trials that actually looked like the country," he said. "So people could look at the trial and say, 'I see myself in there, I see people like me benefitted from this vaccine as well.'"

He credited some of this success in enrolling diverse populations to establishment of the Community Engagement Alliance. CEAL's mission is to provide trustworthy information through active community engagement and outreach to people in communities hardest hit by the pandemic – including African Americans, Hispanics/Latinos and American Indians/Alaska Natives – with the goal of building long-lasting partnerships and improving diversity and inclusion in the NIH's COVID-19 research response, according to the alliance's website.

"You've got to have the infrastructure for that kind of community engagement at the start," Collins said. "You don't build that on the fly, at least it's not going to work very well. You have to invest in that. We have to remember that lesson going forward, not just for the next pandemic but for everything we do."

Collins and Woodcock also discussed another lesson learned from the pandemic - the need for a coordinated approach to clinical research.

Unlocking Resiliency In Clinical Research And Improving Access For All

BY SANSKRITI THAKUR AND NICOLE PARAGGIO

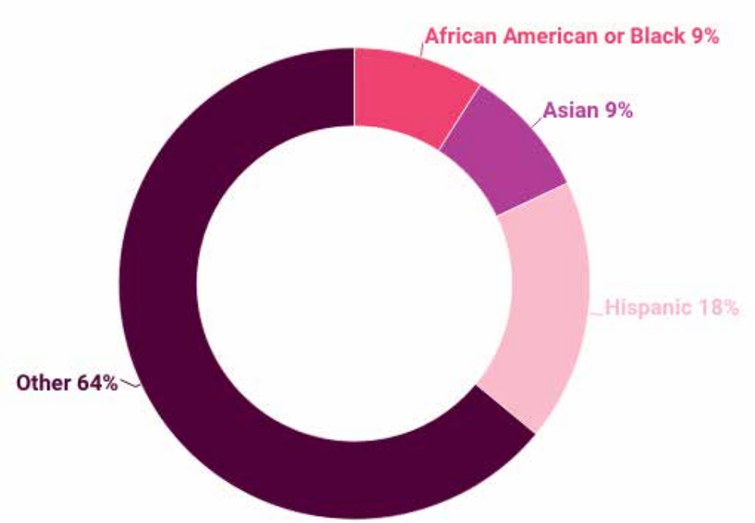
EXECUTIVE SUMMARY

The pharma industry has grappled for years with its role in improving equitable access to clinical research. The needle has moved, but impactful changes have not come quickly enough.

Clinical research is the key to developing and evaluating innovative treatments, yet marginalized communities continue to be under-represented in clinical trials. Without diverse participation that reflects the broader population, the full scope of potential risks and benefits of a product cannot be fully understood by developers. In addition, the exclusion from clinical research can deprive these communities from access to cutting-edge, potentially life-saving treatments, and perpetuate existing inequalities in health care.

2019 FDA Drug Trials Snapshot

Across 48 newly approved drugs from studies that included more than 46,000 participants, only 9% of participants identified as African American or Black.



Source: FDA Center for Drug Evaluation and Research

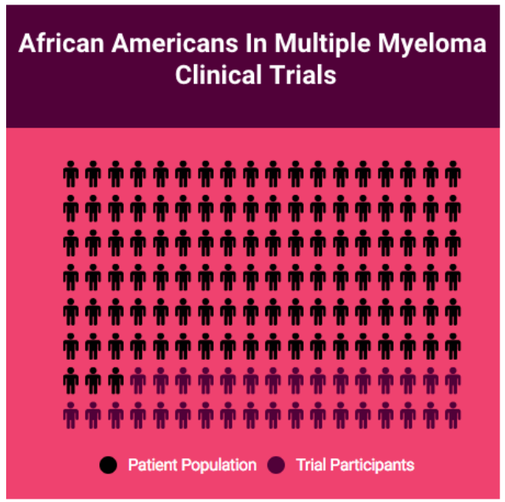
The FDA Center for Drug Evaluation and Research publishes an annual Drug Trials Snapshot capturing the diversity of participants in trials for approved novel drugs that year. In 2019, across 48 newly approved drugs from studies that included more than 46,000 participants, only 9% of participants identified as African American or Black, only 9% identified as Asian, and only 18% identified as Hispanic. Many marginalized communities suffer the consequences of exclusion from clinical research; racial and ethnic minorities, LGBTQ+ individuals, people over 65 years of age, and women are often under-represented. Exclusion has significant consequences that can resonate across the health care community.

