# *SMarter*: Multicentre, cross-sectional, observational, time-and-motion, real-world evidence study on the impact of the intravenous and subcutaneous formulations of ocrelizumab on the patient journey and healthcare system cost in multiple sclerosis.

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Objectives: Multiple sclerosis (MS) is the most prevalent immune-mediated disorder affecting the central nervous system (CNS). The increasing number of patients requiring disease modifying therapies (DMTs) places a significant burden on MS centres, demanding a higher level of care and medical resources. Ocrelizumab (OCR), available in both intravenous (IV) and subcutaneous (SC) formulations*, is currently used for the treatment of MS. The aim of this project is to evaluate the impact of OCR IV and OCR SC on medical facility workflow and cost in patients with relapsing-remitting multiple sclerosis (RMS).

Materials and Methods: SMarter is a cross-sectional time and motion observational study conducted in Italian MS centres, involving until September 2025 14 RMS patients (12 received the OCR IV formulation and 2 the OCR SC formulation). Each patient is evaluated once following a single OCR administration (IV or SC). Patients are divided between those who receive OCR IV treatment, and those who receive OCR SC treatment. Inclusion criteria include adult RMS patients with an Expanded Disability Status Scale (EDSS) score ranging from 0.0 to 4.5. Data are collected via electronic surveys administered to patients and HCPs on the day of the administration of the therapy. Patient and caregiver surveys evaluated duration of stay at the MS center and their experiences and perception, the HCP surveys evaluated active working time associated with IV or SC administration of OCR.

