Advisory Board

For U.S. health care leaders

An ecosystem approach to achieving diversity in clinical trials

Key takeaways from Advisory Board's cross-industry research and workshop

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About our research on clinical trial access and diversity

Leveraging our cross-industry perspective to help leaders pursue health care's clinical trial diversity mandate

Covid-19's disproportionate impact on Black, Hispanic, and indigenous groups has amplified pressure on health care leaders to address longstanding health inequities. Clinical trials and research have been identified as areas where historic barriers to inclusivity have significant negative downstream consequences. Fortunately, there are no shortage of good ideas on how to do so—industry leaders like the Food and Drug Administration (FDA), Clinical Trials Transformation Initiative (CTTI) and Multi-Regional Clinical Trials Center (MRCT) have published extensive guidance on enabling diverse patient enrollment.

Nonetheless, our research and interviews on this topic uncovered two overlooked questions that require honest dialogue across industry sectors:

1. What principles and practices must the ecosystem revisit as we layer on a new goal—diversity—to an enterprise built to generate product safety and efficacy data?
2. Does our current value framework for clinical research impede adoption of best practices for promoting diverse patient enrollment?

Advisory Board's research focused on answering these questions. Through research interviews and a cross-industry workshop, we landed on three necessary mindset shifts and a value framework aimed at advancing the ecosystem's pursuit of more diverse clinical research.

DATA SPOTLIGHT

Our workshop, in numbers

23
Executive-level leaders in attendance

5
Industry sectors represented

Five key takeaways from our research and workshop

1. Despite cross-industry consensus on the uniqueness of today's opportunity, there is no agreement on the right approach to achieve change.
2. Focusing efforts to advance diverse enrollment on communities, rather than sites, enables us to choose better locations and partners to support our trials and health equity at large.
3. We must address the non-clinical exclusions within the current clinical trials paradigm that prevents patients and clinicians from marginalized groups from participating.
4. Legacy identities and partnership structures must change to enable significant system-level change.
5. We must expand how we assess the value of diverse clinical research to maximize support for change.

Takeaway #1

Despite cross-industry consensus on the uniqueness of today's opportunity, there is no agreement on the right approach to achieve change.

Covid-19 catalyzed an opportunity to advance diversity in clinical trials by exposing deep health disparities at a time when drug development and racial justice were front-of-mind to the public. Building on a vital pre-pandemic foundation, health care leaders have responded by investing in the regulatory and operational capabilities to sustain the ecosystem's focus on this issue.

Factors creating today's unique opportunity for foundational change

Pre-pandemic foundation

Vital groundwork in the form of advocacy, legislation, regulatory guidance, investments, and trial experimentation creates a foundation for real change

- 21st Century Cures Act supports for novel trial design, patient consent
- Decentralized clinical trial platforms provide proof of concept

A historic moment in time

Covid-19 exposed the inequities at the bedrock of our health care system as the public focused on vaccine development and advancing racial justice

2.0x Higher death rate for Black Americans from Covid-19, compared to white Americans

Sustained ecosystem focus

Governments and leading biopharma organizations have acted more rapidly and boldly than previously to align policies and operations with the pursuit of health equity

- Medicaid will cover "routine patient costs" for trials starting in 2022
- Sponsors expand health equity, trial diversity workforce, leadership

Takeaway #1 (continued)

As a result of these investments, the ecosystem now has not only the appetite, but also the capacity, to drive clinical trial diversity at scale. Yet the ecosystem lacks a multi-sector roadmap for the future. Although progressive organizations have established operational best practices for enrolling diverse patients in specific trials, the ecosystem still lacks guiding principles for how to fulfill its mandate to diversify clinical trial populations.

The following three takeaways outline principles for success that Advisory Board has captured from its original research and workshop.

Other resources on achieving clinical trial diversity

Industry leaders have published extensive regulatory and operational guidance on best practices for promoting clinical trial diversity. Two that have stood out to us are:

1) Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry
Food and Drug Administration (FDA)
November 2020

- **What it provides:** Regulatory guidance that "recommends approaches that sponsors of clinical trials intended to support a new drug application or a biologics license application can take to increase enrollment of underrepresented populations in their clinical trials."

Read now

2) Achieving Diversity, Inclusion, and Equity in Clinical Research
Multi-Regional Clinical Trials Center
August 2020

- **What it provides:** 300+ page guidance document that "aims to clarify the importance of, advance the goals of, and provide practical and actionable ways to improve diverse representation of participants in clinical research."

Read now

Takeaway #2

Focusing efforts to advance diverse enrollment on communities, rather than sites, enables us to choose better locations and partners to support our trials and health equity at large.

Many clinical trials leaders have long centered efforts to increase recruitment, access—and now, diversity—around rethinking site selection. They believe that choosing sites in ethnically diverse areas will enable broad participation of historically excluded patient populations.

