



October 12, 2021

Review of In-Depth Interview Results

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Overview

 Research objectives

 Methods

 Findings

Research objectives

Identify organizational-level practices that promote participation of diverse study populations in clinical trials of investigational medical products

Describe incentives and evidence that encourage—and disincentives that limit—investment by decision makers in promoting participation of diverse study populations in clinical trials of investigational medical products

Methods

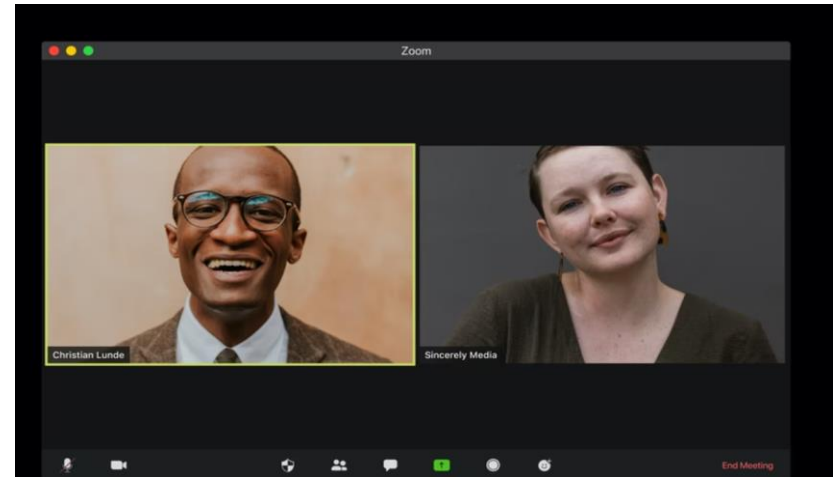
➤ Telephone/Zoom, individual and group in-depth interviews

➤ **Participants:** Senior-level representatives —

- Pharmaceutical and medical device companies
- Academic institutions
- Healthcare organizations
- Patient advocacy organizations

➤ **Dates:** October 2020 to February 2021

➤ **Analysis:** Applied thematic analysis



@Visuals, Unsplash

Results

Study participants (1)

- ▶ 36 representatives from 20 organizations
 - 5 academic institutions (9 representatives)
 - 8 pharmaceutical and medical device companies (12 representatives)
 - 4 patient advocacy groups (9 representatives)
 - 3 non-academic medical care centers (6 representatives)

Study participants (2)

Demographics

- 50% identified as female and 50% as male
- 72% (n=26) identified as White; 14% (n=5) identified as Black or African American
- 11% (n=4) identified as Hispanic or Latino
- 86% (n=31) served in the role as president, vice president, director, CEO/CFO/CCO, or dean

Results

Participants' narratives are described thematically within four categories—

- ▶ **Drivers** of organizational-level diversity and inclusion (D&I) efforts
- ▶ **Operationalization** of D&I organizational-level efforts
- ▶ **Return on investment** from D&I on organizational-level efforts
- ▶ **Disincentives** to invest in D&I organizational-level efforts

Drivers

Ethical and moral imperative

➤ Recognition of the importance of health equity

- Aware of the disproportionate:
 - Disease prevalence and burden, and health outcomes
 - Impact of COVID-19
 - Impact of social determinants of health, acknowledging systematic racism
 - Participation in clinical trials

➤ Right thing to do

- Trial populations should mirror the population at large, real world

Recognizing that factors such as systemic racism and legacy of oppression have impacted communities disparately and there's issues that are connected to medical racism and disenfranchisement in communities.

*—Director of Center/Department of a
Community Medical Center*



Mission and organizational culture

➤ Diversity and inclusion are—

- Core institutional values, institutional priorities, or included in the overall mission
- Central to all organizational activities
- A philosophy embedded within organizational culture

➤ When diversity and inclusion are part of overall mission—

- Staff are held accountable for making efforts to increase diversity
- Resources are allocated to diversity initiatives
- Diversity and inclusion serves as “guide posts” for decision making

[D&I is] interwoven into everything that we do. It's part of our strategic response. It's part of goals for the staff...It's also interwoven into the work that we do in workforce development, and in training fellows, and in peer reviewers... the general importance of minority representation [is] in everything that we do...where appropriate, we do hone in specifically on why minority representation is important.

