# OPTIMISE:MS – A Prospective, Real World Pharmacovigilance Study in Multiple Sclerosis

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## Introduction

- In the UK individuals diagnosed with active RRMS (around 85% with MS) are eligible for treatment with DMTs
- In 2016 56% of eligible patients were being treated with approximately 44% of people with MS (of >11,000 surveyed) remaining untreated in the UK
- Whilst the therapeutic armoury in MS has increased rapidly, the availability of real-world data concerning safety is limited
- Safety signals from clinical trials and early clinical experience suggests both lymphopaenia and increased infection rates with newer MS therapies
- The rates at which these occur in the real-life treated population is, as yet, unknown. The current adverse event reporting system (yellow card scheme) has a high risk of missing longer-term rare adverse events; as such there is an urgent need for a formalised reporting system

## Aims

The aim of this study is:

- To provide for the first time an estimate of overall rates of SAEs associated with DMT (including MS relapses or opportunistic infections) in the Scottish and UK population with MS
- To capture this information using OPTIMISE as a platform
- To help facilitate a way of exploring related questions regarding the relative benefits vs risks of treatment

## Methods

- This is a pragmatic prospective non-interventional observational cohort study over 7 years recruiting 4000 patients across multiple sites (12-15 in UK and Scotland)
- All patients with MS who are eligible to receive treatment will be recruited. This includes those on treatment, those intending to start treatment and those who have elected not to be treated with any DMT
- Study participants are not subjected to any additional investigations or clinical visits beyond those received as part of their usual clinical care

## Primary Objective

To characterize the incidence and compare the risk of SAEs in people with MS treated with DMTs.

**SAEs of interest in this study will be defined as:**

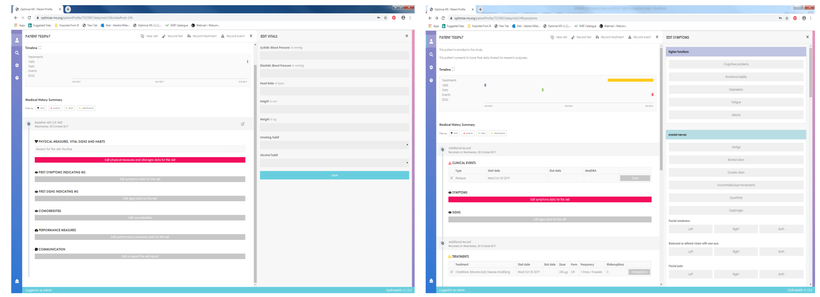
- Any infection requiring hospitalisation
- Any opportunistic infection (i.e. typically associated with immunosuppression)
- Any other serious adverse event believed to be related to treatment (e.g. lymphoma, non-melanoma skin cancer)
- Any MS relapse
- Death

## Results & Conclusion

- The study is currently in the early phase of recruitment having opened MAY_2019
- To date 10 /15 participating NHS sites are active and 412/4000 patients have been consented and enrolled

## Results & Conclusion

**View of OPTIMISE - New Visit & Events Screen**



- OPTIMISE captures SAEs in real-time from a real-world cohort of MS patients
- Sites found the data capture tool useful when entering data
- OPTIMISE software can be used off and online when connected to the local network

**Take Home Points About Recruitment**

- Recruitment can take place alongside your clinical consultation with a patient
- Easy study to recruit to because no extra appointments for patients
- All patients who are eligible or on DMTs can be approached
- Multiple avenues to approach patients i.e. clinic setting, patient attending infusion therapy, blood monitoring appointments etc.
- OPTIMISE software is being used as a clinical tool in everyday practice