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Achieving Diversity in Clinical Trials

Expanding Hospital Capacity to Offer Clinical Trials in the Community

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Table of Contents

Executive Summary

The inclusion of racial and ethnic groups in clinical trials has been a national priority for decades, but progress toward that end has been limited. When the Covid-19 pandemic threw into stark relief the underlying inequities in health care access (and thus in access to clinical trials), Congress and the Administration were moved to action. In parallel, trial sponsors, hospitals, and other stakeholders have been accelerating efforts to increase diverse populations' access to clinical trials. Given the complexity of the challenge, much more action is needed at multiple levels and by all involved.

A patient's access to clinical trials depends upon how easily he or she can access care generally, whether providers offering the appropriate trial for the patient are nearby, whether the patient has trust in the physician recommending the clinical trial, and whether the patient has health care coverage to pay for care. These conditions often are not met, resulting, even under the best circumstances, in the exclusion of people of color and lower-income patients. Many initiatives aimed at breaking down barriers to access focus on the need to build trust between providers and diverse populations in the community. Of equal importance is the need to strengthen the overall capacity of the health care delivery system infrastructure to support clinical trials at the point of care. For most people, including diverse populations, this point of care is a community hospital. Though there are examples of robust clinical trial programs being offered by community hospitals, most do not offer trials—or their capacity to do so is limited.

A patient's access to clinical trials depends upon:

- How easily he or she can access care generally;
- Whether providers offering the appropriate trial for the patient are nearby;
- Whether the patient has trust in the physician recommending the clinical trial; and
- Whether, and at what level, the patient's health insurance will cover the care that is not paid for by the clinical trial.

This paper focuses on ways to strengthen community hospitals' capacity to offer clinical trials for all people in their communities, ways to leverage the hospitals' ability to contribute to advancing science by supporting research related to the trials, and ways to proceed with developing such efforts.

As it is important to understand the broad set of factors that influence trial access in the community, we begin by reviewing the health care ecosystem within which clinical trials are offered. We describe efforts by key stakeholders—Congress and the Administration, the National Institutes of Health (NIH), the pharmaceutical industry, academic medical centers (AMCs), advocacy groups and professional societies, and payers—to increase diverse accrual. Finally, we propose concrete strategies for use by community hospitals and trial sponsors, which we define broadly to include the pharmaceutical industry, NIH, AMCs, and others.

Strengthening hospital capacity for trials is a complex undertaking. The engagement of hospital and health system executives by trial sponsors and others will be central, both in addressing the challenges of infrastructure and clinical practice culture and supporting development of a mission and business case for expansion of clinical trials to reach diverse populations in the community.

Only by bringing robust clinical trials to local communities and their diverse populations—and offering them through trusted high-quality providers—can accrual to trials be significantly expanded, and thereby, improved treatments and better health for all be achieved.

Introduction

The need for greater representation of racial and ethnic groups in clinical trials has long been recognized; however, progress to date has been modest at best. Innovative medical advances are made with increasing frequency, but not all patients have equal access to these procedures and treatments or to the clinical trials in which they were tested. Participation in clinical trials in the United States (U.S.) is generally low, which impacts the rate at which new treatments can be introduced into clinical settings; as many as 20% of clinical trials are terminated early for failing to meet recruitment targets or are completed despite failing to meet the original target.[1] Further, many trials that accrue a sufficient number of participants suffer from a lack of diversity. In 2020, the clinical trials supporting applications for Food and Drug Administration (FDA) approval of new drugs and biologics included only 8% Black or African American, 6% Asian, and 11% Hispanic or Latino participants.[2]

The historic barriers to participation by minority populations have been well-documented,[3] but the Covid-19 pandemic also laid bare and exacerbated systemic health inequities that affect diverse accrual.[4] In response, beginning at the height of the pandemic in 2020, Congress called for change. Congressional representatives and the Biden Administration enacted and introduced important new measures (see Appendix). Still, much more progress is needed, and indeed, many health care providers, research institutes, and the pharmaceutical industry have recognized the need to redouble efforts to reach and recruit diverse populations to more clinical trials.

Strategies to improve diversity in clinical trials must achieve two aims. First, as a top priority, they must advance ways to build trust and engagement with diverse populations, a complex and long-term undertaking. More fundamentally, the overall capacity of the health care delivery system infrastructure to support clinical trials must be improved, such that more trials are offered at the point of care and all have equal access. As most patients receive their care in the community setting, there lies the greatest opportunity for expansion of trials and accrual of a wide range of patients.