—President/Vice President, Patient Advocacy Group

First, we said, “This is really important. We’ve got to figure out strategies, how to do this at the institutional level.” Saying: “This is one of our top five priorities, to improve diversity and inclusion, not in just racial but all kinds of disparities,” I think has risen it. Our ultimate governing board, our board of trustees, has now made this part of the routine evaluation of [our organization]. Again, putting value behind diversity, and that has not typically been called out so publically.



—President/Vice President, Academia

Leadership (1)

- ▶ Commitment from leadership or champions. Ensures that—
 - Institutions can move funding
 - Staff effort can be put towards diversity and inclusion goals
 - Funding is directed toward diversity and inclusion efforts
 - Diversity and inclusion goals are more achievable
- ▶ Senior level leaders most impactful (e.g., CEO)—they hold the decision-making power

Leadership (2)

▶ Leadership drives the mission—

- Ensure that staff report on efforts to increase diversity
- Revisit and revise documents focused organizational-wide diversity efforts
- Enable staff to learn and grown in the field of diversity
- Ensure longer-term commitment/investment

It starts at the CEO level. And then we have leadership in the clinical trials in each of our markets. And then we have some of our physician leaders who are champions for this. So, I would say it starts at the CEO level, quite honestly, and then it translates into leadership across the board but including a lot of the high-level clinical leadership.

—President/Vice President of a Community Medical Center



Operationalization

Hiring, staffing, and dedicated effort (1)

- ▶ Human resources was the most commonly-mentioned investment to support D&I activities: *“You’ve got to have investment in staff.”*
- ▶ Participants discussed the need for—
 - Supporting full-time positions to focus on D&I efforts
 - Funding staff time to work on specific programs/initiatives
 - Establishing smaller teams, cores, centers, taskforces to focus on D&I initiatives
 - Maintaining a representative and diverse staff
 - Hiring strategically, with a priority to hire diverse staff to mirror intended study populations

Hiring, staffing, and dedicated effort (2)

- Dedicated effort important for D&I to remain a viable priority, identified as an important long-term infrastructure need

The long-term cultural change is the most important. And that's one we're just at the beginning of a long reflection on the institution... Our institution, like many, needs to change the representation of its [employees] to look more like the communities that we live in. So, a lot of this is targeted towards the clinical trials.

—President/Vice President, Academia



As an institution, for the first time this year, we established a corporate officer position, the Chief Diversity and Inclusion Officer. Included in this person's charge is promoting efforts to diversify our study subject accrual in various different trials.

—President/Vice President, community health center



Training

- ▶ For faculty and staff that stresses—
 - The importance of diversity in trials, why good for science
 - Racial bias
 - Cultural competency
- ▶ For communities to help with the development of protocols
- ▶ For investigators from underrepresented demographic groups

Infrastructure (1)

- ▶ Need enhanced systems to support sites
 - Recruiting in underserved neighborhoods
 - Using telehealth services
 - Creating customized study materials for diverse audiences
- ▶ Improved infrastructure on how to select sites. Focus on:
 - Recruiting, screening, and retention strategies
 - Operationalizing “the diversity of the people in our clinical trials to parallel the diversity of the population”

Infrastructure (2)

Better IT systems to:

- Track diversity in participants
- Help to identify where collaborations might be needed to maximize efforts
- Create dashboards for trials to monitor diversity in real-time

Resources (1)

- ▶ Financial investments were a large part of D&I efforts
 - Anticipated that the financial capital spent → return on investment
- ▶ Providing funding for:
 - Sites to focus more efforts on recruitment activities that will lead to a diverse study population
 - Creating systems to track, monitor, and report on diversity
 - Staffing and internal programs and training

Resources (2)

- ▶ Funding and budgetary adjustments are critical for ensuring long-term commitment
- ▶ Funder priorities and requirement for diversity highly influential
 - Provides actual funding to organizations for D&I
 - Encourages organizations to focus efforts and programs on D&I

Obviously, a number of us realized the value in a representative population being exposed to drugs or devices, but at an institutional level, when you have to spend more money, there has to be a return on investment, which, typically, is related to increased funding.

And so, to link increased funding with the expectation that you're going to enroll a representative sample, and actually be able to apply for grants based on your ability to do that, I think is the driving force behind what a lot of people did before it became the right, morally, and ethical thing to do... and I don't think I can stress enough that at the federal and funder level, that expectation of diversity, I think drives culture more than the culture itself....

...When the FDA tells pharma, “We need a representative population, or your drug won’t get approved,” you’re going to influence a lot of behavior at the site level because those sites are going to be heavily incentivized to find an appropriate population. So, I really think it’s expectations and return on that expectation that drives behavior more than waiting a generation or two for change in culture.