Examples demonstrating this issue:

- **Race:** African Americans have 2x the incidence of multiple myeloma as White Americas, accounting for 20% of the currently diagnosed multiple myeloma patient population, and yet, account for only 6% of participants enrolled in multiple myeloma clinical trials. There are known differences in the cancer genetics of African Americans and White Americans, putting at risk the opportunities to identify new therapies that adequately address this population.
- **Gender:** Research has shown that women are at a 1.5-1.7x greater risk of experiencing adverse drug reactions. This represents

hundreds of millions of dollars in associated health care expenses for treating those drug reactions. Accenture Research (using FDA information alongside data collected by HEOR and biotech companies) calculated the average cost of treating adverse events from oncology products across the most prevalent types of cancer. This research indicated that adverse drug reactions could account for an additional $780m-$825m in health care expenses.

- **Minority Groups:** Use of mobile tech can improve the representation of sexual and gender minorities (SGM) in clinical research. The 2019 "PRIDE" (Population Research in Identity and Disparities for Equality) study enabled SGM people to provide demographic and health data. Of more than 16,000 participants, more than 98% identified as a sexual minority, and more than 15% identified as a gender minority.



There is no single solution for the problem of clinical under-representation; the barriers to inclusion vary for demographic, economic, geographic, and historic reasons. For example, from an economic perspective, patients who do not attend regular medical visits because they cannot afford to also cannot be referred into clinical research by the traditional methods of recruitment due to prohibitive out of pocket related expenses.

From a geographic perspective, patients from marginalized communities are impacted by their proximity to research centers – the distance from a clinical research site or academic medical center is often a significant burden on patients. According to Sean Lynch, director of study operations at TrialSpark, half of FDA trials in the US occur within 1-2% of zipcodes. It is critical to note, these systemic issues are amplified by mistrust of the US health system due to historic and, sadly, contemporary abuse from the health care community on marginalized communities. A seismic shift is needed to address these barriers and to increase access for marginalized communities.

REVELATIONS FROM COVID-19

The realities of the COVID-19 pandemic are now a burning platform for addressing equitable clinical representation and underscored the importance of a deliberate effort to transform our traditional clinical research approaches. In the US, people of color (including African Americans, Native Americans and Hispanic Americans) have suffered greater risk of contracting, being hospitalized by, and dying from COVID-19, ranging from a scale of 3-4x greater risk of being hospitalized and dying from COVID-19 than White communities.

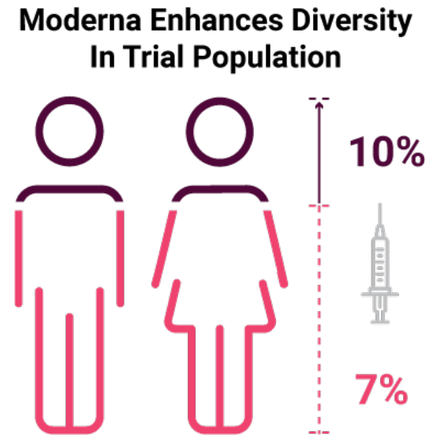
Additionally, the pandemic has laid bare the inadequacies of having a fully centralized clinical trial strategy (i.e., dependent on the traditional site-based model) and essentially forced an overnight shift to adopting some digital solutions. Nearly 50% of clinical trial sites stated that COVID-19 had impacted their ability to start new trials, with approximately 31% of sites reporting delaying their trials and 14% reporting cancelling trials altogether. A growing majority of clinical sites have scrambled to re-evaluate their study operations, with approximately 40% shifting to virtual or remote patient visits. The industry needs to find a path forward that provides resiliency, and it cannot do so while actively excluding whole swaths of the population. The implementation of patient-centric clinical trial design and digital solutions that account for the specific needs across communities can contribute to improving the efficacy of the product and the ultimate success of that product – while driving more equitable access for the marginalized patient population.

It is highly appropriate to evaluate the success that Pfizer Inc., Moderna, Inc. and other COVID-19 vaccine manufacturers have had with enrolling diverse populations. While no company has reached the gold standard achieving parity with census numbers, they managed to beat the clinical trial average and stay in line with the 2019 averages for new drug applications and biologics license applications. And all while operationalizing in record times.