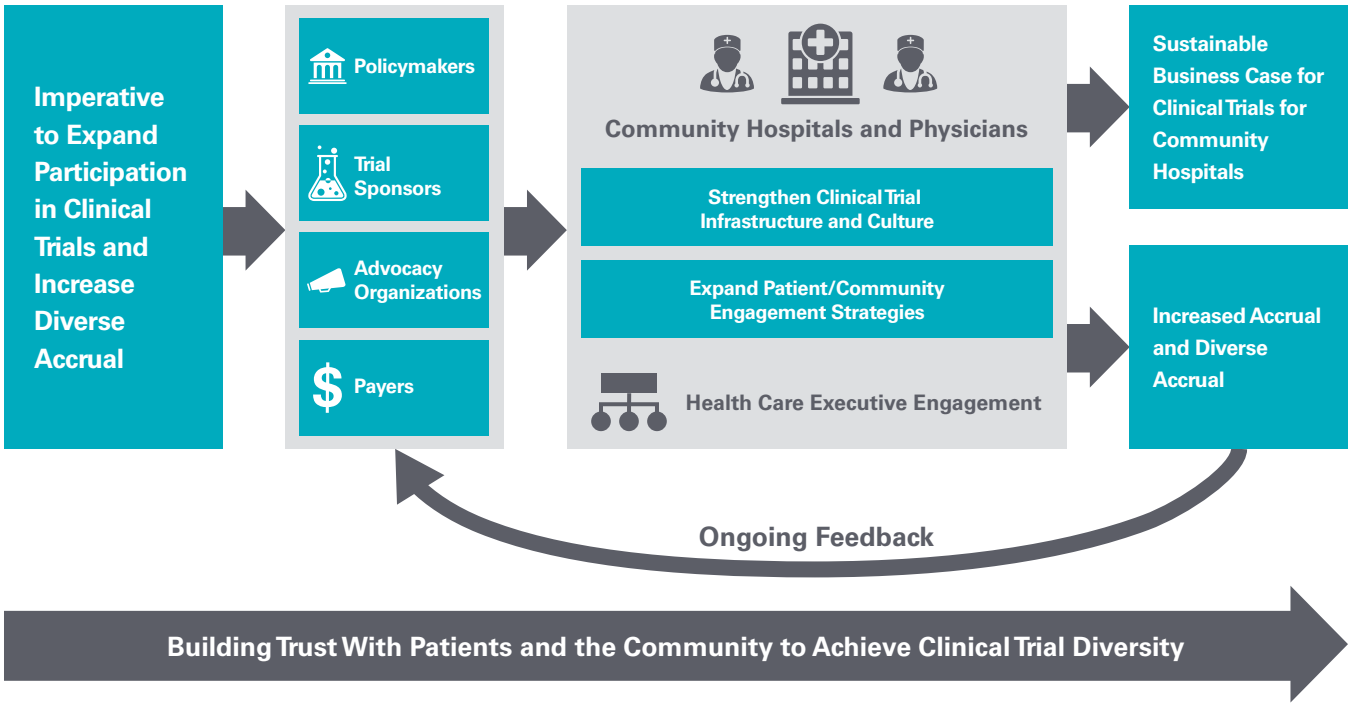
To address the challenges of bringing more clinical trials to patients in the community and diverse populations, this paper will:

- Describe the health care ecosystem within which clinical trials are offered;
- Provide an overview of some efforts undertaken by policymakers and government; pharmaceutical companies, AMCs, and advocacy organizations and professional societies to create a high-performing clinical trials platform in community hospitals and to reach diverse populations; and
- Offer concrete strategies for expanding capacity and increasing accrual, including diverse accrual, to trials in the community.

A number of strategies are underway to increase accrual of diverse populations, including efforts by AMCs, trial sponsors' direct outreach to patients, sponsored trial sites in the community, and collaborative efforts to grow decentralized trials designed to ease patient burden and reach patients where they live.[5] However, we focus here on the role of community hospitals in providing more clinical trials to accelerate development of new treatments and to improve access for diverse populations.

Given the moral and scientific imperative to expand participation in clinical trials and increase accrual of diverse populations, and the complexity of achieving this goal, progress will be made only when policies and initiatives link together all stakeholders. Such stakeholders include trial sponsors, policy makers, payers, advocacy organizations and professional societies, and providers. As shown in the figure below, these and others must engage community hospital and health system executives in efforts to strengthen the hospitals' capacity to conduct trials. Through that engagement, more effective strategies can be developed to increase accrual overall and to reach diverse populations.

