Advancing Equity, Diversity, Inclusion, and Belonging in Patient-Centered Drug Development With Patient-Preference Research

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BACKGROUND

- Regulators and pharmaceutical and medical device manufacturers acknowledge the role patient-preference research can play in patient-focused drug development (PFDD).
  - Guidance issued by the United States Food and Drug Administration (FDA) provides a framework for the use of patient-preference studies to support regulatory decisions.[1,2]
  - The FDA's guidance document[1] indicates that patient-preference information (PPI) can be considered in regulatory benefit-risk assessments and during premarket approval applications.
- The growing recognition of the value of equity, diversity, inclusion, and belonging (EDIB) initiatives has challenged stakeholders to identify opportunities to promote diverse healthcare perspectives from underserved populations.
  - The FDA will soon require researchers and companies seeking approval for late-stage clinical trials to submit a plan for ensuring diversity among trial participants.[3]
  - ISPOR, the leading professional society for health economics and outcomes research (HEOR) globally,[4] aimed to promote EDIB initiatives by establishing frameworks "to facilitate greater diversity and inclusion" as part of the 2015-2019 ISPOR Governance Initiative.[5]
  - ISPOR included "embracing diversity of perspectives" as a core organizational value in its 2020 strategic plan.[5]
- Applying EDIB principles to the collection, interpretation, and use of PPI in PFDD can support not only more inclusive and equitable health outcomes, but better health outcomes.[6-7]

APPROACHES TO APPLYING EDIB PRINICPLES

- PPI research systematically presents patient perspectives to regulators and the pharmaceutical industry to inform PFDD.[1,8]
- We identify 3 ways preference research can and does address diversity and representation in PFDD to ensure that PPI and PFDD processes and outcomes are inclusive.

Study Design

- At the study design phase, include a diverse set of preference researchers, patient scientists, clinical experts, and/or healthcare providers who can ensure the study design, execution, and interpretation of preference research comprise diverse perspectives and historically underrepresented stakeholders.
  - Healthcare disparities across racial and ethnic groups have been well documented in recent decades,[9-10] and structural racism persists as a fundamental root of such disparities, including health outcomes and access to healthcare.[11]
  - Not including medically underserved populations in professional and academic settings perpetuates a lack of diversity and inclusion in research teams.
    - Bouvy and Mujoomdar (2019)[12] investigated the gender diversity of issue panels and plenary sessions at ISPOR Europe conferences between 2016 and 2018. They found that 64% of all panels had a majority of male speakers and that almost 30% were made up entirely of male speakers.
  - Breathett and colleagues (2021)[13] assert that the inclusion of "patients, community leaders, and scientists that experience racial and ethnic disparities" in quality and outcomes research can not only uplift the voices of historically underserved groups but also promote equity in the field of clinical research.
- Diversifying research teams requires deliberate thought and planning. Researchers may need to seek out new connections, and the study leads must create an environment where everyone feels their input is valued. Researchers will also need to strategize on how to remedy the significant mistrust of scientific institutions in many underserved communities that could otherwise positively contribute to research.

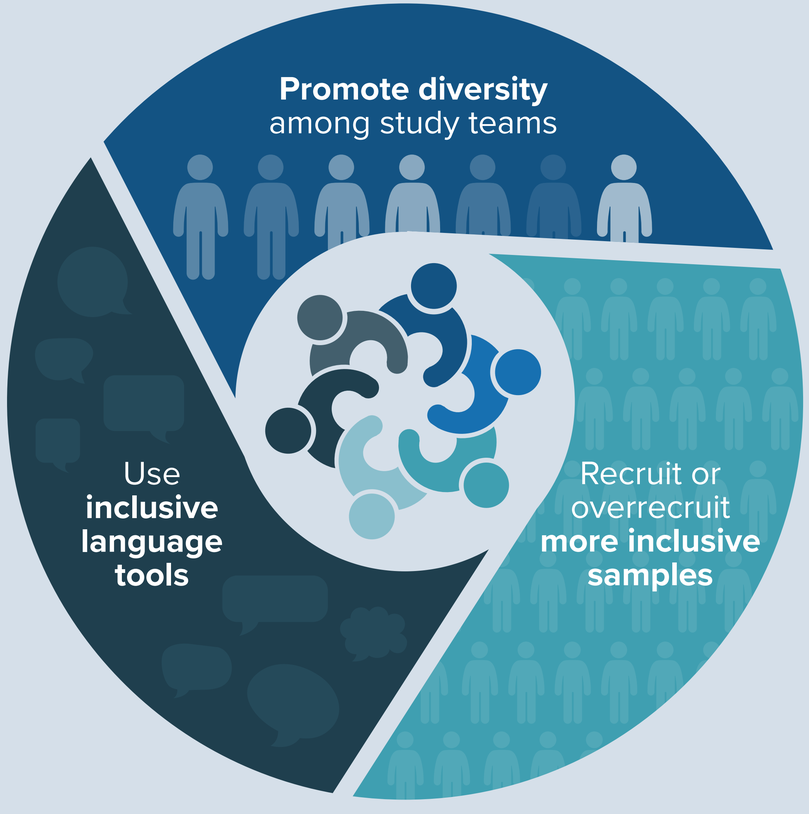
Study Recruitment

- Recruit more inclusive study samples for research studies to ensure that PPI characterizes the perspectives of a diverse group.
  - Interest in evaluating heterogeneity across clinical, social, and demographic characteristics in patient-preference studies has increased in recent years, and such evaluations have been used more frequently in premarket approval submissions to regulatory bodies.[1,14,15]
  - When designing a study, preference researchers may include recent empirical studies of preference heterogeneity to highlight insights that could be gained from more diverse samples as well as the challenges in recruiting diverse samples.
    - Preference researchers have access to a growing portfolio of analytical methods (e.g., subgroup models, latent class analysis) for identifying and evaluating heterogeneous preferences across both self-identified and societally imposed racial, ethnic, and gender identity characteristics.[15]
  - Preference researchers may also consider including intentional oversampling into their recruitment strategy to investigate the preferences of specific subsamples of patient populations, such as marginalized or underserved communities.
    - Recent patient-preference studies have oversampled patients who identify as African American or Black, and results of the preference analyses of these studies indicated systematically different preferences across racial and ethnic identities that might not have been uncovered if intentional oversampling had not been conducted.[16-17]
- Study sponsors have a responsibility to allocate the resources necessary to recruit the sample needed to capture the diversity of preferences in the population. Patient organizations and companies involved in recruiting should prioritize diversifying their subject pools.

Creating Data Collection Tools and Disseminating Results

- Use inclusive language in data collection tools and medical writing.
  - Adopting inclusive language practices can make data more accurate and robust, help respondents and decision-makers feel validated,[11,18,19] and increase the likelihood that more diverse populations will want to participate in the research.[18]
  - Preference researchers should seek out resources for inclusive language at the onset of the study design stage.
  - Leading health organizations (e.g., FDA, American Medical Association, Centers for Disease Control and Prevention) have developed inclusive language guidance to enrich research and contribute to greater inclusion and diversity.

Patient-preference research is a field of study that is particularly well suited to **promote equity, diversity, inclusion, and belonging**



DISCUSSION

- We identify areas to advance EDIB principles in patient-preference research to ensure PFDD addresses the needs of a more diverse constituency and yields more equitable health outcomes.
- Researchers are challenged to address EDIB principles and create solutions for diversifying patient-preference research.

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