

Pregnancy and family planning:

Italian real world data in women with multiple sclerosis receiving Ocrelizumab

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OBJECTIVES

In recent years, there has been a reported increase in pregnancies among women with multiple sclerosis (MS) who are being treated with ocrelizumab, with similar findings in other disease-modifying therapy (DMT)-exposed pregnancies (1). Although current data on ocrelizumab suggest no increased risk for pregnancy or neonatal outcomes (1, 2), two prospective Phase IV studies (MINORE NCT04998812 and SOPRANINO NCT04998851) are collecting additional data on the transfer of the drug across the placenta or through breast milk.

The “Maternity Care” is a collaborative project involving Roche and a board of experts from different specialties and the Italian MS Patient Association, with the aim to promote pregnancy reporting through a multi-channel approach.

We evaluate the rate and accuracy of ocrelizumab-exposed pregnancy reports in Italy reports within three years of the project’s implementation.



MATERIALS

According to the project plan, educational sessions, hospital meetings and advisory board were organized from 2022 to date. Post-marketing surveillance of pregnancy and lactation cases by Roche included structured questionnaires and an informational letter from neurologists to other specialties (3).



METHODS

The annual rate of Italian MS pregnancies exposed to Ocrelizumab reported to Roche Safety Database until March 2025 was assessed utilizing quantitative and qualitative measures. Data from 2022, 2023, 2024, and 2025 were compared.



RESULTS

Italian Cases vs. Global: The percentage of MS pregnancy reports from Italy, as a portion of all global pregnancy reports, increased from 1.53% in March 2024 (31/2,020) to 2.26% in March 2025 (114/5,053). This trend suggests a likely increase in the reporting of ocrelizumab-exposed pregnancies by Italian patients and their healthcare providers.

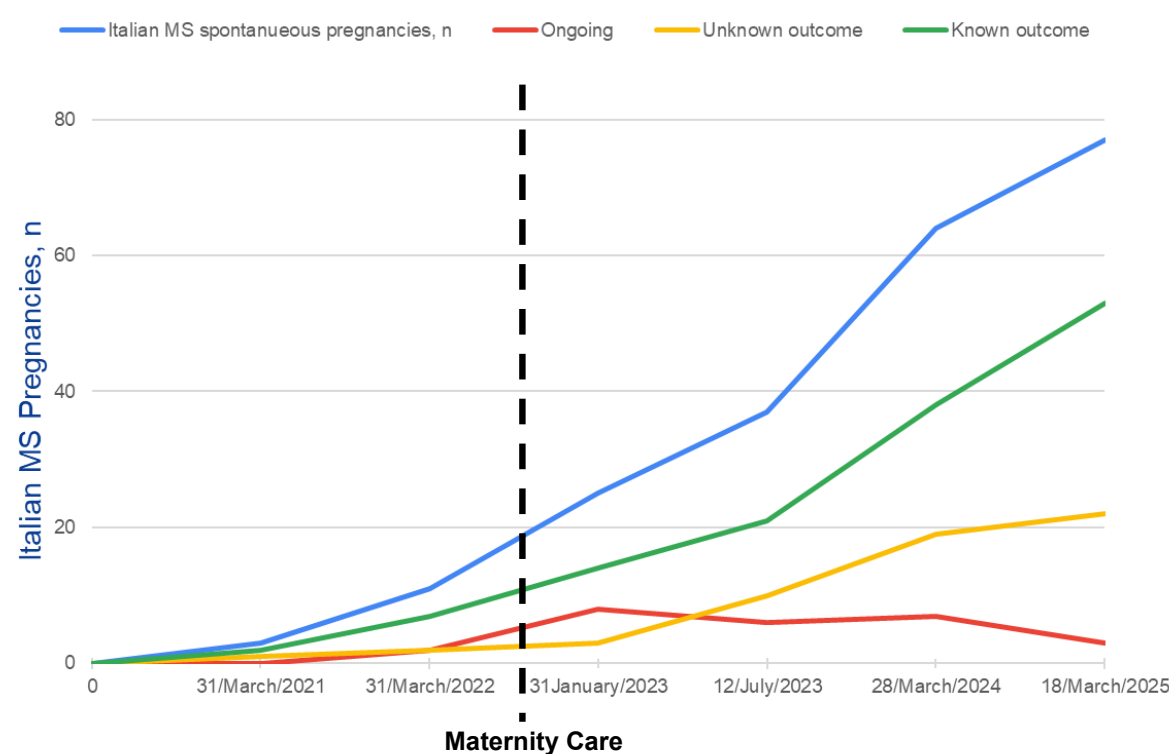
Spontaneous Reports: The number of spontaneous reports significantly grew from 35.5% (11/31) in March 2022 to 67.54% (77/114) in March 2025, suggesting increased awareness among neurologists.

