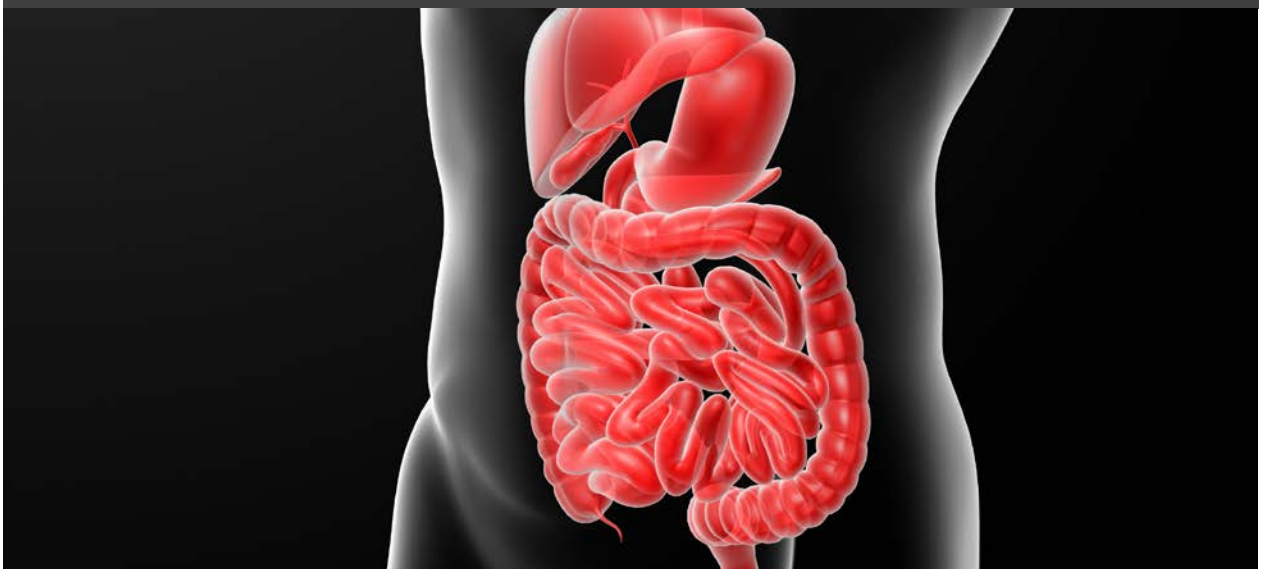
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2015
EMA/306638/2015
Human Medicines Evaluation Division

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

Programme

29 June 2015
European Medicines Agency, Canary Wharf, London, United Kingdom



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Send a question via our website www.ema.europa.eu/contact

Background

The “Guideline on the development of medicinal products for the treatment of Crohn’s disease (CHMP/EWP/2284/99) currently requests clinical indices as the primary measure of efficacy. However, there is growing evidence that mucosal healing as judged endoscopically, histologically or via imaging techniques reflects long term clinical outcome better than remission/response based on classical clinical indices such as CDAI.

Likewise, the “Guideline on the development of medicinal products for the treatment of ulcerative colitis (CHMP/EWP/18463/2006) currently requests clinical indices as the primary measure of efficacy. However, there is growing evidence that mucosal healing as judged endoscopically or histologically reflects long term clinical outcome better than remission/response based on classical clinical indices.

Regarding the conduct of clinical studies in children, both these guidelines currently only include more general comments. In 2010, an expert meeting of European experts in paediatric gastroenterology and rheumatology published a statement, which in some areas is more demanding as regards the needs of and the mode of conduct of paediatric studies in Crohn’s disease and in ulcerative colitis than the respective guideline document, leading to obvious discrepancies, with a subsequent need of reconciliation.

Furthermore, during the last decade there has been increasing discrepancy between the adult part of the current guidelines and development plans presented for new drugs. In particular, the current guidelines’ request for separate studies aiming at demonstrating efficacy in the induction and the maintenance of remission settings has been questioned.