MODERNA CASE STUDY

With the race on to develop a suite of vaccines across manufacturers, Moderna took meaningful steps to ensure late-stage development for its vaccine included significant representation of the communities most at risk during the pandemic, actually slowing their trial timeline. Moderna CEO Stephane Bancel said, "I would rather we have higher diverse participants and take one extra week … [Diversity] matters more to us than speed."

Moderna changed recruitment and study operations in a way that allowed them to enhance the diversity of their participant population. They shifted away from the traditional model of recruitment and utilized a massive online registration process and targeted specific enrollment sites to meet their goals. Within just three weeks, the enrollment of Black patients within their Phase III trial grew from 7% to 10%.



MODERNA ENHANCES DIVERSITY IN TRIAL POPULATION

Moving beyond clinical recruitment and enrolment, Moderna also stood up a new vision

of patient engagement to alleviate the burden of participation on these patients and improve long-term retention in the study. Instead of the often burdensome trial design requiring patients to frequently make in-person visits to the clinical trial site, patients were surveyed remotely via tele-consults and e-Diary logs for the duration of the study, and even patients with COVID-19 symptoms could opt for either in-person visits at their convenience or receive a medical consultation in their home. For patients, this can be the difference between finishing a study or dropping out early due to the expense of transportation and childcare, time away from work or dependents, and other significant inconveniences that often disproportionality affect marginalized communities.

The success Moderna and other manufacturers have had in developing the COVID-19 vaccines provides lessons to take forward as we redefine best practices for clinical trial recruitment. The industry can prioritize equitable representation to improve how it pursues recruitment, enrolment and handles retention. Moving forward from this pandemic there are opportunities to revolutionize the way clinical research is conducted. Research can be more resilient while simultaneously serving a broader population of patients.

IMPROVING TRIAL DIVERSITY

To better understand tactical actions the industry may take to improve diversity and access in clinical trials, Accenture research analyses were conducted on the full venture and mature landscape of clinical trial offerings. Remarkably, out of more than 1,100 individual companies creating assets and solutions for this category, less than 19% proposed to deliver impact on outcomes that would affect underrepresentation. Even fewer actively address diversity and access as a service benefit.

Industry action is slowly taking root: PhRMA announced the first industry-wide principles for diversity in clinical trials in November 2020, which will take effect in April 2021. It pledges to address health equity in underserved populations, including racial inequality. Individual companies have programs in place to have trials represent the composition of patient population. For instance, Eli Lilly and Company, Johnson & Johnson and Pfizer are seeking to improve participation of diverse populations, in some cases providing transportation assistance to trial sites, and improving diversity in site staff and investigators who provide the care.

The aftermath of government shut-downs and human isolation has boosted the virtual and decentralized clinical industry. Across more established entities, Accenture estimates that between 300-500 trials have virtual components, and that these numbers are likely to triple in the next 3 years. In discussions with contract research organizations and other key stakeholders, improved access, diversity and experience are clear attributes of modern virtual trial offerings. In most cases virtual trials that include virtual patient matching, consents, education and onboarding can increase patient overall recruitment by between 50-65%. More advanced capabilities will enable early patient findings and create awareness of early intervention opportunities and even engage with patients via social channels. When considering the average cost to develop and discover a medicine is between $2.6bn-6.7bn, Accenture estimates that with continued conservative adoption of virtual trials the industry can save between $630m-820m per asset. This is not just significant from a cost perspective, but mitigates the barriers of geography, hurdles of consent, and recruitment, to list a few of the advantages.

The future is here. With the tools available, and the willingness to deploy them, the industry could (1) accelerate to equitable representation in clinical research enabling them to (2) more rapidly recover from the pauses, halts and slowdowns of their pipeline due to the pandemic and (3) be more resilient in future major regional and world events. This could change the face of medicine and the clinical outcomes for some of our most impacted communities.

ABOUT THE AUTHORS

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Assessing eHI's Guiding Principles For Ethical Use Of SDoH Data During COVID-19

EXAMPLES FROM THE FIELD

BACKGROUND

COVID-19 was declared a pandemic by the World Health Organization in March 2020. Since then, health systems in the United States have been severely challenged by unprecedented demand. The pandemic has highlighted the vulnerabilities of populations whose healthcare access, quality, and affordability are impacted by social determinants of health (SDoH).

