More Than Good Intentions: DE&I Requires a Program-Level, Strategic Framework

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Sponsors understand the importance of diversity, equity and inclusion (DE&I) efforts and have begun to implement them in their trials, but diversity in clinical trials has yet to be achieved.

To address this gap between aspiration and execution, sponsors--as well as sites and CROs-- must recognize that DE&I is not merely another project. Neither is it a series of tactics. It is a systemic, top down transformation that must be managed strategically at the program level. The DE&I strategy must be communicated and implemented across your trial sites, including referral sites. It needs to extend into the nearby community-based sources of potential patients. Most importantly, no one can execute a diversity strategy alone.

COLLABORATION AND STAKEHOLDER ENGAGEMENT

No sponsor or research organization will achieve trial diversity without the meaningful participation of essential stakeholder groups from under-represented communities.

The first step is to identify the best group of stakeholders within the context of your portfolio, program or trial. Look for those who demonstrate through their words and actions a strong commitment to patients and their families, and who believe in a shared mission and vision of eliminating health and research disparities.

What is the best way to engage with these stakeholders? If you've chosen wisely, you are cultivating relationships with people who are deeply committed to creating systemic change within their communities. This is not the time for cold calling or mass emails. Show the respect you would show in any other professional interaction. Ideally, sponsors should empower experienced individuals to conduct this outreach who are either already known to these stakeholders or who can reach out to a common acquaintance and get a personal introduction.

For best results, you need to demonstrate an enduring commitment to the stakeholder group

and one that represents not just what they can do for you in a single transaction or event, but what value you can return to their community over time. Preferably, this is a commitment that extends beyond the individual clinical trial. Be prepared to describe examples of how your company is working to support the DE&I mission through systemic change, even if you are at the beginning of that journey.

The value proposition is simple. It is: "Come partner with us to do the work that will benefit the health and welfare of your community. Work with us as trusted advisors in trial design, execution and delivery. We place a high value on your time and contribution."

At WCG, we believe that patients, caregivers and advocates should be fairly compensated for their time and advice. The individual you choose to conduct this outreach should be able to address the subject of compensation for individual contributors and/or funding for non-profit organizations. Prepare them in advance with information about desired activities or events by role and any pre-determined compensation or funding ranges based on fair market value.

A FRAMEWORK TO IDENTIFY AND ADDRESS BARRIERS

The pharmaceutical industry has a strong community of program and project managers. We know how to take big goals and break the work into manageable units. Let's use these skills and tools at our disposal to go beyond the talking and get DE&I done.

Avoid common pitfalls. Most DE&I efforts begin with an assumed list of barriers for getting the target population enrolled. While it's fine for your internal teams to look to industry articles and consortium sources for generic assumptions about what the barriers might be for your program or trial, this should not replace contemporaneous, deeper conversations with your chosen set of diverse external advisors.

The easiest way to get this feedback is to use an advisory board model where you can work with patients[1], caregivers, families and advocates to generate a list of perceived barriers and solutions. Ideally, these boards are conducted as a sustained cohort throughout the development program lifecycle, starting in the design phase of the program and within each Phase II-IV study. However, if that is not possible, and you are about to embark on a new trial with no external input, you should consider putting an advisory board in place at the trial level. If you do not, you risk missing real-world obstacles that often cost more in protocol amendment delays than you would have spent on the advisory board activity.

Once you have refined your list of barriers and suggested solutions with the board members, create a 'barrier breakdown structure'. All project managers are familiar with a work breakdown structure. This is a hierarchical

diagram used to categorize areas of a project and break it down into manageable work units that the study team can understand and implement. You can use this approach with your DE&I barrier list to ensure you have identified pragmatic solutions that will be implemented by your study teams and sites. Some suggested categories you can use are study design, recruitment planning, patient outreach and education, site identification, patient identification, site readiness and training, and site support. Of course, all these areas are already part of your study plan, so you simply need to add the new solutions into these activities in a way that will help you to achieve your DE&I goals.

THE OBSTACLES ARE THE WAY FORWARD

Each solution within your diversity plan is based on your barrier breakdown structure, so spend some time to ensure it is comprehensive. Consider the program or therapeutic area versions as dynamic, evolving reference documents. Ensure each new study team member is trained and understands how these insights help to shape their operational plans.

In summary, DE&I is strategized top down but planned horizontally across many traditional aspects of clinical development. At the trial level, it is informed by trusted external advisors and then planned in the form of site-specific action plans for each local community from which you are hoping to recruit and retain under-represented patients. WCG has a full suite of service offerings to ensure your program, trial- and site- DE&I strategies are successful. **Click here to learn more.**

[1] Note: the patients you engage on your advisory board should not be targeted for enrollment in your trials. Instead, they should be treated as trusted advisors. If an advisory board patient expresses a desire to enroll, they should be dropped from the board.