Multiple Sclerosis: Challenges to Defining and Achieving Enrollment Goals

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BIO Clinical Trial Diversity Roundtable
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Brief Overview of Situation/Background

- Multiple sclerosis (MS) trials have historically underrepresented the demographics of the disease

- Black MS patients typically accounting for <2% of Ph3 trial populations over the last decade

- As part of ongoing MS studies, we committed to a multichannel approach to improve inclusivity, including:
  - Opening additional sites
  - Optimized communications with sites
  - Optimized data collection/usage
  - Development of a Diversity Plan

MS COMMUNITY PLACING NEW FOCUS ON INCLUSIVE RESEARCH

RESEARCH ARTICLE

Enrollment of Non-White Participants and Reporting of Race and Ethnicity in Phase III Trials of Multiple Sclerosis DMTs

A Systematic Review

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RESEARCH ARTICLE   **OPEN ACCESS**

Racial and Ethnic Disparities in Multiple Sclerosis Prevalence

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MULTIPLE SCLEROSIS CASE STUDY ON COMMITMENT
FENEBRUTINIB Phase 3 Studies - ONGOING

SITUATION	OPPORTUNITY	ACTIONS
FDA release Diversity Plan Draft Guidance in April 2022	Investigating the enrollment trend in our Ph 3 trials relative to epi data identified significant gaps in Black representation The trials were midway in enrollment (30-50% recruited) which provided a window to impact our recruitment strategy	Roche prioritized the FENEBRUTINIB studies and devoted additional resources to have impact The FENEBRUTINIB team quickly organized around several work packages to drive representation in our trials with cross-functional membership

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MS TEAM ACTIVITIES FOR ADVANCING INCLUSIVE RESEARCH

Team quickly organized to drive representation in our trials with **cross-functional** membership

Site Communication	Broad External Communication	US impact: New US Site Selection
Output: New AIR-specific communication with sites to educate and engage on AIR, including AIR workshop with US investigators **Impact:** Investigators committed to and capable of AIR, resulting in improved recruitment numbers	**Output:** New communication with MS community to highlight Roche commitment to AIR **Impact:** Develop wider awareness of Roche commitment to AIR and create opportunities for partnership with MS community	**Output:** Addition of high-potential Inclusive Research sites **Impact:** Improved recruitment of diverse patients and capability building of new sites
Global impact: New Country Additions	**Diversity Plan & Evidence Generation**	**Optimizing Data Collection & Usage**
Output: Addition of high-potential IR countries **Impact:** Improved recruitment of diverse patients and capability building of new countries	**Output:** Diversity Plan, including Ph 3 data and beyond-Ph 3 data generation, to engage FDA **Impact:** Come to common understanding of IR in Fenebrutinib trials with FDA in advance of filing	**Output:** Complete and accurate reporting of race/ethnicity information (collection) as well as provide data driven insights (usage) **Impact:** Will enable evaluation of fenebrutinib across all race/ethnicity categories enrolled in the study (collection) as well as support AIR in MS using data analytics (usage)

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The Diversity Plan and Goal-setting challenge #1

- There is a lack of race and ethnicity data for the MS population in the US and worldwide

- Roche conducted a literature review which revealed <10 studies, and only 2 of which were considered to have adequate representation and methodology to extrapolate to the US population

- There are no Global demographic numbers for MS, ex-US demographics can possibly be approached country by country

- The team used this data to set an aspirational enrollment goal

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Goal setting Challenge #2: US vs. Global

- Despite the limited data sources, this revealed the large gap between the <2% of Black MS patients typically enrolled in Global trials and the >15% of the US MS population that is Black

- Challenge:

  - Should the team be comparing US MS demographics to Global enrolment demographics or only to US enrolment demographics?

  - Should tactics employed by study teams to improve diversity be focused on US or Global?

  - When capturing in a Diversity Plan for communication with the FDA, should we present global trial or US/ex-US?

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