*Therapeutic Advances in*
# Neurological Disorders

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***Read the primary publication***
Naismith RT, et al. *CNS Drugs*. 2020;34(2):185-196.

## Improved gastrointestinal profile with diroximel fumarate is associated with a positive impact on quality of life compared with dimethyl fumarate: results from the randomized, double-blind, phase III EVOLVE-MS-2 study

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## STUDY BACKGROUND

**EVOLVE-MS-2** (NCT03093324) compared GI tolerability of diroximel fumarate (DRF) versus dimethyl fumarate (DMF) in adults with relapsing-remitting MS.

Patients completed **IGISIS** and **GGISIS** eDiary questionnaires each day to track their gastrointestinal (GI) symptoms.

**A previous analysis of EVOLVE-MS-2 showed DRF significantly improved GI tolerability compared with DMF.**[1]


- Significantly fewer days with an IGISIS score ≥2
- Lower incidence of GI adverse events (AEs)
- <1% DRF treatment discontinuation due to GI AEs

[1]Naismith RT, et al. *CNS Drugs*. 2020;34(2):185-196.

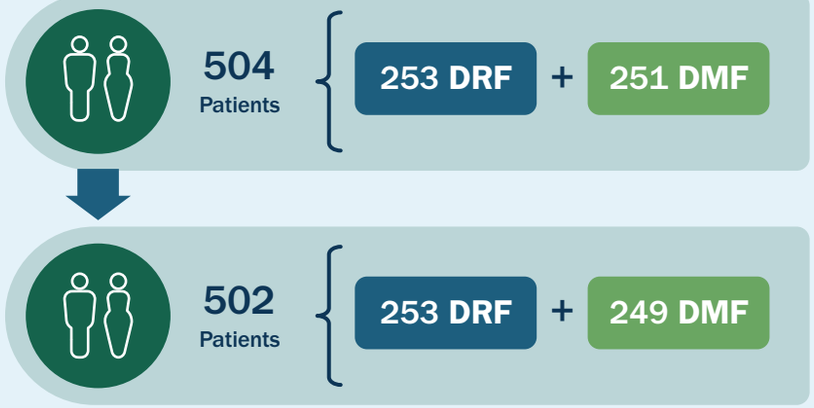
## WHY THIS STUDY WAS CARRIED OUT

This *post-hoc* analysis evaluated the impact of GI tolerability events on **quality of life** for patients with relapsing-remitting MS who received DRF or DMF in EVOLVE-MS-2.

## STUDY OVERVIEW AND METHODS

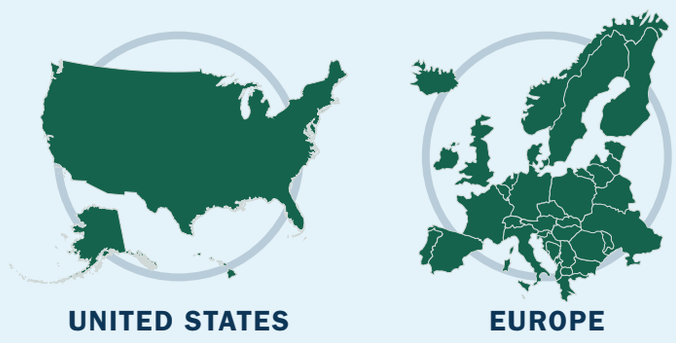
- 5-week treatment period with DRF or DMF
- Randomized, double-blind, phase III
- Patients completed daily questionnaires to assess GI symptoms and their impact on daily activities and work
- Physicians assessed AEs at weekly study visits

Based on DMF/DRF studies showing that most GI AEs occur in the first month of treatment




### STUDY SITES

70 sites

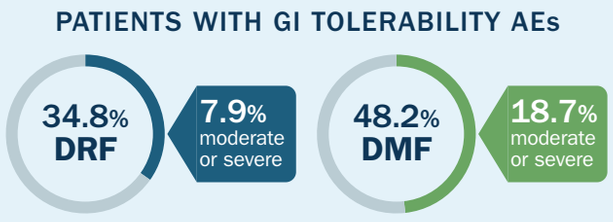



### ELIGIBILITY CRITERIA

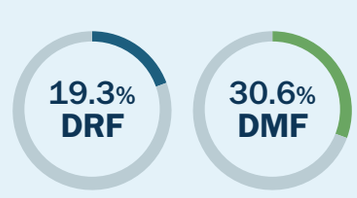
Adults with relapsing-remitting MS and no active/recurring GI symptoms, prior GI surgery, or prior DRF/DMF treatment.

