Leveling the playing field: Diversity, equity, and inclusion (DEI) in clinical research and publications

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Introduction
- Although racial and ethnic minorities are disproportionately impacted by several diseases (e.g., diabetes and infectious and autoimmune diseases), the underrepresentation in clinical trials and treatment biases limit the generalizability of study findings and impact other social, economic, cultural, and environmental determinants.
- Guessed lacks of diversity in clinical trials perpetuates existing health inequalities and reduces the quality of individual patient care.
- Accurate reporting of data, contextualizing the underrepresentation in trials, and taking steps to address these issues are crucial to ensure fair, equitable, and informative practices.

Objective
- Evaluate journal requirements for reporting diversity in clinical trial publications and outline best practices and recommendations for key stakeholders to ensure enforcement of diversity guidelines.

Research design & methods
- DI-related guidelines from the US Food and Drug Administration (FDA) and European Medicines Agency (EMA), and the top journals by impact factor across 5 therapeutic areas were collected (Google Scholar).
- Journal impact factors and rejection rates were identified using journal Select (Elsevier), Anju Software Company, and information posted on journal websites.

Results

Conclusions
- Despite DI guidance from the FDA and EMA, few very journals require authors to address the lack of diversity in clinical trial publications.
- Journal editors should enforce standardized guidelines that require reporting of any potential biases and disclosing the lack of generalizability across patient populations as a study limitation in clinical trial publications.
- Given the updated guidance in SPP 2022, publications professionals can ensure greater transparency in reporting the impact and interpretation of underrepresentation on clinical trial results.
- Encouraging diversified clinical trial investigators and authors could also be a step towards overcoming healthcare disparities.

Recommendations
Moving Towards Diverse & Equitable Participant Inclusion in Clinical Trials

Ongoing Clinical Trials
- Provide statistical support to allow pharmaceutical companies to conduct post hoc analyses evaluating trial data for underrepresented patient groups.
- Review SAPs for ongoing trials for generalizability to affected populations.

Planned Clinical Trials
- Ensure diverse participant selection by:
  - Trial eligibility criteria evaluation
  - Site screening
- Ensure diversity across trial investigators and authors
- Provide alternatives to clinical visits
- Develop patient-friendly resources to improve recruitment diversity

Quick Wins for Medical Communications Professionals to Ensure Inclusion

Tactics
- Plan language content
- Accessible content
- Diverse and minority voice
- Expertise in language
- Expertise in design and graphic support
- Engagement and personal connection

Tools
- Create agency-wide awareness of DEI guidelines
- Familiarize with relevant style guidelines
- Understand regulatory requirements (FDA guidelines, etc.)
- Collaborate cross-functionally
- Leverage technology to ensure quick translations of manuscripts, using AI
- Calibrate compliance assessment

Journals
- Require reporting of any potential biases and limitation of generalizability across patient populations in clinical trial publications.
- Require a brief background on how the disease affects different populations, highlighting high-risk groups.
- Require detailed outcomes across racial and ethnic subgroups.
- Encourage submission of the diversity plan as a supplemental material for clinical trial publications.
- Require diversity in authorship and journal editorial board.