

# Predicting Relapse Episodes in Patients with Multiple Sclerosis Treated with Disease Modifying Therapies in a Large Representative US-based Real-World Cohort

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## Background

- A relapse of multiple sclerosis (MS) interferes with a patient's ability to function at home and work.
- Early and accurate identification of patients with a higher risk of relapse improves the quality of life for the patient and reduces the cost of care.
- Successfully identifying relapse using only information already present in EHR systems reduces the burden of data collection and provides a simpler method for clinicians and patients to assess risk.

## Objective

- To use advanced analytics to predict relapses among MS patients treated with disease modifying therapies (DMTs) identified from a large, representative database of linked EMR-Claims data.

## Methods

- The OM1 Data Cloud collects, and links structured and unstructured data, including extensive clinical and claims data on patients from a variety of provider practice types across the US.
- A cohort of MS patients was selected from the OM1 MS Registry, a population of patients with MS within the OM1 Data Cloud.
- The study includes data from January 2015 through June 2018.
- MS patients treated with a DMT prior to December 31, 2017 (index date for all patients), with no evidence of relapse in the 30 days prior to the index, and with linked EHR-claims data were included in this analysis.
- A relapse event was defined as an MS-related inpatient stay, emergency room visit, or outpatient visit with documented MS and a corticosteroid prescription within 7 days.
- The outcome of interest was whether the patient experienced a relapse within the 6 months following the index date.
- Random forests, classification, and regression trees were used to identify pre-index predictors.
- Over 150 factors were initially assessed for inclusion in the model, including demographic factors, comorbidities, MS-related symptoms, medication use, healthcare utilization, and prior relapses.
- Models were built in a training set created by randomly selecting 80% of the eligible patients and validated in the remaining 20% of the eligible patients.
- The cutoff value for high-risk patients was determined based on observed optimal model performance.

## Results

- This study included 18,137 patients, 7.8% of whom had relapses.
- The median age was 54 (IQR: 45-62) years, approximately 80% were female, and a majority were Caucasian.
- In the validation set the model correctly identified the presence of a relapse within 6 months in 84% of patients.
- A total of 17 factors were identified for inclusion in the final model, with the most significant predictors being: the number of relapses in the previous 12 months, antiemetic medication use, skeletal muscle relaxants, and MS-related fatigue symptoms. A patient was defined as high-risk if the model assigned a risk score of 6 or higher to the patient.
- The area under the curve for both the training and validation sets was above 0.70.
- Among patients identified as high-risk (14% of patients treated with a DMT), 20.3% experienced a relapse.
- Among the remaining patients, identified as low-risk by the model, 5.8% experienced a relapse.
- Patients identified as high risk by the model had 4.17 (95% CI: 3.70, 4.67) times the unadjusted odds for relapsing within 6 months.

Table 1. Baseline Characteristics

	Patients with Relapse Within 6 months	Patients without Relapse Within 6 months
All Patients (n)	1,416	16,721
Female (n, %)	1,110 (78.4%)	13,242 (79.2%)
Age (Median, IQR)	53 (44 – 61)	54 (45 – 62)
BMI (Median, IQR)	29.2 (24.5 – 34.8)	28.5 (24.2 – 33.9)
Race (n,%)		
African American	184 (15.8%)	1,806 (13.1%)
Asian	3 (0.3%)	37 (0.3%)
Caucasian	959 (82.3%)	11,559 (83.8%)
Other	19 (1.6%)	393 (2.8%)
Missing/Unknown	251	2,926
Charlson Comorbidity Score (Median, IQR)	1 (0 – 2)	1 (0 – 2)
Relapses in 12 months prior to index (n, %)		
0	941 (66.5%)	14,963 (89.5%)
1	312 (22.0%)	1,482 (8.9%)
>1	163 (11.5%)	276 (1.7%)
Outpatient visits in 12 months prior to index (n, %)		
0	24 (1.7%)	474 (2.8%)
1	59 (4.2%)	1,211 (7.2%)
>1	1,333 (94.1%)	15,036 (89.9%)
Inpatient visits in 12 months prior to index (n, %)		
0	1,135 (80.2%)	14,902 (89.1%)
1	162 (11.4%)	1,253 (7.5%)
>1	119 (8.4%)	566 (3.4%)
ER visits in 12 months prior to index (n, %)		
0	1,052 (74.4%)	14,012 (83.8%)
1	161 (11.4%)	1,577 (9.4%)
>1	202 (14.3%)	1,132 (6.8%)