Increasing Participation in Clinical Trials in Community Hospitals—a Long Process With Many Stakeholders



The Current State of Clinical Trials in Community Hospitals

Clinical trials usually are conducted through major AMCs, while most patients are treated in community settings, including in rural areas.[6] Having to travel to a distant center creates hardship for a patient, especially for an older adult or someone with serious illness. An even greater barrier to trial participation can be insurance coverage, which often excludes out-of-network and out-of-state care. For many patients, such expanded coverage would be necessary to access trials easily and affordably. Many, especially patients of color and those with lower incomes, must decline participation in clinical trials due to high co-payments.[7] While not the primary focus of this paper, the importance of adequate insurance coverage with respect to trial access should not be underestimated. (See box on page 9, "The Relationship Between Health Care Coverage and Access to Clinical Trials.") Patients with rare diseases who could be served by clinical trials only offered in AMCs face particular access, coverage and travel burdens, and this slows the completion of these trials.

The deficits of access and coverage underscore the need to expand the number of clinical trials offered in the community setting. As the primary source of care for local patients, community hospitals have a broad imperative to serve all in their communities and to reach out proactively to engage diverse populations. These institutions also can play an essential role in advancing science by making clinical trials available to their patients.

Community hospitals have a broad imperative to serve all in their communities and to engage diverse populations. By making clinical trials more accessible in the community, they also can play an essential role in advancing science.

There are examples of effective clinical trial programs in community hospitals, including organizations that offer early-phase and complex trials.[8] However, in general, community hospitals provide few, if any, clinical trials. A recent survey of active clinical trial sites across the U.S. showed that 63% of non-AMC sites have fewer than 25 open clinical trials.[9] The reasons for this are several. Historically, clinical trials have not been part of the hospital's mission and organizing and supporting local trials is logistically and financially challenging. Moreover, the focus of the hospital's clinical practice culture is on clinical care and on having highly productive providers; such a focus does not enable the extra time needed to participate in research. When a clinical trial is offered, it usually is driven by a physician's interest in research (e.g., cancer or cardiology) and not as an organizational strategy.

There are many examples of effective clinical trial programs in community hospitals, including those offering early phase trials, but generally it is not part of their mission and many do not offer trials.

The pharmaceutical industry, the policy community, and AMCs, through their community outreach programs, have undertaken efforts to promote clinical trials at the point of care, such that clinical trials can be a care option for more patients.[10,11] However, progress working with community providers is slow. What will be required to strengthen the capacity of community hospitals to offer clinical trials? To offer a robust portfolio of trials for their diverse populations, community hospitals and health systems will need:

- A community hospital organizational strategy for offering clinical trials with a sustainable business model;
- A clinical practice culture that embeds trials into clinical care and supports physician participation in research;
- Strong and efficient research administrative services and clinical trial operations; and
- Initiatives that effectively engage diverse populations in their communities, including ways to remove culture-specific barriers to participation in clinical trials.[12]

These are difficult and costly organizational changes to make, but there are strategic benefits for a community hospital that offers a robust clinical trials program. Such a program would attract more patients as a result of this advanced level of care, reduce outmigration, and improve the recruitment and retention of specialty physicians.[13]

Hospitals now have viable business model options for outsourcing critical clinical trial support functions and gaining access to associated technology solutions.

To address some of the challenges, new companies have entered the market—and existing companies have expanded—to offer business solutions aimed at meeting hospitals' needs for building or strengthening clinical trial infrastructure. Models are now available for outsourcing or partnerships that allow hospitals to access research administrative services, clinical trial operations support, and ethical review or institutional review board (IRB) services.* Given the difficulty of community hospitals building these services internally, it makes economic sense for hospitals to consider outsourcing some or all of these functions. The aforementioned companies have operational scale and can offer expertise, processes and technology investment that community hospitals often are not able to develop or fund.[14] While this option may benefit some health care organizations, these solutions address only some of the challenges.

* Research administrative services may include trial budgeting, contracting, coverage analysis, a clinical trials management system, e-trial matching, study calendar builds, and trial invoicing, for example. Clinical trial operations support may involve providing clinical research associates, establishing patient engagement centers, etc.

The Relationship Between Health Care Coverage and Access to Clinical Trials

While clinical trial sponsors may cover many costs associated with a clinical trial, federal law requires, since 2000, that "routine clinical costs" be covered by Medicare.[15] A similar coverage requirement has applied to commercial plans—including employer-sponsored and Marketplace plans—since the Affordable Care Act went into effect in 2010.[16] As of January 2022, Congress extended this policy to the Medicaid program with the Clinical Treatment Act[17] (although some states voluntarily had adopted a policy of covering at least some routine patient costs under clinical trials[18]). Most patients who are recommended for a trial must therefore first get approval for coverage of their care, and then meet in- and out-of-network deductibles and co-insurance requirements.

