

# Real-world longitudinal outcomes of preventive treatments targeting the CGRP pathway in migraine: HIT-6 and MIDAS responder analysis according to the minimal clinically important difference (MCID).

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## BACKGROUND AND IMPORTANCE:

Patient-reported outcome measures (PROMs) are essential to evaluate the real-world impact of preventive therapies in migraine. Minimal clinically important difference (MCID) thresholds allow the identification of meaningful improvements, yet their longitudinal evolution in clinical practice remains underexplored.

## AIM AND OBJECTIVES:

To assess the proportion of patients achieving clinically meaningful improvements in HIT-6 ( $\geq 3$  points) and MIDAS ( $\geq 4.5$  points) over 24 months in a real-world migraine cohort, and to characterise patient demographics and treatment exposure.

## MATERIALS AND METHODS:

Prospective observational study in patients with preventive treatments targeting the CGRP pathway were included. PROMs were collected remotely via a telepharmacy platform at baseline and follow-up (1, 3, 6, 12 and 24 months). Responder analysis was conducted in patients with paired baseline–follow-up data. Responders were defined as  $\geq 3$ -point reduction in HIT-6 or  $\geq 4.5$ -point reduction in MIDAS. Proportions of responders were calculated at each timepoint; chi-square tests assessed differences across visits.

## RESULTS:

A cohort of 244 patients with migraine from 10 centres was followed: Mean age was 45.2 years (SD 12.3; range 18.0–75.0; IQR 37.0–54.0); 82.1% were women. 55% of ePROMs were completed

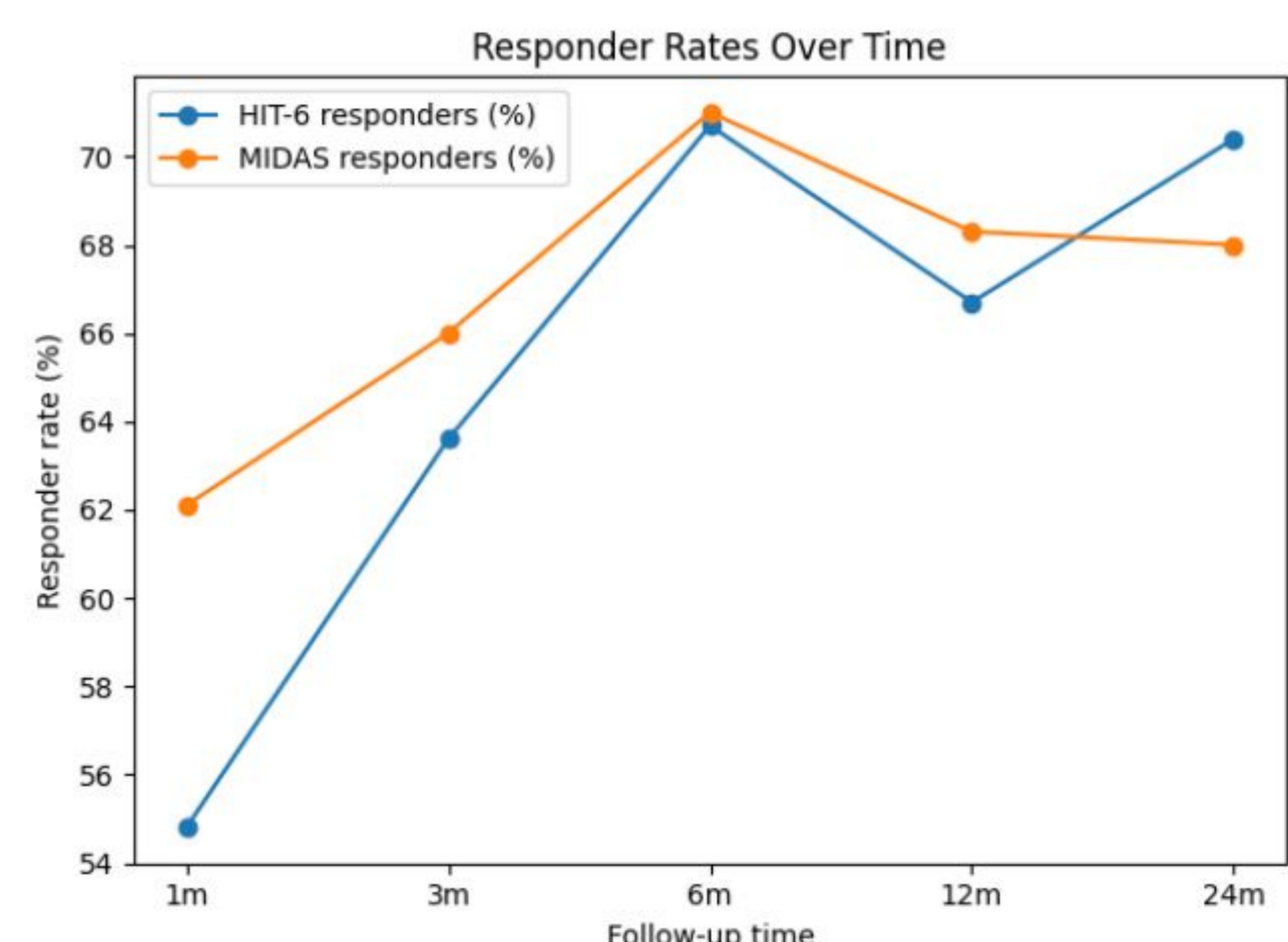
Patients received the following CGRP pathway-targeted preventive treatments: 32.4% galcanezumab, 28.1% erenumab, 24.3% fremanezumab, 8.2% atogepant, 2.5% eptinezumab, 4.5% others

The overall response rate to ePROMs was 54.8%

**HIT-6 responders:** 1m 54.8% , 3m 63.6% , 6m 70.7% , 12m 66.7% , 24m 70.4%

**MIDAS responders:** 1m 62.1% , 3m 66.0% , 6m 71.0% , 12m 68.3% , 24m 68.0%

Responder rates remained stable over time, with no statistically significant differences across visits (HIT-6:  $\chi^2=6.36$ ,  $p=0.174$ ; MIDAS:  $\chi^2=6.54$ ,  $p=0.162$ ).



## CONCLUSION AND RELEVANCE:

In this real-world migraine cohort of patients, preventive therapies targeting the CGRP pathway led to sustained clinical improvements, with ~55–70% of patients achieving MCID in HIT-6 and MIDAS at all follow-up points up to 24 months. Although only ~55% of ePROMs were completed, the results indicate that clinical benefits can be maintained long term. These findings support the effectiveness and durability of anti-CGRP therapies in routine clinical practice and underline the value of PROM-based longitudinal monitoring through telepharmacy platforms.

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