

10 May 2012
EMA/308884/2012
Human Medicines Development and Evaluation

EMA workshop on multiplicity issues in clinical trials

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

The European Medicines Agency is hosting a one-day workshop on multiplicity issues in clinical trials.

The workshop will be held on 16 November 2012 at the EMA in London, UK.

Objectives of the planned workshop

1. Discuss current standards and strategies to address multiplicity in clinical trials.
2. Identify issues where the current PtC document on multiplicity issues in clinical trials needs to be updated and issues where guidance is missing so far.

Sessions

- Current experience with the current guidance document – how are multiplicity issues addressed in MAAs and their assessment?
- Usefulness and limitations of newly developed strategies to deal with multiplicity.
- Multiplicity arising from interim decisions (e.g. different endpoints tested in the interim and final analysis, test of primary and secondary endpoints)
- Implications of multiplicity for estimation.

Expressions of interest

Although speakers will be by invitation and capacity will be limited, we invite interested experts and stakeholders to send an expression of interest to attend this workshop by 1 August 2012 to Biostatistics@ema.europa.eu.