EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 May 2014
EMA/257188/2013
Human Medicines Evaluation Division

EMA workshop on the investigation of subgroups in confirmatory clinical trials

Invitation for expression of interest: Biostatistics@ema.europa.eu

On 23 January 2014, the European Medicines Agency published a draft Guideline on the investigation of subgroups in confirmatory clinical trials. It is currently open for public consultation; comments can be sent using the template to Biostatistics@ema.europa.eu until 31 July 2014.

Following public consultation, EMA will be hosting a one-day workshop on the topic at the EMA premises in London, UK, on 7 November 2014.

Objectives of the planned workshop

1. Discuss the role of subgroup analyses in clinical trials submitted for marketing authorisation.
2. Receive input on the positions outlined in the draft EMA guideline from experts and stakeholders.
3. Provide an open forum for discussions of subgroup issues in the planning and at the assessment stage of phase III clinical trials.

Sessions planned

- Considerations underlying the development of the draft EMA guideline and discussion of key concepts with representatives from other regulatory agencies.
- Views from experts and stakeholders on positions outlined in the draft EMA guideline and particularly the presented assessment strategies for confirmatory clinical trials.
- Methodological implications of, among others, subgroup definition, heterogeneity and consistency assessment, the role of pre-specification with and without precise control of the type-1-error.
- Questions and answers.

Expressions of interest

We invite all experts and stakeholders who wish to attend this workshop to send their expression of interest to Biostatistics@ema.europa.eu by 1 August 2014. Please note that capacity is limited.

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