Many organizations use SDoH data to identify communities at risk of COVID-19. In 2019, eHealth Initiative (eHI) released the *Guiding Principles for Ethical Use of Social Determinants of Health Data*, which proposed recommendations for the ethical use of SDoH data by healthcare organizations. This report provides examples of organizations applying these principles as they address the COVID-19 pandemic.

The Guiding Principles put forth an ethical framework for SDoH data, specifically focused on five principles: employing SDoH in care coordination; recognize risk through analytics; map resources and identify gaps; assess impact; and customize interventions and allow individuals to determine the best fit. More details on each area are outlined in the table below:[1]

Five Guiding Principles

Employ SDoH in Care Coordination	Identify individuals with SDoH needs (economic, education, community, healthcare access and environment), coordinate and deliver more holistic care, facilitate connections to additional interventions or services, consistent with privacy and security protections
Recognize Risk Through Analytics	Identify risk using analytic tools in order to develop population health management interventions for individuals and communities
Map Resources and Identify Gaps	Assess individual SDoH needs (economic, education, community, healthcare access and environment) against available community resources to identify gaps that address health and wellness
Assess Impact	Assess the impact of SDoH interventions and services
Customize Interventions and Allow Individuals to Determine Best Fit	Use SDoH as a guide for quality discussions with individuals (or their designated guardians) and caregivers to jointly decide which services and interventions are the best fit

APPLYING ETHICAL PRINCIPLES DURING COVID-19

As healthcare organizations began using SDoH data to address the COVID-19 pandemic, eHI sought to determine how the Guiding Principles were being applied. Therefore, a year after releasing the Guiding Principles, eHI convened a group of executives at a roundtable entitled *Using Social Determinants of Health Data Ethically During COVID-19*.

The purpose of the session was to inform the audience of the various ways that government agencies, healthcare, and other organizations applied the principles to their SDoH programs. In attendance were high-level executives from healthcare programs, providers, and payers.[3]

"We've always been focused on it, but COVID certainly has accelerated it, and it's been within the last couple of years that social determinants were added as one of our main points of influence."
– Caraline Coats, Vice President, Bold Goal, Humana

Participants underscored the importance of harnessing SDoH data to tackle health and social problems.[2] The key questions answered during the roundtable were:

- How do the Guiding Principles work in the real world?
- Do they work in the existing COVID-19 healthcare environment?

Many of the challenges facing healthcare organizations and government agencies this year shone a bright light on health disparities. Examples of populations with health disparities are:

- Homeless individuals
- Underserved rural residents
- Elderly people living in nursing homes
- Patients with underlying chronic conditions
- Low-income and uninsured patients
- Racial and ethnic minorities

This report identifies real-world examples of how each of the five principles can be applied during COVID-19. Studying SDoH, and how they impact disadvantaged populations during times of crisis, will help governments to better manage health emergencies so that every individual has an equal opportunity to be and stay healthy.

PRINCIPLES IN ACTION

1. Employ SDoH in Care Coordination

Use Case: Utilization of SDoH for Care Coordination with Humana's Basic Needs Food Program

COVID-19 has broadened the definition of food insecurity beyond affordability and providing resources during a pandemic is challenging. Humana, one of the largest healthcare payers in the United States, wants to help make the system a better place through innovation, transformation, and partnership. At the beginning of COVID, Humana collected data through proactive outreach to members and from members who called for assistance. Food insecurity was heightened and amplified by the lack of access caused by limited transportation, instructions for vulnerable populations to stay home, and supply chain interruption. In response to the needs of its members, Humana created the Basic Needs Program in a matter of days. Since its inception, the Basic Needs Program has provided more than 900,000 meals by coordinating with national, local, and regional partners.

Humana learned that providing food was not the only consideration for addressing food insecurity. To solve the problem, they also needed to consider housing barriers such as not having the space to store frozen food. As a result, the Humana team needed to provide shelf-stable food. Humana also considered the sensitivities of using predictive analytics to identify members who might become food insecure in the future. Most importantly, the organization considered future support that could be provided beyond its capabilities to ensure that its members were referred to local resources.