When a person with commercial insurance is offered a trial by an out-of-network provider, which is a common occurrence, the patient is often responsible for the balance not covered by the trial sponsor or insurance carrier. With co-pay amounts ranging from tens of thousands of dollars to well over one hundred thousand, it is not only lower-income patients who are forced to decline participation in the trial. This is a challenge overall, but in particular, for those with a rare disease whose only access to a clinical trial would be at an AMC that often is out-of-network.

By contrast, an enrollee in a Medicare Advantage plan is entitled to coverage of routine patient costs for clinical trials, regardless of whether the provider is in their plan's network or located in their home states. This coverage is provided through traditional Medicare and not the Medicare Advantage Plan. These older patients, however, are often not in a position to travel if the trial site is far from home.

For patients with Medicaid insurance, the Clinical Treatment Act was an important step toward ensuring access to clinical trials, and it also requires coverage of routine costs associated with clinical trials for in- or out-of-network and out-of-state providers. However, the processes and criteria for out-of-state provider enrollment (where the best trial may be for the patient) remain a barrier in many state Medicaid programs.[19] This circumstance, which affects low-income and often diverse populations, can preclude an individual's receiving potentially disease-altering treatments, and it also reduces the diversity of patients accrued to clinical trials.

When payers are considering whether to approve care, they are generally unaware that a patient is seeking approval because s/he has been recommended for a clinical trial. In many cases, a patient on a clinical trial costs the payer less, as the high price of drugs and other trial-related expenses is covered by the trial sponsor. As an example, one recent cancer study using CMS claims data found that the mean Medicare cost per episode of care for a specific set of diagnoses was $36,590 for patients on a clinical trial, compared to the Medicare per-episode spending target of $48,124 for patients with the same diagnoses who were not participating in a trial.[20] There may be an opportunity to make the case that patients on trials can be a value strategy for payers and that out-of-network and out-of-state approval processes should be adjusted for patients on clinical trials. Community hospitals and health systems also are lower-cost providers, another financial benefit for payers.

This reality underscores the need for clinical trials to be offered close to where patients live and have the most insurance coverage.

The Need to Engage Health Care Executives

Clinical trials can only be offered effectively when there is easy access to care, especially for diverse populations, and when care is high-quality. As this is the domain of hospital executives working with their clinical leaders, their engagement is critical. Executives also determine other aspects of a successful clinical trials program, e.g., the level of investment in a clinical trial infrastructure and the clinical practice culture; the organization-wide support from departments (e.g., pharmacy, IT, finance, marketing); and the resources, expertise and commitment to an overall organizational-level community engagement strategy that builds trust and partnerships with the diverse communities they serve.[21] (See the National Cancer Institute case study, "A Community-based Cancer Program Model With Hospital Executive Engagement," on page 11.)

Hospitals and health systems routinely develop business and growth plans for their many programs and initiatives, yet most have not pursued such a plan with respect to clinical trials. Expanding clinical trials and achieving trial diversity require a comprehensive assessment (see assessment questions noted in Table 1 on page 15) and an enterprise-wide strategic and financial plan for clinical trials. (See the Henry Ford Health case study, "An Integrated Delivery System With an Enterprise-wide Clinical Trial Business Plan and a Partnership/Outsourcing Model for Research Support Services," on page 12.)

Expanding clinical trials and achieving trial diversity require a comprehensive assessment of capacity and an enterprise-wide strategic and financial plan for clinical trials.

Trial sponsors should work with hospital executives to expand capacity for conducting clinical trials and optimize diverse accrual.

All stakeholders must work with community hospital and health system executives to expand capacity to conduct clinical trials and optimize diverse accrual. Such an effort begins with developing a deeper understanding of the organizational and financial environment for clinical trials in the community hospital setting and identifying ways to support the health care organization's role as a high-performing clinical trials platform. This includes finding funding sources for building infrastructure and a favorable clinical practice culture that supports trials as a care option for patients. National and regional health systems should be a priority for pilot projects, as these offer the potential to scale new approaches across large geographies.

National Cancer Institute

A Community-based Cancer Program Model With Hospital Executive Engagement

The NCI Community Cancer Centers Program (NCCCP) was launched in 2007 with 30 hospitals from 22 states. The program aimed to reach rural, suburban and urban areas, with goals that included the creation of a high-performing research platform in the community, where 85% of cancer patients received treatment and where there would be access to diverse populations to support NCI health disparities goals.