## RESULTS

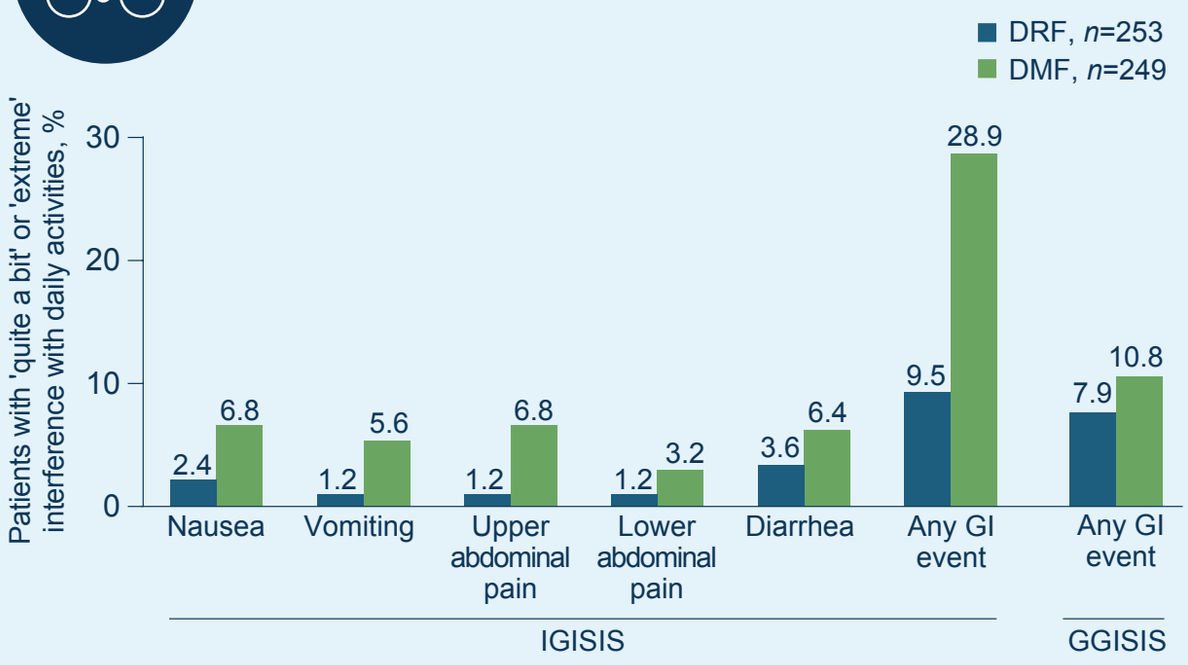
Patients treated with DRF experienced fewer and less severe GI tolerability AEs



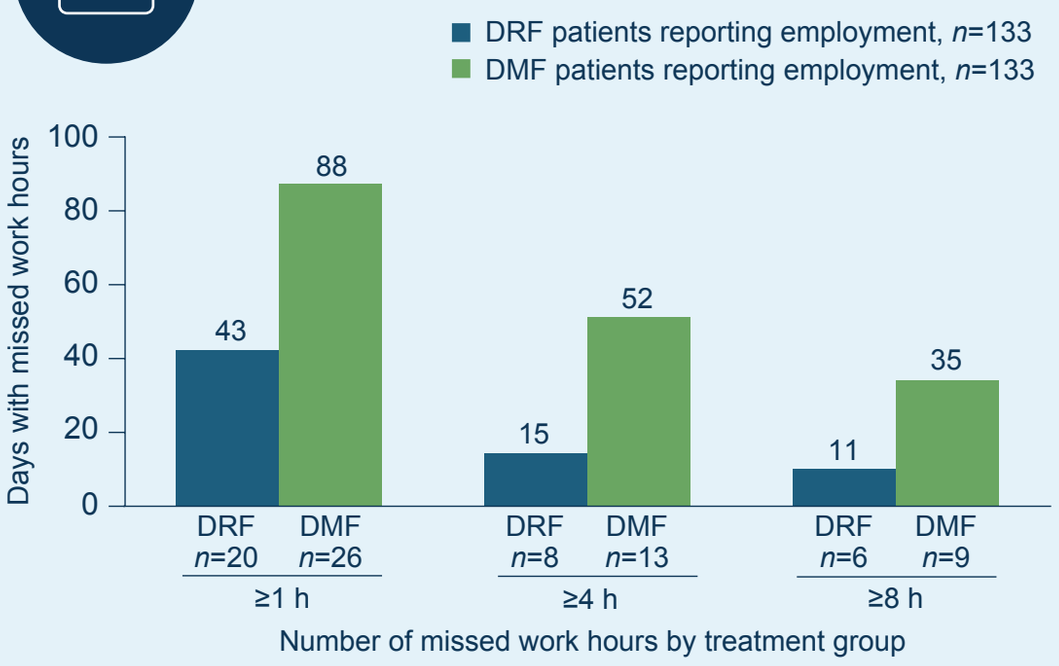

Patients treated with DRF used fewer concomitant medications (e.g., antacids) to treat GI symptoms




**Patients treated with DRF had GI symptoms that interfered less with regular daily activities**




**Patients treated with DRF missed less work**




IGISIS score ≥2 and quality of life

**The majority (~90%) of patients who reported interference of GI symptoms on daily activities, missed work, and concomitant symptomatic medication use also had a worst IGISIS score ≥2. These data suggest that an IGISIS score ≥2 represents an appropriate threshold for comparing GI tolerability with DRF versus DMF.**

## WHAT WAS LEARNED FROM THIS STUDY?

The **improved GI tolerability with DRF** translated into clinically meaningful **benefits to quality of life**, as patients experienced less impact on daily life and work, and required less concomitant symptomatic medication use.

FULL CITATION placeholder