> **"Social determinants data is at the core of our strategy. Now that we have all of this data, we need to turn it into actionable information. There is a lot of sensitivity around that and making sure that we have the right resources… in responding to our members' needs."**
> **– Caraline Coates, Vice President, Bold Goal, Humana**

To ensure confidentiality and maintain patient dignity, members provided verbal consent to discuss their food insecurity concerns. After consenting, they were informed of available services and asked about their existing situations and interest in receiving help before their information was submitted to a vendor for assistance.

> **"Community-based organizations before COVID-19 were taxed and they certainly were challenged during all of this. Leveraging data in the right way for the main purpose of creating better sustainability within our community- based organization, and then just continued integration to really make it part of our DNA, became our priority."**
> **– Caraline Coats, Vice President, Bold Goal, Humana**

The Basic Needs Program for food insecurity is just one example of Humana's ethical approach of turning data into action – and employing SDoH in care coordination. Due to COVID, Humana expanded and fast-tracked its telehealth services, resulting in a change from 51,000 visits in 2019 to 25 million in 2020. As of August 2020, it has conducted 3.3 million screenings to identify food-related needs, executed SDoH pilots to more than 60,000 members, potentially reached 6.5 million people in 16 Bold Gold Communities, invested in sophisticated data collection, and integrated SDoH throughout the organization's portfolio of work.

Humana's social determinants strategy has transformed the organization from an insurance company to a fully integrated health company employing SDoH data to coordinate care. Its threepronged approach consists of collaboration, innovation, and human care to understand the nonclinical needs of the members4, simplify consumer experiences, and improve health outcomes.

As numerous organizations recognize a growing number of individuals vulnerable to COVID-19, the need to ensure responses are coordinated will only increase. Healthcare organizations should continue to use SDoH data to employ interventions.

2. Recognize Health and Wellness Risks Through Analytics

Use Case: Bringing Together Data Science & SDoH

> **"Race, ethnicity, and social economic status are really fundamental components of influencing health outcomes."**
> **– Eliseo J. Pérez-Stable, MD, Director. National Institute on Minority Health and Health Disparities (NIMHD) National Institute of Health (NIH)**

The second principle emphasizes that predictive models and data used in algorithms ensure accuracy and relevance related to use cases. Choices made about modeling and analyzing data elements should be free from bias, and standardization may be a means to help eliminate potential bias and discrimination. Further, it is important to recognize and support cultural sensitivities. Parkland Center for Clinical Innovation (PCCI) provided an example of using algorithms to ensure accuracy and relevance, while the National Institute of Minority Health and Health Disparities

at the National Institutes of Health (NIH) provides an excellent example of how to standardize data to help eliminate potential bias. Their experiences provided insights into the role of data to inform decision makers, influence stakeholders, and respond to population specific needs.

COVID-19 is a complex disease from a clinical, social, and public health perspective. At the beginning of the pandemic, there were many unknowns about transmission and testing. PCCI and the Department of Health and Human Services (HHS) collaborated to determine how to prioritize resources using data using analytics and incorporate SDoH in figuring out this prioritization. They recognized that communities needed help prioritizing resource allocation and that timely data was required for decision-making.

PCCI developed the framework below to understand, forecast, and reduce community spread and hospitalization. The framework identifies data required at each step of the infection cycle, from exposure to diagnosis.

PCCI Framework

Exposure	Activity and Living Situation
Symptom Onset	Surveillance and Patient Self-Identification
Health Behavior	School and Work Absenteeism
Healthcare Encounter	Physician, ER Visit, Hospitalization
Medical Evaluation	Tests

PCCI used the data provided by the Dallas County Health System on confirmed cases to create multiple solutions. One of those solutions is the COVID-19 Vulnerability Index, which identifies the communities within Dallas County that are at higher risk for COVID-19. The Vulnerability Index is a method to standardize the data. It incorporates SDoH, COVID co-morbidities, age and demographics, personal mobility, and COVID positive-case data sources to drive the prioritization of additional testing site selection for county leaders. Importantly, the Index also provides real-time surveillance of areas to support cultural sensitivities for engagement and education. Walmart set up testing sites in response to the hot spots that were identified by the Index, demonstrating the importance and influence of the tool.