Those involved recognized that building a robust clinical trials platform, with the capacity for early-phase trials, molecular characterization studies, and programs for health disparities and community engagement, would require a broad organizational base of support, the engagement of community hospital executive management, and a business case for investment.[22]

The NCI and the 30 hospital organizations established a public-private partnership structured as a learning collaborative and created a program roadmap and tools to strengthen access, quality, and research.[23] With a 40% focus on health disparities, each hospital developed plans to engage the diverse populations in its community using evidence-based strategies with specific milestones. To understand the barriers to screening and enrollment of underserved populations to clinical trials, members of the collaborative developed and implemented specific tools and strategies.[24,25]

Within the program was a cohort of national health system entities, each with multiple sites, to assess how well their system operating models and cultures contributed to effective dissemination. One health system, Catholic Health Initiatives (now CommonSpirit), leveraged the program to create a national cancer clinical trials program with more than 40 participating hospitals.[26,27]

The program's external evaluation included an economic study and annual interviews with hospital financial and chief executive officers (CEOs) to understand the business case for the participating hospitals.[28] The overall evaluation results showed that hospitals began to see an increased volume of patients, and they were able to strengthen physician alignment. The key factors cited in interviews as influencing the hospitals' performance in the program included the availability of a specific roadmap for capacity-building, access to expertise, participation in a learning collaborative, and executive engagement.[29]

Several hospitals demonstrated that they could be high-quality contributors to molecular characterization studies, including The Cancer Genome Atlas, and could offer early-phase clinical trials.[30,31] One of the hospital CEOs recommended leveraging this expertise. He engaged other CEOs of community-based health systems across the country to form a not-for-profit clinical trials network with a technology solution to match patients to trials.[32]

The NCCCP program achievements would not have been possible if the NCI had not engaged CEOs at the outset and worked together with the hospitals in a learning collaborative.

Henry Ford Health

An Integrated Delivery System With an Enterprise-wide Clinical Trial Business Plan and a Partnership/Outsourcing Model for Research Support Services

Henry Ford Health (HFH) is a leading academic, integrated-delivery system with five hospitals in Southeast Michigan. Henry Ford Hospital, the academic hub of the system, is located in Detroit where it serves a very diverse population. As part of an initiative to strengthen administration of its research and academic programs, HFH embarked upon an assessment of its clinical trials operation, aiming to create a highly efficient infrastructure that would advance practice-changing research. HFH has access to diverse populations and effective community engagement strategies, and was one of the largest accruing organization of diverse patients to COVID-19 vaccine trials in the country. While they were able to mobilize effectively for the vaccine trials, their clinical trial operation had bottlenecks, silos and high staff turnover, which limited their ability to expand clinical trials and accruals.

To address these challenges, they engaged Manatt Health to launch a comprehensive assessment of all processes, from scientific and feasibility review to protocol development, budgeting, coverage analysis, IRB, contracting, the use of the Clinical Trials Management System, and the clinical practice culture for supporting physician participation in research. The resulting plan required restructuring and culture change. With many staff vacancies, it likely would have taken 12 to 18 months to make significant operational changes and orient new staff, and staff turnover would remain a challenge.

A stakeholder advisory committee determined that a partnership option, with experts assuming functions, many off-site, might enable more rapid change. After considering several firms and models, an enterprise-wide clinical trial business plan was developed with a return-on-investment analysis, and a partner was selected. A new position, Vice President for Clinical Research, was created for a physician researcher who would oversee the clinical trial operation and serve as an advocate for the various clinical departments' research priorities. Funds flow was also reviewed as a critical step for improvement and for recognizing and promoting physician participation in clinical trials.

The support of executive leadership was critical to the initiative's success, with the CEO of the Henry Ford Medical Group and the Chair of Medicine driving the project. The reorganization and the new partnership will allow an expedited path to a more efficient operation, increased physician satisfaction, and expanded relationships with pharmaceutical sponsors. The new arrangement allows HFH to focus its efforts on bringing more novel trials and practice changing medicine to the community it serves.

Efforts by Trial Sponsors and Professional Associations and Advocacy Groups to Increase Diverse Accrual

Various trial sponsors also have launched efforts to increase clinical trials accrual overall and improve trial access for diverse populations. Many are more recent, but some have been in place for more than 30 years.

National Institutes of Health (NIH)

The NIH has been a longtime sponsor of programs to increase access to trials and diverse accrual, with the National Cancer Institute (NCI) providing significant leadership. Because 85% of cancer patients are treated in a community setting, where they are most likely to have health care coverage and access to care, the NCI developed programs for community providers and the diverse populations they serve. Examples include the Community Cancer Oncology Program (CCOP) and its Minority-Based CCOP,[33] launched in the 1980s. These programs demonstrated that community-based oncologists could be effective in accruing patients, including diverse patients, to NCI clinical trials.

