

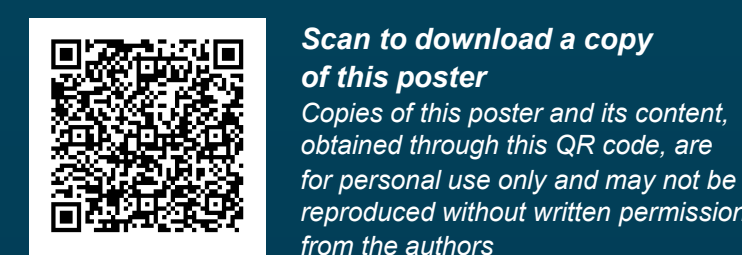
Compliance and Persistence With Ofatumumab Treatment in Patients With Relapsing Multiple Sclerosis in Clinical Trials for Up to 4 Years

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SUMMARY

- Long-term compliance and persistence with ofatumumab treatment were investigated in patients with RMS enrolled in ALITHIOS, an ongoing, open-label, umbrella extension study
- Approximately 95% of patients were ≥80% compliant with ofatumumab treatment over the long term (up to 4 years), indicating high compliance with monthly 20 mg subcutaneous therapy
- Persistence with ofatumumab remains high over the long term with nearly 9/10 patients remaining on treatment in the ongoing ALITHIOS extension study

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INTRODUCTION

- Ofatumumab (OMB) demonstrated superior efficacy and a similar safety profile to teriflunomide in the ASCLEPIOS I/II trials in relapsing multiple sclerosis (RMS)¹
- Sustained efficacy of OMB and a consistent safety profile have also been observed in the long-term ALITHIOS open-label extension study for up to 4 years^{2,3}

OBJECTIVE

- To evaluate the long-term compliance and persistence with OMB treatment in patients with RMS for up to 4 years

METHODS

PATIENT POPULATION

- Patients who completed the core ASCLEPIOS I/II, APOLITOS, and APLIOS trials could enter ALITHIOS, an ongoing, open-label, umbrella extension trial (Figure 1)

COMPLIANCE ASSESSMENT

- Measurement of compliance was based on dosing information recorded by the patient in a study treatment diary
- Details captured included the time and date of each subcutaneous injection, any administration-related symptoms, and records of missed doses

- Compliance with OMB for up to 4 years (cutoff: September 25, 2021) was analyzed in the pooled ASCLEPIOS I/II core studies, in the overall ALITHIOS safety population, and in the continuous OMB (treated with OMB in the core studies, regardless of whether they entered ALITHIOS) and newly switched (randomized to teriflunomide in the core studies and switched to OMB in ALITHIOS) subgroups

- Compliance was calculated as the duration of exposure to the study drug/duration of the on-treatment period × 100%, with ≥80% defined as the threshold to indicate patients were compliant

PERSISTENCE ASSESSMENT

- Persistence was measured as (1) the percentage of patients who completed the study on OMB in the pooled ASCLEPIOS I/II core studies, and (2) the percentage of patients remaining on OMB from entry into ALITHIOS up to the study cutoff date

RESULTS

- In the overall safety population, 86.5% (1703/1969) of patients randomized in ASCLEPIOS I/II, APLIOS, or APOLITOS completed the core studies and entered ALITHIOS (for patient disposition, see Figure 1)
- Compliance was high in ASCLEPIOS I/II and remained high over the long term for the overall, continuous OMB, and newly switched subgroups (Figure 2)
 - As of September 25, 2021, the proportion of patients compliant with OMB therapy was 94.9% (1868/1969) in the overall group, 95.1% (1229/1292) in the continuous OMB group, and 94.4% (639/677) in the newly switched group, and was comparable with the ASCLEPIOS I/II core studies (98.8%)⁴
- Persistence with OMB therapy remained high over the long term (Figure 3)
 - In the ASCLEPIOS I/II core studies, 82.9% (784/946) of patients randomized to OMB completed the study on treatment for up to 30 months
 - In the ongoing ALITHIOS study, 88.5% (1508/1703) of patients remained on treatment at the time of the data cutoff (September 25, 2021)

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Figure 1. Patient Disposition

