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Patient-Reported Outcomes and Demographic Representation in Contemporary Phase III/IV Neuroendocrine Tumor Clinical Trials: A Systematic Trial-Level Review

Nitya Batra[1], Atulya Aman Khosla[1], Himil Mahadevia[1], Arshi Syal[1], Yajur Arya[1], Jason Starr[1]

[1]Mayo Clinic, Jacksonville, Florida

BACKGROUND

Neuroendocrine tumors (NETs) are rare, heterogeneous malignancies in which treatment decisions must balance disease control, symptom burden, and long-term health-related quality of life (HRQoL). As the therapeutic landscape has expanded substantially since 2006 - spanning somatostatin analogues, targeted therapies, and peptide receptor radionuclide therapy (PRRT) - it remains unknown how consistently patient-reported outcomes (PROs) have been incorporated, and whether enrolled populations reflect the racial, ethnic, and age diversity of patients seen in clinical practice.

METHODS

We identified phase III/IV trials and major extension studies enrolling adults with well-differentiated gastroenteropancreatic, bronchopulmonary, and thymic NETs, including carcinoid syndrome trials from June 2006- June 2026. ClinicalTrials.gov registry records and primary publications were systematically abstracted for: study phase, baseline demographic availability, Black/African American and Hispanic/Latino enrollment reporting, and age-stratified reporting (≥65 and ≥75 years), PRO inclusion, PRO instrument type,and sponser type.

RESULTS

Thirty-six studies met inclusion criteria: 23 industry-sponsored (63.9%), 8 academic (22.2%), and 5 cooperative-group (13.9%). PROs were included in 29 of 36 trials (80.6%), with longitudinal collection in all 29; disease- or symptom-specific NET instruments - predominantly EORTC QLQ-GI.NET21 - were used in 13 trials (36.1%), and PROs served as a primary endpoint in 6 trials. Among 24 mature trials with extractable baseline demographic data, African American enrollment was separately reported in 18 (75.0%) and Hispanic ethnicity in only 9 (37.5%). Across 17 trials with extractable AA enrollment counts, approximately 143 of 3,561 enrolled patients were AA (4.0%). Explicit age ≥65 enrollment was available in 5 of 24 mature trials (20.8%), and age ≥75 was not separately enumerated in any trial (0/24). This is particularly notable given that the median age at NET diagnosis in the United States exceeds 60 years, and that functional status,

polypharmacy, and symptom burden trajectories differ meaningfully in patients aged 75 and older.

CONCLUSIONS

PRO integration in modern NET clinical trials was broader than the prior literature suggests, with 80.6% of trials including longitudinal PRO collection and disease-specific NET instruments used in over one-third. However, critical gaps persist: Hispanic/Latino ethnicity was absent from nearly two-thirds of mature trial records, older-adult enrollment was rarely stratified by age ≥65 or ≥75 years despite a clinically older patient population, and no trial reported age ≥75 enrollment data. Future NET trials should standardize race/ethnicity reporting alongside PRO collection, enumerate older-adult enrollment at pre-specified age thresholds, and align with the NIH CEAL and FDA diversity action plan frameworks to improve the interpretability, equity assessment, and real-world applicability of NET clinical evidence.

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