The data for the Vulnerability Index is collected from several sources and refreshed daily. The SDoH data is based on the Area Deprivation Index (ADI), a multidimensional evaluation of a region's socioeconomic conditions, which have been linked to health outcomes.[5] The Index is a visual representation of existing hot-spots and potential new hot-spots, organized by zip code to easily identify where additional engagement or mask reinforcement are needed. It is publicly available on a website, and the map is then used actively by the Public Health Department of Parkland and other health systems to make sure that their messaging and resources are targeted to the most vulnerable areas. This process also provides transparency.

The mission of the National Institute of Minority Health and Health Disparities is to conduct research that results in improved minority health and reduced health disparities.[6] Dr. Perez-Stable emphasized the importance of data-sharing and data-standardization in research. Collecting standardized data is not always easy when the category is a self-defined construct, such as race, but the data is necessary during a pandemic. The NIH developed a toolkit called PhenX to establish common measurement protocols to inform effective interventions to reduce health disparities.

The misinformation about COVID-19 prompted the NIH to focus on defining common data elements for research that have been posted on its website. For SDoH, NIH suggests that individual measures include things like race, ethnicity, measurement of social economic status, family background, sexual orientation and gender identity, and geographical location. As secondary measures, NIH recommends focusing on structural determinants of health such as broadband access, which has an impact on education and individuals' participation in society. Additional structural determinants are transportation, public safety, green space, healthy food access, and housing. The ability to easily share and combine data from multiple studies has the potential to increase the scientific impact of individual studies.[7]

Standardization can help reduce health disparities that are preventable differences in the burden of disease, injury, violence, or in opportunities to achieve optimal health that are experienced by socially disadvantaged populations.[8] As more healthcare organizations adopt the use of predictive models and algorithms to identify individuals at risk of COVID-19, organizations need to ensure their modeling is standardized to

capture accurate demographic data on race and ethnicity. Both indicators are key to identifying specific population needs; however, people may be incorrectly classified based on assumptions from an observer (patient intake, census taker, etc.).[9] For example, some Native Americans are incorrectly identified as white based on their skin color, even though they self-identify as Native Americans. In some cases, race is left blank, so that is a challenge that makes the data less useful. Collecting race and ethnicity data that is accurate and respectful ensures that the unique healthcare needs of various populations are fulfilled.

3. Map Community Resources and Identify Gaps

Use Case: Maryland Task Force on Vulnerable Populations for COVID-19: Assessing Resources and Risk

The third principle stresses the importance of actually connecting vulnerable populations with interventions and resources. It is not enough to just identify at-risk populations—organizations need to ensure they have programs and interventions to adequately address population-level care obstacles. This is critically important with respect to COVID-19, when at-risk populations have sometimes been identified but not provided with resources to assist them.

"Vulnerable populations require targeted interventions."
– Susan Mani, MD, Chief Population Officer, LifeBridge Health

An example of this principle in action is the state of Maryland, which recognized the potential disproportionate effect of COVID-19 on populations with underlying chronic conditions or socioeconomic challenges. The State also recognized its own limitations when it came to gaining access to and organizing SDoH data integral to designing a data-driven response, so it formed a task force to implement a response strategy to identify gaps and plug in community resources where needed.

"There are non-clinical impacts to health and identifying those is important, but if our outcome is that we need to fund food banks in certain areas because that community doesn't have access to quality nutrition, there needs to be a stronger partnership and awareness between the commercial sector and what's happening with the community resources."
– Josh Schoeller, Chief Executive Officer, LexisNexis Risk Solutions, Healthcare

The Maryland Task Force on Vulnerable Populations was created to address the needs of specific vulnerable populations in Maryland. It is a public-private partnership comprised of health systems, payers, health agencies, and private organizations that are well-versed in understanding the specific needs targeted by the Task Force.

Maryland's private sector partners are:
- LifeBridge Health
- United Way of Central Maryland

- Meals on Wheels of Central Maryland
- Socially Determined
- Health Choice
- Healthcare for the Homeless
- Maryland Department of Community and Housing Development

The Task Force, headed by Dr. Susan Mani, uses data to map resources and needs for vulnerable populations such as the homeless, elderly, and the uninsured. Each group has unique barriers to healthcare that affects their ability to access resources or practice social distancing to protect themselves.

Dr. Mani is the Vice President of Clinical Transformation and Ambulatory Quality at LifeBridge Health, and succinctly stated the challenges of data and resources at the state level: "We were able to identify over 150,000 of the highest risk individuals across the state, and looking at that number we just knew it was a task where there is no way one group alone was going to be able to reach out and provide the kind of complex resources required to address the multitude of needs."