The NCI launched its Community Cancer Centers Program (NCCCP) in 2007 as a 30-hospital-member learning collaborative that engaged hospital management to support building cancer program capacity. With 40% of its funding to be designated to address health disparities, the NCCCP helped to establish the business case for hospitals investing in state-of-the-art cancer care and a culture of research for accrual and minority accrual.[34] (See the National Cancer Institute case study, "A Community-based Cancer Program Model With Hospital Executive Engagement," on page 11.)

The NCCCP and CCOP entities became the NCI Community Oncology Research Program (NCORP) and Minority-Based NCORP in 2014.[35] In 2018, to expand clinical trials to veterans, the NCI and the U.S. Department of Veterans Affairs (VA) announced an interagency agreement to expand access to clinical trials at 12 VA hospitals across the country, with an aim to reach veterans from diverse populations. Four additional VA sites will be selected in 2023. The NCI provides infrastructure funding support to increase accrual to NCI trials for three years, and the VA will develop plans for sustainability.[36] While these programs are increasing accrual and diverse accrual to NCI trials, their funding and scale are limited.

The Pharmaceutical Industry

The pharmaceutical industry funds nine times more interventional studies than does NIH.[37]

However, as 65% of accrual to these studies is from outside the U.S., more opportunities are needed for accrual within the U.S.[38] Given the imperative to increase diverse accrual, the industry has expanded its efforts and developed new programs and clinical studies to better understand barriers for diverse populations.[39]

In 2022, the Pharmaceutical Research and Manufacturers of America (PhRMA) launched a pilot initiative linking a network of community-based trial sites to diverse communities, sponsors, patients, providers, community organizations, academic institutions, and others to identify tangible actions and goals that can increase diverse accrual.[40] Many individual pharmaceutical companies are embarking on similar initiatives. Genentech has established several efforts, such as its CATORI trial, designed to reach American Indians and Alaska Natives,[41] and its Advancing Inclusive Research® Site Alliance, which includes four cancer centers that aim to increase diverse accrual to Roche and Genentech oncology trials.[42]

Academic Medical Centers and Research Institutes

Many AMCs, especially those that also have NCI Cancer Center designation, have launched programs and established consortia to offer access to clinical trials in community hospitals and to reach diverse populations. These efforts have expanded access, but they face challenges in the absence of a strong business case and sufficient community hospital infrastructure and clinical practice culture to support clinical trials. Oregon Health and Science University is an example of a research affiliate program whose staff members work effectively with community hospitals to address barriers to offering clinical trials.[43] Their scope spans many clinical areas and their approach is to have dedicated AMC staff who build relationships with community hospital staff to help break down barriers to offering trials and working with the AMC.[44]

Professional Associations and Advocacy Organizations

Professional organizations and advocacy groups have made diverse accrual a priority. Because so many steps and obstacles are involved in a patient's finding a clinical trial, the Leukemia and Lymphoma Society (LLS), for many years, has maintained a call center staffed by clinical trial nurse navigators and dedicated to helping patients find an appropriate trial. LLS reports that, on average, the call center staff must make 24 contacts to help a patient find the right clinical trial.[45] Even then, as noted in their recent report,[7] coverage-related barriers can prevent access to trials. LLS is studying this issue in greater depth and will be publishing a report in the coming months.

The American Heart Association, with support from Pfizer and the Bill and Melinda Gates Foundation developed its Science-Focused Research Networks on the Science of Diversity in Clinical Trials program,[46] granting its first awards in 2022 to coordinating centers that work with community-based providers serving diverse populations. The American Society of Clinical Oncology, in collaboration with Friends of Cancer Research, developed guidelines for trial sponsors and principal investigators, such that inclusion and exclusion criteria can be more flexible, thus improving diverse accrual.[47] Hypertension, for instance, which is more prevalent in some populations, could serve as a barrier to inclusion. The organizations continue to support implementation of these guidelines and work closely with the NCI Cancer Therapy Evaluation Program and other NCI clinical trial programs. The Michael J. Fox Foundation has advanced, with good results, an initiative using digital strategies to increase participation of diverse populations in its Fox Insight cohort study.[48]

Overall

Stakeholders have developed, through various trial diversity initiatives, strategies that center on building trust. Such strategies include direct engagement with diverse populations, culturally-tailored education for staff, building a diverse pool of investigators, expanding the diversity of research staff, initiatives to address social determinants of health barriers, implementation of decentralized clinical trials, and remote technologies.[49,50]

The NCI Community Cancer Centers Program, however, is the only initiative that also has focused on working with hospital executives to build provider capacity and infrastructure to support clinical trial expansion and diverse accrual. More attention to working with community hospital executives is requisite to building capacity.