Data Sources: Prospective reported pregnancies remained stable in 2025 at around 65.8%, while Italian pregnancy reports from literature sources increased in the last year, indicating growing interest within the Italian scientific community.

		Pre- Maternity Care		Post Maternity Care			
		31/March/2021	31/March/2022	31/January/2023	12/July/2023	28/March/2024	17/March/2024
Overall and by country	Total MS pregnancies	1223	2020	2742	3253	3989	5053
	Italian MS pregnancies, n	19	31	51	64	93	114
	Italian MS pregnancies, %	1.55	1.53	1.86	1.97	2.33	2.26
Reporting type, n	Prospective	13	21	37	48	67	75
	Retrospective	6	10	14	16	26	39
Source, n	Spontaneous	3.0	11.0	25.0	37.0	64	77
Spontaneous, % of Italian cases vs Overall		15.8	35.5	49	57.8	68.8	67.54
Status of all Italian cases, n	Ongoing	3	4	9	7	7	3
	Unknown outcome*	8	8	11	16	27	37
	Known outcome	8	19	31	41	59	74
Status of NIS/NIP cases, n	Ongoing	1	0	1	1	0	0
	Unknown outcome	6	5	7	5	5	5
	Known outcome	2	4	7	10	11	11
Status of spontaneous cases, n	Ongoing	0	2	8	6	7	2
	Unknown outcome*	1	2	3	10	19	22
	Known outcome	2	7	14	21	38	53

*consent denied, or no response received from HCP

Increase in quantity of PV spontaneous reporting - Italy



DISCUSSION AND CONCLUSION

Roche’s robust pharmacovigilance process has created a comprehensive dataset of pregnancy outcomes for a DMT in MS. This data helps patients and clinicians make evidence-based decisions.

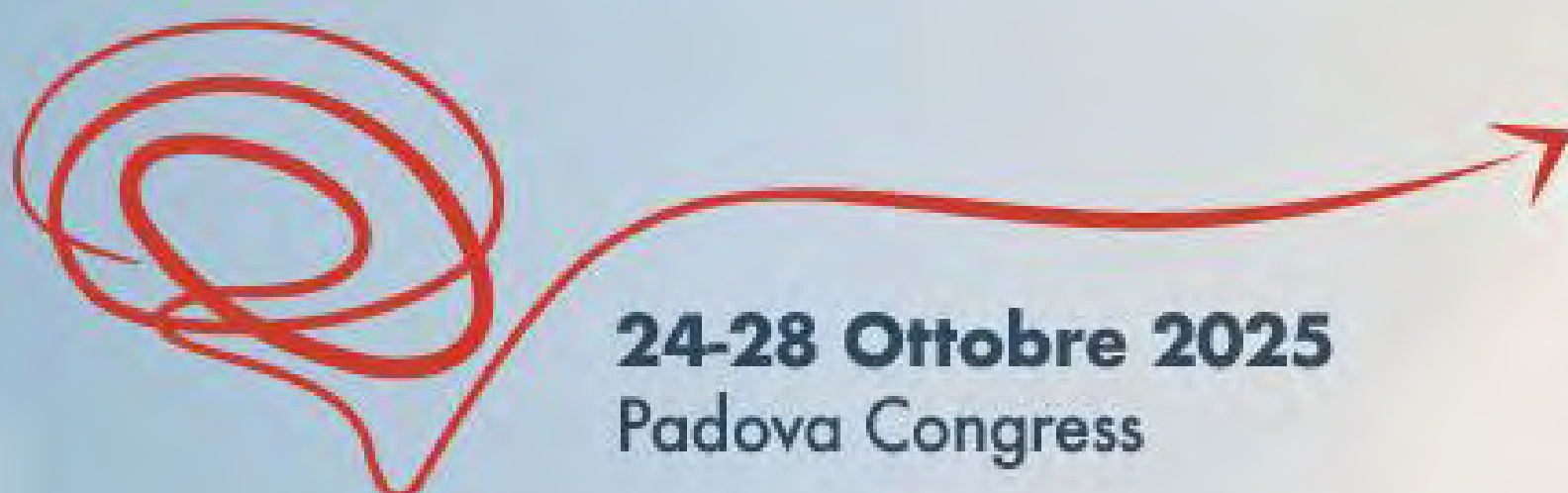
Despite a rise in pregnancies, patient management in Italy is not yet standardized because the most recent scientific evidence has not been included in national guidelines.

Generating a consensus to harmonize and personalize the patient journey is emerging as a topic of interest.



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- 3) Gitman V et al., A Multi-Source Approach to Pregnancy and Lactation Evidence Generation in Multiple Sclerosis: The Ocrelizumab Example. *Pharmacoepidemiology and Drug Safety*, 2024; volume 33 <https://doi.org/10.1002/pds.5891>



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