Socially Determined, a healthcare analytics organization, was engaged to leverage data from multiple sources to generate a COVID-19 risk index at the city, county, and community levels in Maryland.10 One of the sources, Chesapeake Regional Information System for our Patients (CRISP), provided data about 2.6 million Medicare and Medicaid patients, which were then put into Socially Determined's Hi-Trust certified system to create indexes that measure community-level susceptibility and individual-level vulnerability. The output of the index is a visual map that allows state representatives to see risk across the state and provide insights for decision-making. The tool's precision calculated risk for every 200 meters, so it was easy to map the locations of homeless shelters, elderly homes, hospitals, and pharmacies against the population density.

Using the risk index to measure age, disease, and social factors, 900,000 individuals from the initial data set were identified as high-risk. Out of 900,000 people, more than 150,000 were identified as highest risk, and their names were provided to health departments, health systems and managed care organizations (MCOs) to begin outreach for testing, telehealth, and care management. The Task Force created a special team of emergency medical services (EMS) and social workers to test people in their homes, inquire about chronic health conditions, perform social needs assessments, and connect individuals with community resources. This approach resulted in 1,000 positive identifications within 25 days, which was more than double the state average at the time. The COVID-positive patients were sent to the emergency room and more than 50 percent of them were connected to previously inaccessible resources.

As researchers learn more about which populations are "at-risk" for COVID-19, it will be critical to map resources to assist these vulnerable populations. In some cases, communities and governments may need to create resources where they do not currently exist.

4. Assess the Impact of Interventions

Use Case: Marshfield Clinic Health System's Community Connection Team addresses social needs to improve health

The need to assess the effectiveness of SDoH interventions is the crux of the fourth principle. It is not enough for organizations to simply implement interventions; organizations should ensure there is a standard process in place for tracking outcomes and making improvements when necessary.

> **"We have 1.2 million people in our rural service area. We have about 360,000 patients, so we know that a number of those individuals in the community aren't our patients, and for us it didn't matter during COVID. It still doesn't matter."**
> **– Jason Shrader, Vice President, Community Health and Wellness, Marshfield Clinic Health System**

The Marshfield Clinic Health System (MCHS) collects data directly from patients through its Community Connections Team (CCT). The team is staffed by AmeriCorps members and student volunteers who screen patients and make referrals to the appropriate resource. Most of their clients are Medicaid- or Medicare-insured. The data elements collected include the number of patients served, the types of services they requested, the status of the referral, and patient satisfaction. This program and these services are available for clients of any federal healthcare program, even if that person is not a patient of MCHS. By tracking referrals, MCHS is also able to track whether or not interventions have actually occurred.

This year, the Community Connections Team has made more than 11,000 referrals. The three greatest needs identified are utilities, food, and transportation. The Team recognized that due to COVID-19, social isolation has also become a priority to address, so they started an iPad donation program to provide iPads to members of the community to stay in touch with loved ones and, importantly, also have the capability to participate in telehealth. Collecting data about urgent needs helped identify opportunities for new programs – an effective feedback loop that improved services.

In addition, the new program provided an opportunity for patients to provide feedback on whether they were satisfied with their programs and services, including gathering feedback on the quality of the staff. MCHS's program has established ongoing processes to regularly assess their interventions and improved their programs as a result of that feedback. As the pandemic is still raging in the Midwest, this will continue to serve as a ongoing method to gather information about the impact of interventions.

> **"The health systems themselves are not going to solve it, just as the community-based organizations are not going to solve it and just the public health aspect will not solve it. Everyone will have to come together to do this."**
> **– Vikas Chowdhry, Chief Information Officer, Parkland Center for Clinical Innovation (PCCI)**

As the majority of the country continues to battle COVID-19, it will be critical for healthcare organizations to regularly assess the impact of their SDoH interventions.

