**INTRODUCTION:**

PMH46 assess treatment benefit in MDD clinical trials. Well as previously published qualitative data particularly where the use of clinical indicators will be limited.

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**STUDY POPULATION:**

• PMH46 are 46.3% (22.5%) N=40, 44.6 (13.4); [18-59] 73.3% white (non-Hispanic), and had an average HAM-D total score of 24.4 at enrollment (Table 3).

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**OBJECTIVES:**

• Complete qualitative elicitation and cognitive interviews with subjects diagnosed with MDD to support preliminary development of a patient-reported outcome (PRO) measure to assess treatment benefit in MDD clinical trials.

**METHODS:**

**STUDY POPULATION:**

• Recruitment was designed to enroll a diverse sample of patients similar to those who would be using the PRO instrument in future clinical trials of MDD treatments.

• Inclusion criteria: Male and female subjects between the ages of 18 to 65, inclusive, who met DSM-IV-TR criteria for MDD, and were being treated with at least one antidepressant medication with at least one major depressive episode within the previous 6 months; and had a Hamilton Depression Rating Scale (HAM-D) score of 18 or higher at the time of screening.

• Exclusion criteria: Current or past history of a personality disorder, schizophrenia or other psychotic disorder, obsessive compulsive disorder, or panic or other anxiety disorders; significant suicidal risk; positive urine drug screen or recent clinically significant alcohol abuse or drug use.

**CONCLUSION:**

• A total of 15 subjects participated in three waves of Cs. The subjects were an average of 44.6 years old, were 60.0% female, 73.3% white (non-Hispanic), and had an average HAM-D total score of 24.4 at enrollment (Table 1).

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