They are right that we must rethink site selection by investing in non-traditional sites, including community hospitals and federally qualified heath centers (FQHCs). Yet we should avoid centering our strategy for enabling diverse patient enrollment around selecting new sites. That is because focusing on sites leads us to make assumptions and choices that preclude us from identifying more meaningful opportunities to work directly with communities. We recommend starting all initiatives with the communities in need, not sites, at the center.

Taking a community-first approach impacts:

1. **Where we operate** by exposing the need to combine clinical data with other sources to identify geographic locations that have diverse patients who can benefit from our research. We must recognize that many of the patients we need to achieve our diversity goals are invisible, or non-existent, in the datasets we traditionally leverage to select sites.

2. **How we partner** by requiring us to work with a broad range of "trust brokers" favored by local communities to help patients recognize the value they can reap from clinical research and address any mistrust of the medical establishment. This approach stands in contrast to attempts focused on the necessary and time-intensive work of building trust in sponsors and other health care institutions within marginalized communities.

3. **What we do** by elevating the importance of addressing clinical and non-clinical factors standing in the way of participation, including augmenting communities' clinical infrastructure and expertise. The sites we truly need, may not currently be involved in clinical research. Working directly in the community enables us to better understand the patients we will engage in our trials so we can tailor trial design and information to meet the needs of trial volunteers and eventually patients.

Takeaway #2 (continued)

Working directly in communities also enables trial sponsors to impact health equity by making investments in communities that benefit more than just the patients who enroll in a trial. For example, sharing clinical data back to community groups can support their efforts to secure greater funding that can support community investments in education, health, housing, or other priorities.

Questions to audit your trials' community engagement

- What percentage of our trials are in underserved communities with patient populations who would benefit from participation in clinical research?
- What measures do we have to, at a baseline, hold us internally accountable for trial location that is not purely site-driven?
- How will we identify and engage with established trust brokers to foster partnership?
- What steps have we taken to build capacity for community leaders that support patient engagement in our research?
- Are we building longstanding community relationships rather than engaging with communities in a transactional, one-off fashion?

Takeaway #3

We must address the non-clinical exclusions within the current clinical trials paradigm that prevents patients and clinicians from marginalized groups from participating.

Our research and workshop indicated broad agreement that exclusion of any patients from our research must be supported by a clear clinical, operational, or financial rationale. Yet the scope of how industry leaders assess this exclusion has often been too narrowly focused on trials' clinical protocols.

No doubt, we must limit clinical exclusion criteria to only clinically necessary parameters. But we must also assess how our trials may *structurally* exclude patients and clinicians from participating—even if that exclusion is wholly unintentional. For example, a trial that requires weekly site visits to collect lab specimens may exclude patients that cannot easily get off work or coordinate child or elder care. Allowing patients to use labs or facilities in their communities could help offset such a barrier.

This structural exclusion also encompasses the barriers we place between patients and clinical research. Currently, we require that patients go through traditional gatekeepers like physicians and hospitals to participate in research, creating the space for intentional and unintentional bias to dictate selection. We instead should democratize access and allow patients to raise their hand to participate directly, such as by enrolling themselves in databases used by trial sponsors.

Reducing barriers to clinician participation

Structural exclusion also affects clinicians with marginalized identities that could otherwise support diverse patient enrollment. We must make it easier for investigators to participate in research by reducing structural barriers. We should also provide models where trusted clinicians can maintain continuity of care and not feel like they are losing their patient if the patient chooses to participate in clinical research as this current dynamic creates hesitance on the part of both the clinician and patient.

As we dismantle these structural barriers, we must be careful not to let our biases drive us towards solutions that are also exclusionary. For example, technological solutions like decentralized trial platforms—though useful when deployed carefully—could lead to exclusion of patients with less access to technology like smartphones or broadband internet.

Questions to measure structural exclusion in your trials

- Have we integrated the right patient and clinician voices and perspectives?
- Have we minimized the non-clinical burden of trial participation?
- What steps have we taken to ensure that digital technology is being used to close gaps?

Takeaway #4

Legacy identities and partnership structures must change to create significant systemic change.

Equitable participation has not been an established objective, so achieving it requires all stakeholders involved in clinical research to rethink their legacy roles in the enterprise. Our research identifies several shifts stakeholders should consider:

Stakeholder	Legacy role(s)	New role(s)
Sponsors	Fund the trial and design its clinical protocol to achieve market access	Invest in capabilities to make patients and community organizations true co-collaborators
Patients	Volunteer to support evidence generation	Co-design clinical protocol to ensure patient friendliness
Community and advocacy organizations	Work with sponsors in a piecemeal fashion to represent the patient voice	Coordinate, organize to establish industry standards, empower community leaders
Solution providers	Streamline trial operations to support efficiency and reduce time-to-market	Ease barriers to participation for patients and clinicians from diverse backgrounds
Clinicians and investigators	Recruit patients and provide clinical care	Advocate for patients' clinical and non-clinical needs
Regulators	Review clinical data for new drug and device applications	Establish how clinical trial diversity will be incentivized, enforced

As we each reshape our individual roles, we must rethink how our partnerships must evolve. This should include involving entirely new stakeholders, such as community trust-brokers and non-investigator clinicians, that have unique tools to support our efforts.