Table 1: Some Questions to Assess Hospital Clinical Trial Capacity and Efforts to Enhance Diverse Accrual[29]

Leadership and Organizational Support
Organizational support
What are the organizational-level vision and goals for clinical trials?
Which clinical program areas have the highest potential for clinical trials?
How much organizational support is available for clinical trials (IT, pharmacy, research pharmacy, lab, marketing)?
How does the organization provide oversight of clinical trials and program performance?
What are the financial and performance goals for clinical trials?
Community Outreach and Engagement
How does the organization engage with its community (approach, initiatives, staffing)?
To what extent are there formal community partnerships with organizations serving diverse populations?
To what extent are evidence-based community outreach and engagement strategies used? Are culturally-tailored strategies used to address barriers to participation in clinical trials?
What is the perception of the community about the hospital as a community resource and partner?
Clinical Practice Culture and Trial Performance
What is the model of physician alignment and the level of engagement to support clinical trials?
How many physicians are engaged in clinical trials?
To what extent does the clinical practice culture and physician compensation model support participation in trials?
What is the level of trial activity (open studies, accrual/diverse accrual by trial) for each clinical area?
What is the makeup of the trial portfolio (sponsor, clinical areas, type and phase) and processes for portfolio development?
How are patients identified for participation in trials (staff involved, technology used, etc.)?
What is the financial performance of the trial portfolio? How is it managed, and by whom?
Research Administrative Services and IRB
What is the organization's research staffing and expertise? Where are staff members based (e.g., research administration, clinical practice, etc.)? What is the level of staff turnover?
What is the level of efficiency of the clinical trial operation (days to activate trials) by function (budgeting, coverage analysis, contracting, study start-up, invoicing, etc.)?
What technology is used to support trials (e.g., Clinical Trials Management System)? What is the level of optimization?
What financial processes are available to support trials (e.g., invoicing, receivables management)?
What are the reporting structures for oversight of performance and processes for user feedback? What is the level of stakeholder satisfaction (e.g., physicians) with the research administrative functions?

Proposed Actions to Support Community Hospital Clinical Trial Expansion

To achieve clinical trial diversity, more clinical trials must be available in the places where patients live and where they have the most affordable access to care. The greatest opportunity for expansion is through increasing the capacity of community hospitals and their physicians to accrue patients, especially diverse patients, to trials. Community hospital and health systems executives can take steps on their own to strengthen their capacity and develop a business case, but optimizing performance requires support from trial sponsors.

Below are some specific actions that may be considered.

Community Hospital Providers

Proposed actions:

- Assess current clinical trial activity and the supporting infrastructure across the organization (see Table 1 on page 15, which lists assessment categories and questions);
- Identify opportunities for expansion of clinical trials, based upon clinical program strengths (e.g., cancer, cardiology, neurology) and the resources and actions required;
- Develop a sustainable plan with a business and operational strategy for expansion of clinical trials;
- Learn more about outsourcing and partnership models to inform a build/buy decision on research administrative services and clinical trial operations;
- Reach out to trial sponsors to discuss collaborative opportunities and to build a business case to expand capacity and accrual to trials;
- Approach payers to propose a value strategy to support expansion of clinical trials (e.g., grants and/or enhanced reimbursement for patients on clinical trials), such that funds can be used, following best practices for capacity-building;
- Link clinical trial outreach to hospital programs for community outreach and engagement; and
- Identify opportunities to expand use of evidence-based practices to engage with diverse populations and incorporate culturally tailored strategies to build trust and address barriers to accrual.

Trial Sponsors

Trial sponsors include the pharmaceutical industry, NIH, AMCs, and in some cases, advocacy organizations, foundations, and others. Sponsors support many initiatives to increase accrual and diverse accrual, but all may better leverage capacity in community hospitals with these recommended actions:

- Identify high-potential but underperforming community hospital sites for clinical trials, and work with executives to assess those hospitals' organizational and clinical culture barriers to effective accrual and diverse accrual (see Table 1 on page 15);
- Work with these hospitals' executive leadership to support development of a business case for their clinical trial program; and
- Engage executives of community hospitals to develop and fund disease-specific, best-practice-sharing hospital consortia that serve diverse populations and provide expertise for building or expanding support functions.
- Develop an evaluation approach for hospitals to use to assess the factors that influence accrual and diverse accrual to trials to help inform their program investment and a sustainable business case for the hospital.