5. Customize Interventions and Allow Individuals to Determine Best Fit

Use Case: Aunt Bertha Connecting People with Resources in the Community

> **"So much can be done through healthcare, but there are so many places that people eat, live, pray, and work in their communities. We want to make sure that they have not only an equal opportunity, but resources at their fingertips in many of these places as well."**
> **– Jaffer Traish, Chief Operating Officer, Aunt Bertha**

The final principle focuses on the need to not only inform individuals that they are at risk, but allow individuals and/or caregivers to decide which services and interventions are the best fit for them. Programs and interventions should never be forced upon individuals, but individuals should be aware they are at risk and be able to make an informed choice to receive the intervention or service. In addition, it is important to provide resources and interventions that are customized or available to individuals at all of the various places they live their lives.

Providing self-navigating tools to select an intervention is an effective way to apply the fifth principle. Aunt Bertha, a non-profit organization, uses the concept of self-navigation as an intervention. The mission of Aunt Bertha is to connect all people in need to programs that serve them and bring dignity to that process. Its network

receives 42,000 referrals a month, and its belief is that having an open network ensures that the most people are reached, where they need it the most.

Aunt Bertha provides several solutions to non-profits to assist individuals in navigating the services they need. For example:

- The Camden Coalition provides a tablet and kiosk for patients to enter information anonymously in the waiting room to be matched to local resources. This ensures information is kept private and dignity is maintained.
- AARP collects information on its website for seniors to self-navigate to find home employment, support classes, and tools to reduce social isolation. This allows for individuals to select, based on their own needs, which interventions they want to employ.
- To Write Love on Her Arm uses a click-to-call mechanism that allows individuals to decide when they want to talk to a live person about their mental health. This group's unique approach helps non-profits in the education, healthcare, and corrections sectors provide immediate access to services while maintaining their dignity.

As COVID-19 continues to spread, it will be important to educate individuals on how their SDoH may increase their risk for COVID-19 and impact their health. Clinicians will need to review with patients their risks, necessary interventions, and services available to help, and then jointly agree on next steps.

FINAL THOUGHTS

As more healthcare organizations begin to utilize SDoH to identify and treat individuals affected by the COVID-19 pandemic, providers and policymakers must ensure that data is collected and used with clearly defined ethical standards and transparency.

The Guiding Principles can help inform the development and optimization of SDoH interventions and services.

The organizations highlighted in this report illustrate how the five principles can be applied in the midst of a pandemic. As we continue to face this unprecedented health challenge, the ethical use of SDoH data can improve healthcare organizations' ability to provide the right interventions and services at the right time.

ENDNOTES

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Social determinants of health (SDoH) data, which include information on a person's income, education, neighborhood and other social or economic factors about an individual's environment, play a critical role in improving health outcomes and reducing health care costs. In fact, research has shown that as much as 50% of modifiable, health-related behaviors – such as the environment people live in, their income or education level, and other socioeconomic factors – affect health while medical care accounts for only 20% of controllable contributors to healthy population outcomes.

Considering these social determinants of health, health care organizations can help improve health outcomes and minimize medical costs. At the same time, getting a SDoH model off the ground requires a lot of thoughtful coordination and analysis between analytics teams, clinicians, social workers and other community partners and buy-in from leadership.

LexisNexis Risk Solutions is uniquely positioned to support health care organizations interested in using SDoH data to provide more comprehensive patient care. Not only can we provide the data that has been clinically validated to improve patient outcomes, but we can also provide expert guidance with leveraging the data to provide meaningful insight to your teams.

Our Advisory Services are designed to provide support in implementing, understanding and utilizing SDoH Attributes and Scores. They can:

- Increase understanding and impact potential of adding SDoH data to your existing data sets
- Provide a window to obtain critical insights which will unlock additional value
- Shorten R&D timeframes to realize benefits faster

As a trusted advisor for our customers, we know that building a successful business case is essential to getting any SDoH initiative off the ground. It requires a thorough analysis of your patient/member population to determine a focus as well as a methodology for connecting the use case to ROI to achieve leadership and other stakeholder buy-in. LexisNexis Risk Solutions can support your organization from data implementation to business insights.

About LexisNexis® Risk Solutions

LexisNexis® Risk Solutions harnesses the power of data and advanced analytics to provide insights that help businesses and governmental entities reduce risk and improve decisions to benefit people around the globe. We provide data and technology solutions for a wide range of industries including insurance, financial services, health care and government. Headquartered in metro Atlanta, Georgia, we have offices throughout the world and are part of RELX (LSE: REL/NYSE: RELX), a global provider of information-based analytics and decision tools for professional and business customers.

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