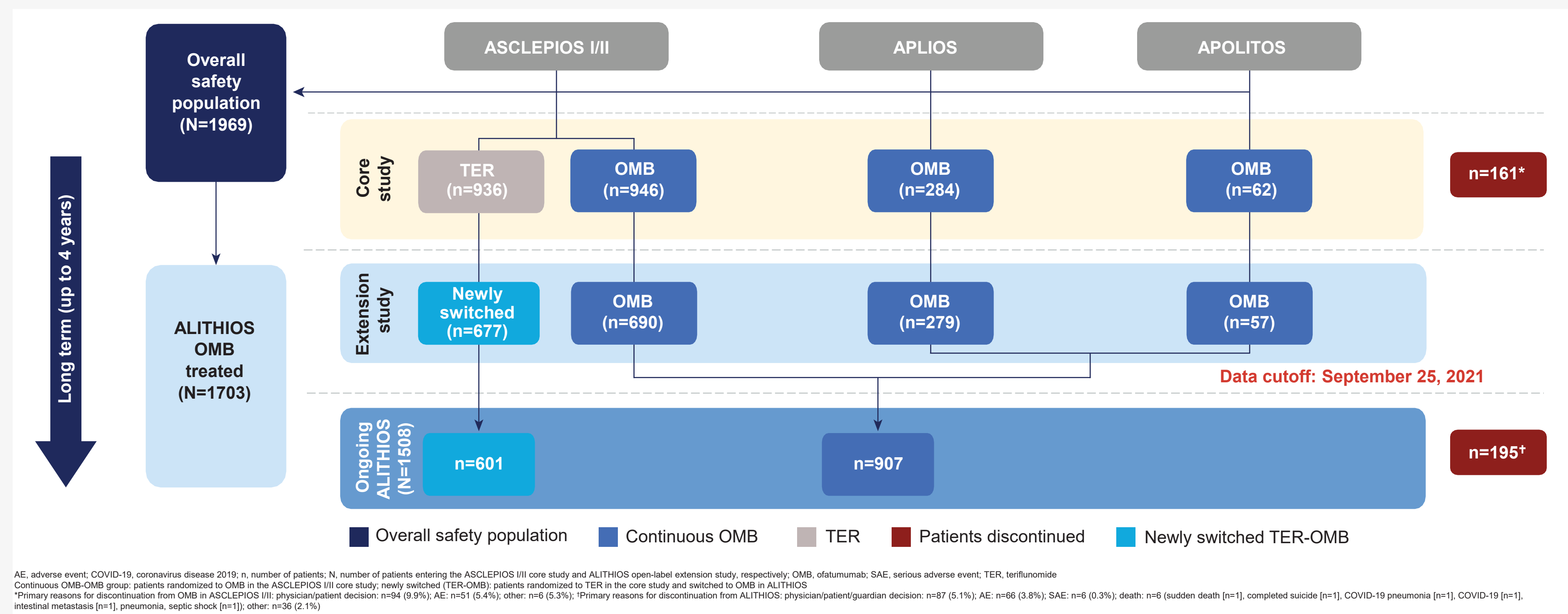


Figure 2. Patient Compliance of the ASCLEPIOS I/II Core Study and ALITHIOS Open-label Extension Study

