

20 May 2015
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Human Medicines Evaluation Division

EMA workshop on the development of new medicinal products for the treatment of ulcerative colitis and Crohn's disease

Invitation for expressions of interest

The European Medicines Agency (EMA) announces a one-day workshop on the development of new medicinal products for the treatment of ulcerative colitis and Crohn's disease. The workshop will be held at the EMA, in London, UK on 29 June 2015.

Objectives of the planned workshop

- To discuss the available data on validity and feasibility of mucosal healing (alone or in combination with clinical remission and/or biomarkers) as a primary measure of efficacy in adults and children.
- To provide a forum of discussion on suitable study designs and possible claims for new substances
- To receive input on the extent of / criteria for extrapolation possible from adults to the paediatric population.

Main topics

1. Study designs and possible claims
2. Endpoints in clinical trials in adults and children
3. Paediatric IBD and placebo control
4. Alternative study designs and extrapolation in paediatric IBD

Expressions of interest

We invite interested experts and stakeholders to send an expression of interest to attend this workshop by 6th June 2015 to IBD_Workshop@ema.europa.eu, bearing in mind that the capacity will be limited.

Please note that registration will be limited to a maximum of 2 participants per company.

A confirmation of registration will be sent by 10th June 2015.