Inclusiveness Achieves More: Clinical Trial Diversity in Oncology and the State of the Post Marketing Requirements and Commitments

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Variances in pharmacological outcomes, distribution, and safety and efficacy outcomes may be attributed to racial and ethnic differences. Drug development should aim to make sure that an evaluation covers a population that is representative of the intended therapeutic population. Clinical trials have lacked enrollment of racial and ethnic minority patients who represent the U.S. population intended to be treated with approved drugs. The purpose of this study is to identify the percentage of oncology post-marketing requirements and post-marketing commitments issued in 2012-2022 with a specific focus on racial and ethnic minority populations. The FDA's publicly available database of PMRs/PMCs, inclusive of drugs and biologic products, and internal agency databases, was searched for PMRs/PMCs issued between 2012-2022. Using keywords, the PMR/PMC search was further constrained to include all pertinent racial and ethnic groups. Following that, the PMRs/PMCs were manually examined for duplication and suitability for malignant indications. Just 7.4% of oncology PMR/PMC approvals between 2012 and 2022 included people of all races and ethnicities, highlighting the need for greater attention to incorporating minorities in clinical studies like PMRs/PMCs. Research on diversity in clinical trials could expand efforts to better increase minority enrollment, such as better communication to increase patient-doctor trust. No matter a person's race or ethnicity, everyone deserves inclusive representation in clinical trials, causing the best treatment possible for any illness or disease.

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