—President/Vice President, Academia

Community and patient initiatives

- ▶ Focused on getting to know the community and their needs better, getting the community to know the organization better
 - Community engagement and outreach programs, engaging with patients
 - Programs to build trust with communities
 - New partnerships with community groups
 - Advisory boards
 - Patient hotlines and interviews

Patients first. That's part of our mission. To know what patients need next...I was in the early research development group running programs...and I saw patients often. So, we have a culture where the patients are in front of us. And that leads to worker-led groups. We ran pilots. And those pilots fueled information to our VP who started to embed goals around inclusion strategy where they were in big disparity of outcomes in populations and indications. So, just the power of interviewing and getting information from our partners' sites to fuel an appetite.



—Director of Center/Department, Pharmaceutical or medical device industry

[One] example is a program [we] started about three or four years ago... That program is now nearly 200 patients nationwide, and these are the key influencers in their communities in the states. They are the ones who come to the Board with new tactics and new recommendations for how to further penetrate the patient population into including voices that may not be online, may include voices of patients who are very active in their churches and local communities, but disconnected from larger efforts. And so, it's just been a wealth of information for us on the tactical level.

—Director of Center/Department, Patient Advocacy Group



Return on investment

Better science (1)

Diverse study populations leads to—

- ▶ Enhanced understanding of clinical trial outcomes among different populations
 - Because disease impact and treatment response may vary among different populations
- ▶ Better treatments for all populations
 - Treatments developed may not adequately address or treat the condition if diverse populations are not enrolled

Better science (2)

Diverse study populations leads to (continued)—

More generalizable study results

- Trial results will be more accurate because researchers will understand how diverse patients respond to the same treatment
- Interventions will be effective and impactful for populations who intend to use them

Better Science (3)

▶ Including diverse populations ensures that:

- Various biomarkers are present
- Varying efficacy and safety indicators across populations can be assessed
- Populations who are impacted differently by social determinants of health are included

I'll tell you, because, simply stated, the scientific reason why is because given the population that is pre-inclined, either genetically or through community health issues, if they are not involved in the science, you could easily end up with solutions that pretend to be for [disease] patients, yet fail to address and serve the biggest populations.



—Director of Center/Department, Patient Advocacy Group

My simple perspective of this is that if you're trying to create a valid study design that can be generalizable to the population, you can't do that if you don't have diversity in your research. We're fibbing ourselves. The people that enroll in studies do not represent the majority of people that you need to use the results of that study for. That's just a scientific basic fact and we tend to ignore that. I think the more we can diversify the population in a variety of ways, racial, women, variety of factors we might look at, the more accurate that scientific information is going to be with regard to the outcomes of the study.

—President/Vice President, Academia



Other

Patient trust

- Diverse populations, especially those who may need the treatment the most, may trust the results of the trial when diverse populations are engaged

Better patient retention

- When patients are included as partners

Metrics

▶ Limited evaluation of D&I efforts

▶ Examples given:

- Examine representation—shifts in trial populations over time
- Examine trust/reputation—community's perceptions of organization's efforts in engaging diverse study populations

Disincentives

Disincentives (1)

Three main disincentives—

Costs

- Time and monetary resources
- Staff and infrastructure needed to implement diversity activities is the biggest reason that organizations are hesitant to implement such activities
- Existing clinical trial start-up timelines do not account for the extra effort required to increase diversity among trial participants—not planned for

It's not that some organizations don't want to invest in certain areas that could bring about diversity. But for them, the requirements to make those advancements may be barriers. They could be financial. They might have to hire more people. And, in today's environment and with a hiring freeze, they might not be able to hire that person. Or, they might not be able to hire that person for another year or two. But if you're talking specifically about disincentives, I know that risk would be high on the list.

—Director of Center/Department, Academia

Disincentives (2)

Immeasurable impact

- Impact/outcomes of diversity efforts are not immediately measurable
- Challenges explaining to funders/investors that large sums of money were used to push forth efforts or initiatives without data to demonstrate the outcome of such efforts

[I]t is hard to measure. When you can say, “Hey, we invested \$50,000 in pilot studies and that brought in \$500,000 in extramural grants,” that’s a very specific and measurable return on investment. Return on investment is more subtle for these kinds of activities. I think that’d be one of the challenges.

—Director of Center/Department, Academia



Disincentives (3)

- ▶ Implementation challenges
 - Practices unfamiliar to staff
 - Organizations are not linked to communities

Questions & Comments