This need is not unique to clinical trial diversity and is a necessary competency for stakeholders to develop to address our industry's most significant challenges like value-based care adoption and care standardization.

Questions to ask as you revisit your role and partnerships

- What elements of my organization's legacy identity are holding back change the most? What would it take to change them?
- Which stakeholders do I know that can add value to our efforts but don't currently have a seat at the table?

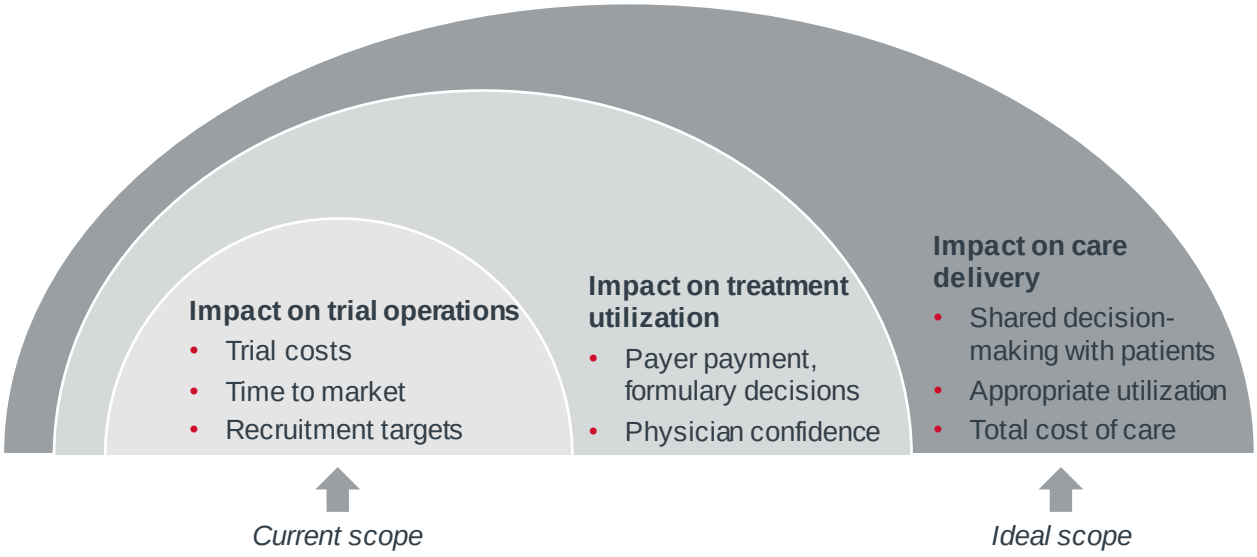
Takeaway #5

We must expand how we assess the value of diverse clinical research to maximize adoption of best practices.

Understanding the necessary mindset shifts and operational changes is no guarantee of success if we don't also revisit how we assess the value of clinical trials. We need to convey the full value of trial diversity and how it relates to organizational success to maximize buy-in from decision-makers.

Historically, sponsors have focused too narrowly on how diversity initiatives impact trials' finances and operations and neglected to include the impact on treatment utilization and care delivery. Expanding this focus makes it clear that diverse clinical trials can drive even grater value to sponsors and other stakeholders.

ROI of clinical trial diversity extends beyond the clinical trials enterprise



This approach addresses a common reservation some clinical trial operators express: that more diverse trials don't produce return-on-investment because they require greater (and more costly) recruitment targets by increasing the heterogeneity of the study population.

That very well may be true. But by widening our value framework, we see that sponsors could still benefit financially from more diverse trials when purchasers and physicians, who are eager to understand how product impact varies across patient demographics, gain more confidence in the anticipated benefit. Further downstream, sponsors also benefit by maximizing their impact on care delivery, such as by helping ensure appropriate care utilization and reducing total cost of care.

Next steps

The mindset shifts captured in this report are meant to contribute to the industry's current reckoning with how to make good on our mandate to ensure diverse and accessible clinical trials—a conversation we expect to advance moving forward. There are a wide range of outstanding questions with which industry leaders must continue to grapple, including:

- **How does the current clinical trial paradigm** prevent clinicians and primary investigators, especially those of color, from participating and advancing our diversity and equity goals?
- **What metrics and trends should we track** to determine how our roles and responsibilities will need to further evolve in the future?
- **What is the role of technology-based solutions** in achieving clinical trial diversity—and how might they exacerbate legacy barriers they sought to erode?
- **How should sponsors and other stakeholders identify** the right communities, organizations, and community leaders to support transformative change?

As we continue our journey to fulfilling our mandate to make clinical trials more accessible and diverse, we must remain consistent in our willingness to collaborate across industry sectors and adapt practices to meet the needs of the moment, our patients, and their communities.

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