Title: Recruitment in multiple sclerosis trials: the MS-SMART experience

## **Abstract**

Randomised, placebo-controlled trials are the gold standard for the assessment of safety and efficacy of new treatments. Although study design is challenging, success ultimately depends on recruitment and retention of subjects. MS-SMART [NCT01910259] is a multi-arm, phase 2b study in secondary progressive multiple sclerosis (SPMS), currently recruiting 440 patients in the UK. We describe here in detail our recruitment experience so far in the largest centre (planned 40% of total). Potentially eligible participants were identified through a number of routes: consultant referrals (22%); dedicated website [www.ms-smart.org] (76%); presentations at MS centres (0.4%), referrals from MS nurses (2%). Of c700 patients, 150 were uncontactable, and so 550 underwent a simple pre-screening telephone questionnaire. Two hundred were eligible of which 150 agreed to attend for formal screening and 130 were randomised. We conclude that direct consultant referral and a dedicated website are the most successful recruiting methods in this SPMS trial. This independent research is awarded by the Efficacy and Mechanism Evaluation Programme (EME) and funded by the Medical Research Council (MRC) and the Multiple Sclerosis Society (MS Society) and managed by the National Institute for Health Research (NIHR) on behalf of the MRC-NIHR partnership.