To shore up these efforts, other stakeholders can expand their initiatives. Health care executives are central to all discussions, as are trial sponsors and payers, including the Centers for Medicare and Medicaid Services (CMS). Payers are essential to the ecosystem that influences access to clinical trials. They could consider funding studies that show the impact on the cost of care for patients in clinical trials. (One study suggests as much as a 25% savings for patients participating in trials.[20]) Payers also may consider opportunities for enhanced reimbursement to support in-network, community-based centers of excellence that offer clinical trials, such that needed infrastructure investments can be made in these programs.

Conclusion

Community hospital and health system executives face daunting challenges in a number of arenas. However, they should be encouraged and supported in leveraging their power to advance science by providing more universal access to trials. Only by bringing robust clinical trials to local communities, and offering them through trusted, high-quality providers, can accrual to trials be significantly expanded—and thereby, improved treatments and better health for all be achieved.

Appendix: The Evolving Policy Environment

Recent federal legislation has aimed to improve access to clinical trials, including for historically marginalized people.

- The Henrietta Lacks Enhancing Cancer Research Act (P.L. 116-291), became law on January 5, 2021. It requires the Government Accountability Office to complete a study reviewing how federal agencies address barriers to participation in federally-funded cancer clinical trials by individuals from underrepresented populations. The Act also provides recommendations for addressing such barriers.[51]
- The Clinical Treatment Act, ratified in December 2020 as part of the year-end funding package and effective as of Jan. 1, 2022, requires Medicaid to cover "routine costs" associated with clinical trial participation in order to help reach underrepresented populations. While there is variation by state on insurance mandates, Medicare and many private payers have covered routine costs that accompany clinical trial participation, such as fees associated with physician visits, hospital stays, diagnostic tests, and other standard clinical services that would have been covered absent the patient's participation in a trial. Medicaid, however, has provided coverage on a spotty, state-by-state basis.[52]
- As part of the end-of-year spending package in 2022, Congress enacted FDA-related reforms that included a provision requiring drug and device sponsors to submit "diversity action plans." These plans are for the purpose of articulating goals to enroll historically underrepresented patient populations in the clinical trials supporting their applications. The provision embraced the approach previously set forth in an April 2022 draft guidance issued by FDA.[53]

Beyond these legislative reforms, numerous efforts to increase clinical trial diversity have been initiated within federal agencies in recent years, **including**:

The Food and Drug Administration (FDA)

- FDA issued draft guidance in April 2022 on "Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials" and continues to focus on strategies to boost enrollment of diverse populations in clinical trials. FDA also will update the April 2022 guidance to align it with the recently enacted legislative changes described above.
- **FDA's Oncology Center of Excellence** launched its Project Equity to increase representation of diverse populations in clinical trials.[54] At various points throughout the pandemic, FDA also issued guidance on the conduct of clinical trials during the COVID-19 Public Health Emergency, which provided advice on utilizing remote, or decentralized, clinical trials to permit the safe continuation of such trials.[55]
- **In May 2023, FDA issued newly updated draft guidance** on the use of decentralized clinical trials. The update was a clear sign of the Agency's commitment to ensure that lessons learned from the pandemic about the positive impact of such technologies would be applied in regard to clinical trial enrollment.
- **The FDA also increased regulatory requirements** to streamline local IRB processes and increase utilization of central IRBs. These requirements place pressure on organizations to improve their local IRB approval process or increase their reliance on commercial IRBs.[56,57]

The National Institutes of Health (NIH)

- The NIH released a Request for Information in spring 2021, seeking suggestions about ways to advance racial equity, diversity, and inclusion within all facets of the biomedical research workforce, and expand research to eliminate or lessen health disparities and inequities.[58]
- **The NIH's Advanced Research Projects Agency for Health (ARPA-H)** has stated clearly that diversity and health equity will be a key component of funding.
- **The NCI and the U.S. Department of Veterans Affairs** released an RFP April 3, 2023 for an Interagency Group to Accelerate Trial Enrollment including a focus on minority populations.[59]

The White House Office of Science Technology and Policy (OSTP)

- OSTP issued an RFI in late 2022. The RFI aims to acquire stakeholder input on the status of the Clinical Research Infrastructure and Emergency Clinical Trials to address preparedness, equity, diversity, and trust in science.[60]

The Government Accountability Office (GAO)

- A GAO Study "Cancer Clinical Trials; Federal Actions and Selected Non-Federal Practices to Facilitate Diversity of Patients" completed in December 2022, describes best practices to increase diversity in cancer clinical trials.[61]

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