

## Results

Out of 103 respondents 90 (87,4%) have complained about having headaches at least once a month, meanwhile 44 (42,7%) respondents noted presence of a history of suicidal thoughts or actions (SB). Statistical analysis revealed a significant predominance of anxiety and depression levels in patients with headaches and SB (HAD-A – 21,0 ± 7,1, HAD-D – 17,1 ± 5,9,  $p < 0,001$ , ANOVA test) comparing to a group of patients with headaches (HAD-A – 14,7 ± 8,3, HAD-D – 11,4 ± 6,4) and control group (HAD-A – 8,1 ± 3,4, HAD-D – 6,0 ± 4,6). There is also a tendency of increased risks of active SB in patients with headaches (43,3%) in comparison with the group with a history of SB, but without headache (38,5%). Besides, the conducted correlation analysis showed a direct association between the levels of anxiety, depression and headaches and an increase in the risks of SB (correlation coefficient 0,399,  $p < 0,001$ ).

## Conclusions

Patients with primary headaches have a significant association with high levels of anxiety and depression, as well as an increased risk of developing SB. Identification of psychiatric disorders in patients with headaches, especially chronic forms, is required.

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### Design of the contemporary prospective understanding of migraine real-world evidence (CAPTURE) study

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## Background and aims

Insufficient longitudinal evidence is available describing the impact of migraine. This global study will assess how headache/migraine frequency, disability, and treatment patterns change over a 2-year period in individuals being treated for migraine.

## Methods

ContemporAry Prospective Understanding of Migraine Real-world Evidence Study (CAPTURE) is a 2-year, global, observational,

longitudinal, prospective study that will enroll individuals  $\geq 18$  years of age being treated for migraine. Participants will be stratified into 3 baseline monthly headache day (MHD) cohorts: 4–7 days; 8–14 days;  $\geq 15$  days. Eligibility criteria include men/women diagnosed with migraine for  $\geq 1$  year,  $\leq 50$  years of age at migraine onset, taking  $\geq 1$  migraine medication, and a history of  $\geq 4$  MHDs in the 3 months prior to screening, which was confirmed prospectively with headache e-diary data in the 30-day screening period. Key study design elements and endpoints are depicted in the Figure and Table.

Figure. CAPTURE Study Design

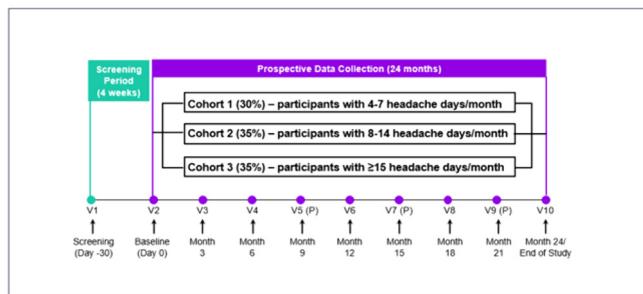


Table. Study Endpoints

Endpoints	Timepoints Assessed
<b>E-diary Outcomes</b>	
<b>Change from baseline in:</b>	
<ul style="list-style-type: none"> <li>Monthly headache days</li> <li>Monthly migraine days</li> <li>Monthly acute medication use days</li> </ul>	Months 3, 6, 9, 12, 15, 18, 21, and 24
<b>Patient-Reported Outcomes</b>	
<b>Change from baseline in:</b>	
<ul style="list-style-type: none"> <li>Headache Impact Test-6 (HIT-6)</li> <li>Migraine-Specific Quality of Life Questionnaire version 2.1 (MSQ V2.1) Role Function–Restrictive, Role Function–Preventive, Emotional Function domain scores</li> <li>Work Productivity and Activity Impairment Questionnaire (WPAI): MIGRAINE Absenteeism, Presenteeism, Overall work productivity loss, and Activity impairment</li> <li>Patient Global Impression - Severity (PGI-S) score</li> <li>Hospital Anxiety and Depression Scale (HAD-S)</li> <li>Migraine Treatment Optimization Questionnaire-6 (mTOQ-6)</li> <li>Migraine Interictal Burden Scale-4 (MIBS-4)</li> <li>Migraine Disability Assessment (MIDAS) total score</li> </ul>	Months 3, 6, 12, 18, and 24
<b>Changes Among Migraine Cohorts</b>	
<ul style="list-style-type: none"> <li>Number of patients changing among migraine cohorts</li> <li>Switching from current to subsequent migraine treatment</li> <li>Switching from monotherapy to combination therapies</li> </ul>	Months 12 and 24 Months 6, 12, 18, and 24

## Results

The target enrolled sample size is approximately 2000 (cohort 1: 30% [ $n = 600$ ]; cohorts 2–3: 35% [ $n = 700$  each]). Patients will be enrolled from approximately 135 sites in 15 countries. The target for first patient enrollment is early 2023 and the last patient completion is anticipated to be late 2025. The study will collect clinical outcomes, patient-reported outcomes, and changes in the number of patients among the migraine cohorts. Only the methodology of this study will be described.

## Conclusions

CAPTURE will provide a better understanding of headache/migraine frequency, disability, and treatment patterns in individuals being treated for migraine and will be one of the first global prospective longitudinal studies of its kind.

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