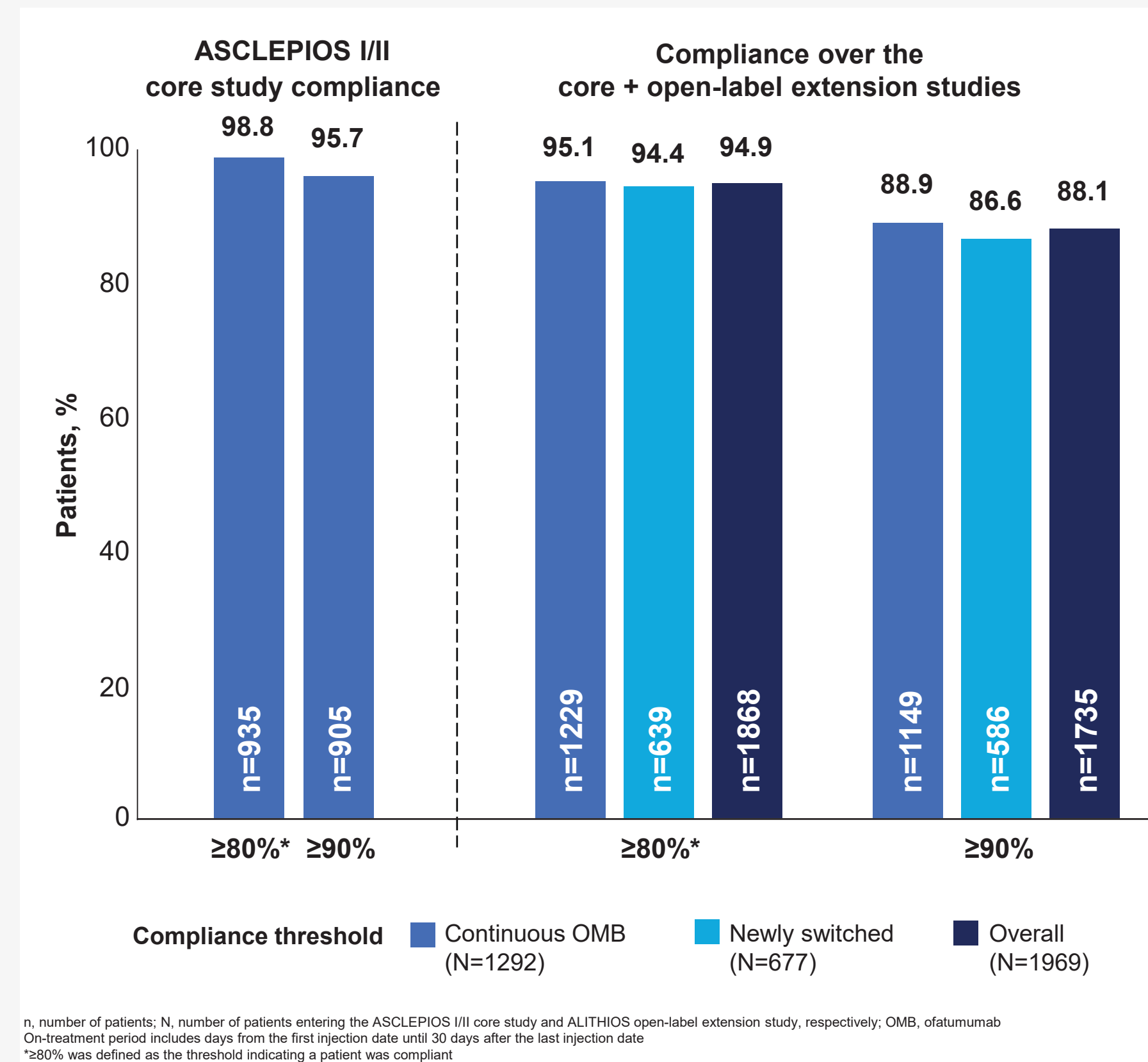
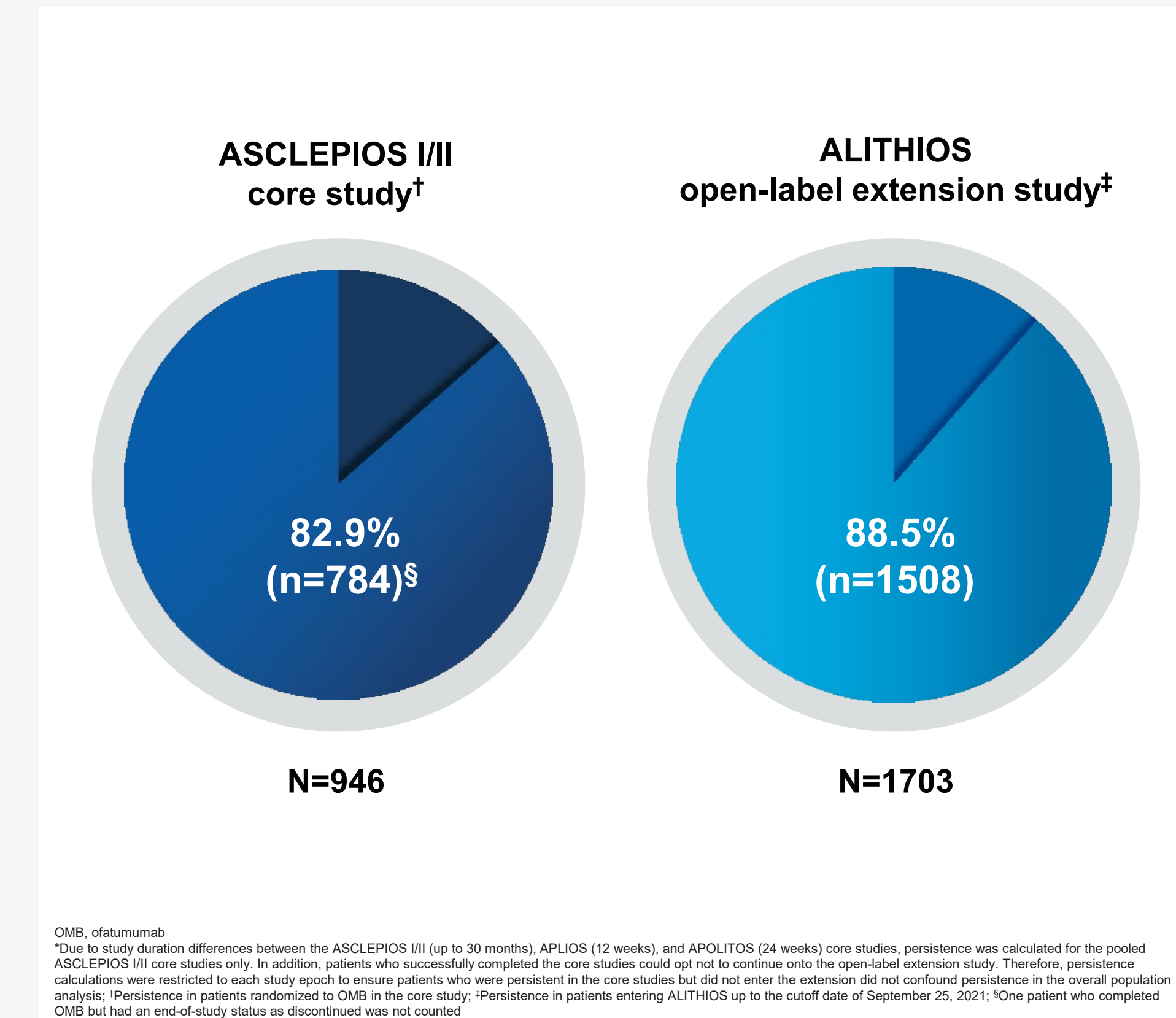


Figure 3. Persistence in the ASCLEPIOS I/II Core Studies and the ALITHIOS Open-label Extension Study*



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