



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

EMA workshop on the clinical investigation of new drugs for the treatment of Multiple sclerosis

Invitation for expressions of interest

The European Medicines Agency (EMA) announces a one-day workshop on the clinical investigation of new drugs for the treatment of Multiple sclerosis (MS). The workshop will be held at the EMA, in London, UK on 17 October 2013.

Objectives of the planned workshop

In response to the considerable interest created by the on-going revision of the current MS guideline, the EMA has decided to provide an opportunity for the different stakeholders to come together and discuss the key scientific issues in the field.

The main goal of the workshop is to make sure that in the revision of the MS guideline EMA can take into consideration the most up-to-date, state of the art scientific developments in multiple sclerosis, as well as the positions of the experts in the field on the main topics in the guideline.

Main topics

1. New outcome measures in MS: possible better ways to assess disability that overcome limitations of the EDSS.
2. New perception of disability – including cognition, fatigue, pain and other symptoms specifically related to MS.
3. The staggered “two-step approach” for treatments with significant effect on immunity:
 - How to address safety concerns in new drugs with significant effect on immunity?
 - What data on safety should be presented at initial MAA?
4. Changing MS population, definition of “insufficient treatment response”, and their impact on the benefit-risk assessment of new drugs.
5. The need for placebo in controlled trials in multiple sclerosis and how to design them.
6. Patient reported outcomes, biomarkers and novel methodologies, and their role in the development of new MS drugs.



Expressions of interest

We invite interested experts and stakeholders to send an expression of interest to attend this workshop by 16 August 2013 to MSworkshop@ema.europa.eu, bearing in mind that the capacity will be limited.