Figure 1. Adjusted Odds Ratios of Relapse for Selected Factors

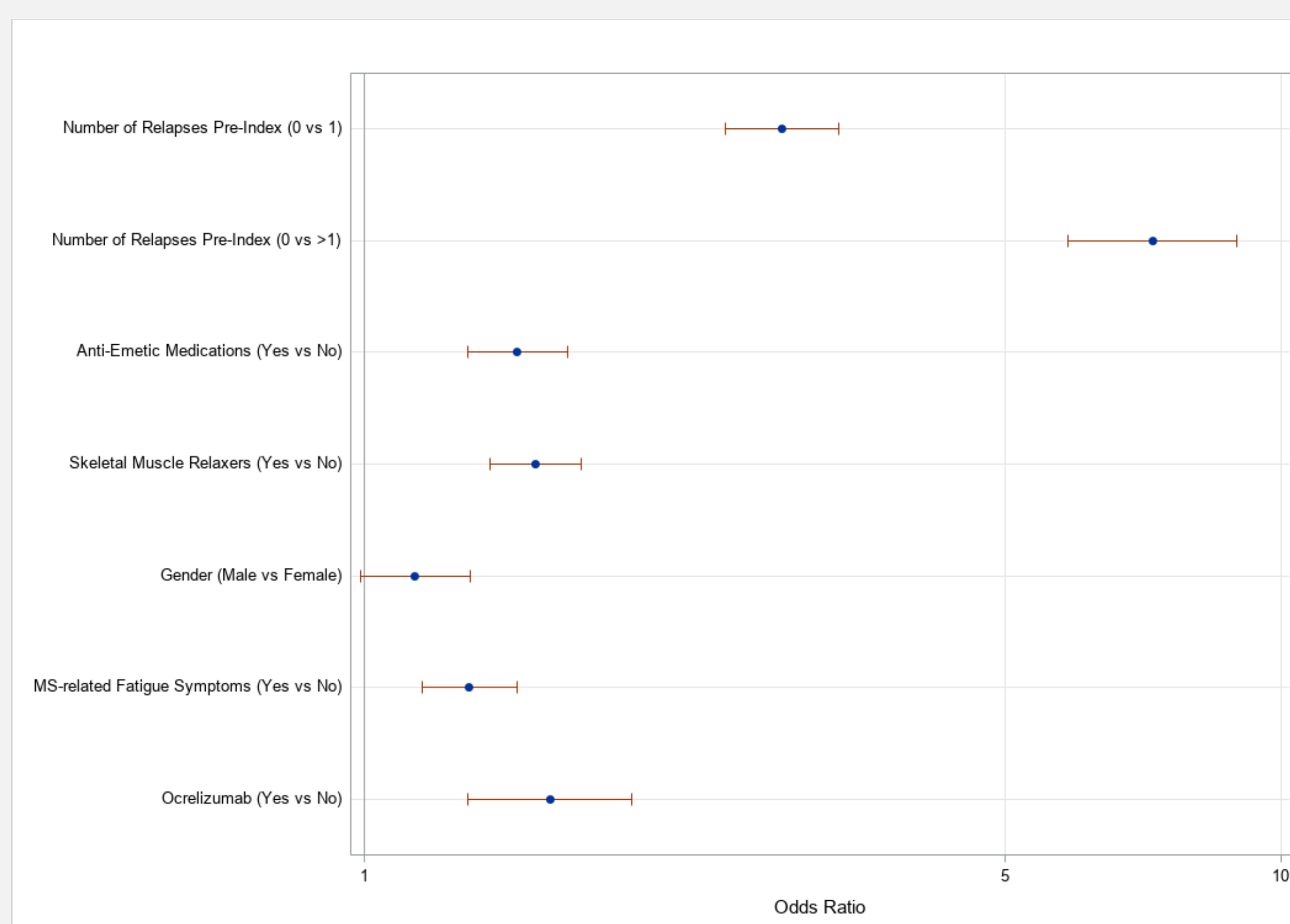
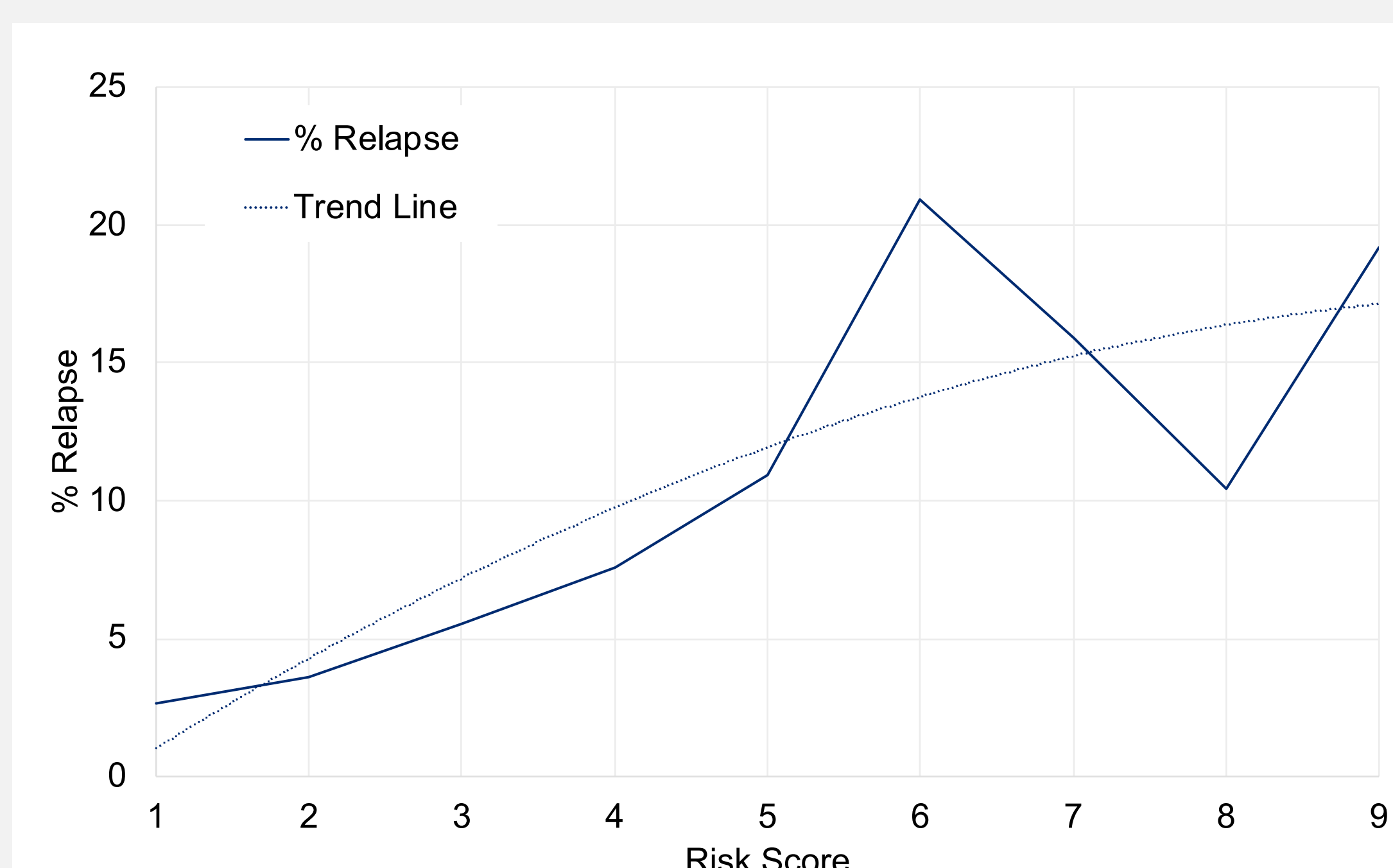


Figure 2. Risk Score and Percent of Patients with Relapse Episodes



## Conclusions

- Patients with MS relapses were able to be defined and identified within a cohort of patients with MS.
- We developed a predictive model for relapse using data elements routinely collected in electronic medical records and insurance claims among DMT-treated MS patients.
- 14% of patients were identified at high risk, having a 4-fold higher odds of relapse within 6 months than patients identified at low risk.
- The model correctly identified relapse outcomes for 84% of patients in the validation set.