**Figure 1. Sample description**

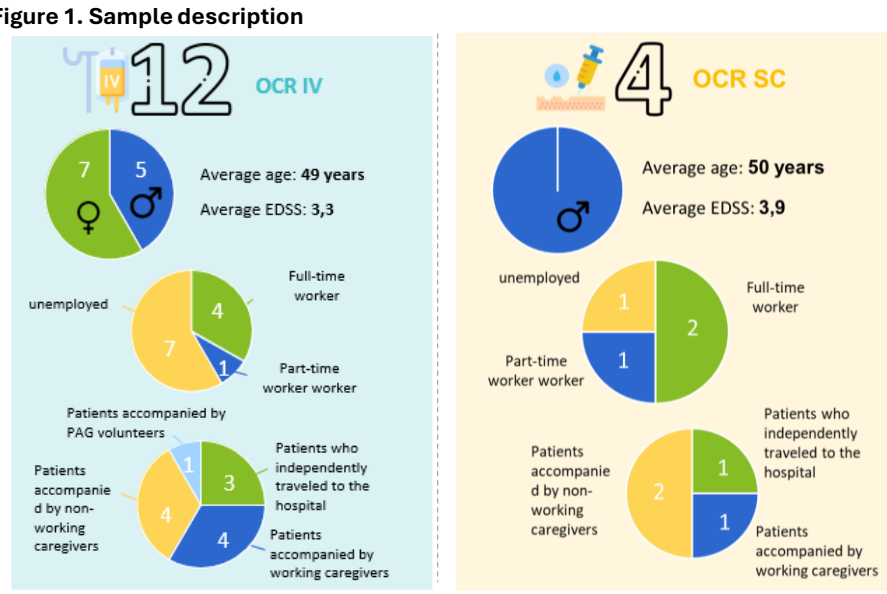



**Figure 2. Measurement of patient flow time through the hospital**

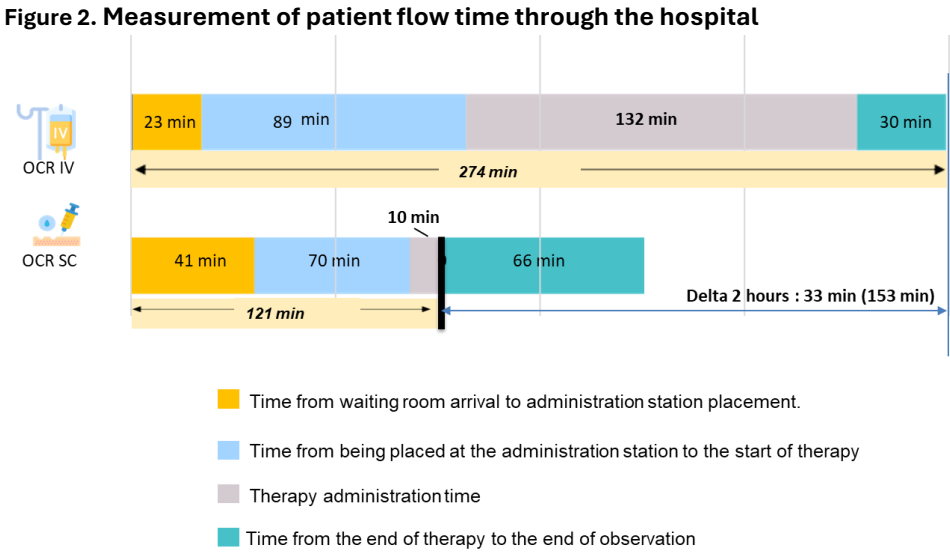



**Figure 3. Evaluation of the therapeutic experience - patient perception**

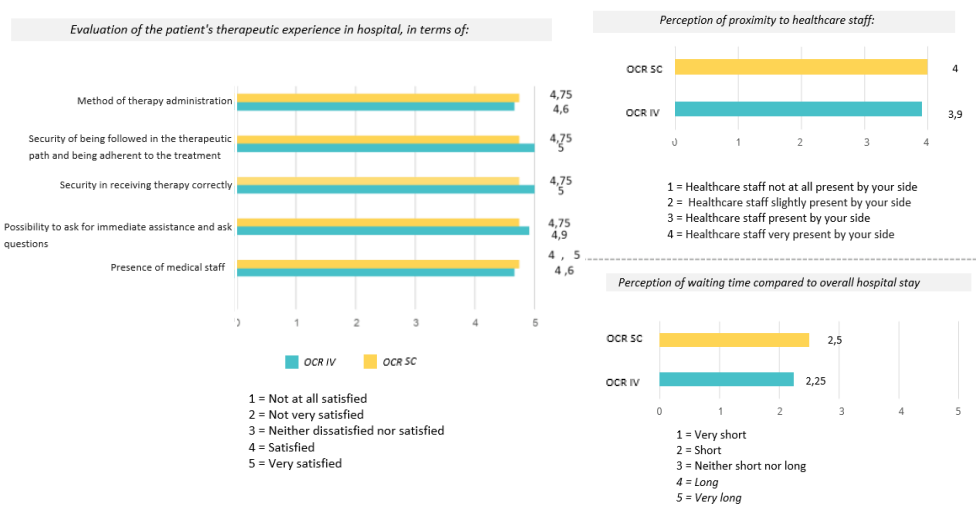
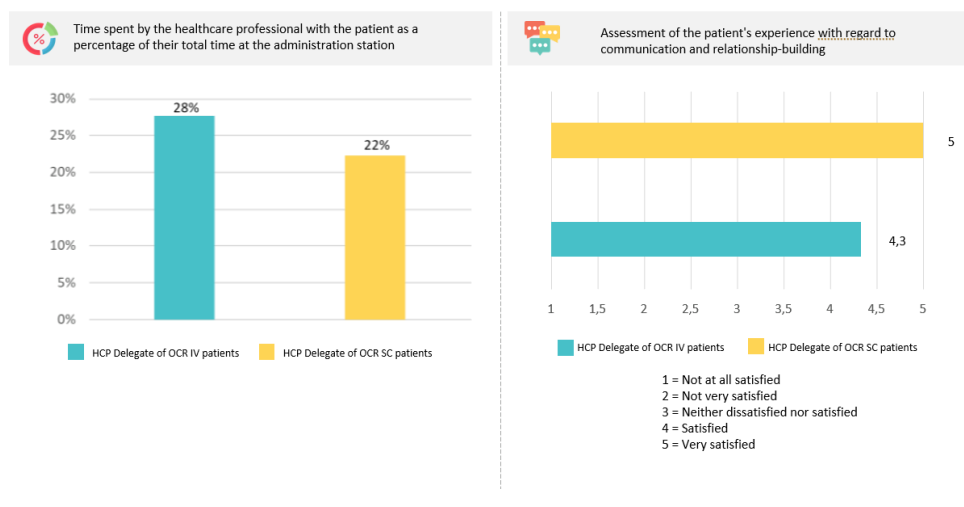



**Figure 4. Evaluation of the therapeutic experience - HCP Delegate perception**




Results and Discussion:
Slight differences are observed in the average EDSS score between the IV and SC patients. Further heterogeneity in the two arms of the sample (e.g., workforce participation, accompanying person) does not require reconsideration of recruitment (**Figure 1**).

The average patient transit time for the SC group is 2 hours and 33 minutes shorter than for the IV group, representing a 44,6% reduction when we do not consider for the SC formulation the monitoring time that is related only to the first administration. The time from arrival in the waiting room to being seated for administration is longer for OCR SC patients. The time between being seated for administration and the start of therapy is notably longer for IV patients, which accounts for the time needed for premedication. (**Figure 2**)

The overall patient experience is identical for both formulations. There are no differences in how patients perceive the support or approachability of the healthcare staff. The OCR SC patients perceive the waiting time as slightly longer relative to their total time spent at the hospital (**Figure 3**).

The proportion of time of the healthcare professional was present near the patient, relative to their total occupation of the administration station, was slightly greater for the IV formulation. The evaluation of the experience in terms of communication and establishing a relationship with the patient was greater when associated with the OCR SC patient, despite the shorter time available for rapport-building (**Figure 4**).

Conclusion: Overall, the adoption of the SC formulation of OCR showed potential benefits for patients compared to the IV formulation, with a reduction in hospital stay time. However, due to the small, imbalanced patient sample, we cannot draw any definitive conclusions. Although the SC formulation could offer advantages, we also observed that subcutaneously treated patients experienced longer pre-administration wait times, indicating a need for improved organizational procedures. This data might be influenced by the fact that SC patients, being on their first ocrelizumab administration, are followed with greater attention by the healthcare staff.

Selected references: Battaglia et al., Patients with multiple sclerosis: a burden and cost of illness study, J Neurol, 2022;269(9):5127-5135. doi: 10.1007/s00415-022-11169-w.

Disclosures and funding: This project was supported by Roche SpA, Monza, Italy and Deloitte Consulting, on the basis of a Sponsored Research Agreement.

*The subcutaneous formulation of Ocrelizumab is co-formulated with recombinant Hyaluronidase rHuPH20