Objectives of the 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.

Scientific Organising Committee

Elmer Schabel	Federal Institute for Drugs and Medical Devices (BfArM), Germany Gastroenterology Drafting Group (GDG)
Joachim Musaus	European Medicines Agency (EMA)
Mark Ainsworth	University of Copenhagen, Denmark Gastroenterology Drafting Group (GDG)
Peter Szitanyi	First Faculty of Medicine and General Teaching Hospital, Czech Republic Gastroenterology Drafting Group (GDG)
Johannes Taminiau	Universitair Ziekenhuis Antwerpen, Belgium Gastroenterology Drafting Group (GDG)
Richard Vesely	European Medicines Agency (EMA)
Chrissi Pallidis	European Medicines Agency (EMA)
Thorsten Olski	European Medicines Agency (EMA)

Programme details

Room 3A

08:00 Arrival and registration

Reception, ground floor (45')

08:45 Welcome and introduction

Joachim Musaus, Richard Vesely, EMA **(10')**

08:55 EU Paediatric Regulation

Paolo Tomasi, EMA **(5')**

09:00 Session 1: Study designs and possible claims

Chair: Elmer Schabel, BfArM & GDG Chair, *Germany*

Co-Chair: Joachim Musaus, EMA

Overview of authorised medicines for IBD in Europe - previous regulatory positions

Elmer Schabel, BfArM & GDG Chair, *Germany* **(15')**

Induction and maintenance of remission in IBD: Where are we coming from; where could we go?

Geert D'Haens, Academic Medical Center, University of Amsterdam, *The Netherlands* **(20')**

Similarities and discrepancies between adult and paediatric disease and differential drug effects

Frank Rummele, Hôpital Necker Enfants maladies, *France* **(20')**

Discussion (60')

10:55 Coffee Break

11.15 Session 2: Endpoints in clinical trials in adults and children

Chair: Mark Ainsworth, University of Copenhagen & GDG member, *Denmark*

Co-Chair: Daniel Brasseur, Federal Agency for Medicines and Health Products & CHMP member, *Belgium*

Evaluation of treatment effect in UC and CD (adults)

Simon Travis, John Radcliffe Hospital, *United Kingdom* **(15')**

Evaluation of treatment effect in UC and CD (children)

Nick Croft, Barts and the London NHS Trust **(15')**

Discussion (60')

12:45 **Lunch break**

13:45 **Session 3: Paediatric IBD**

Chair: Andrew Mulberg, FDA
Co-Chair: Richard Vesely, EMA

PDCO current approaches
Chrissi Pallidis, EMA **(10')**

Oxford debate: Placebo control in paediatric clinical trials
Dan Turner against placebo, Shaare Zedek Medical Center, Israel **(15')**
Athos Bousvaros pro-placebo, Children's Hospital Boston, USA **(15')**

Discussion (30')

14:55 **Coffee Break**

15:15 **Session 4: What are the alternatives?**

Chair: Jan Taminiau, Universitair Ziekenhuis Antwerpen & PDCO member, Belgium
Co-Chair: Chrissi Pallidis, EMA

Alternative study designs and their suitability for paediatric development
Frank Petavy, EMA **(15')**

Extrapolation in paediatric IBD
Richard Vesely, EMA **(20')**

Pharmacokinetics and dose finding
Christine Hon, FDA **(20')**

Discussion (40')

17:00 **Break**

17:30 **Session 5: Compiling Discussions**

Chair: Richard Vesely, EMA
Co-Chair: Joachim Musaus, EMA

19:30 **End of meeting**

Conference venue and Secretariat

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Website www.ema.europa.eu

Registration

Your registration is personal and non-transferrable. Should you not be available and wish to send a representative, please contact the Conference team via IBD_Workshop@ema.europa.eu

Travel and Accommodation

Participants must possess valid travel documents and, where relevant, a visa for entry into the United Kingdom. Should you require an official letter of invitation, please contact IBD_Workshop@ema.europa.eu

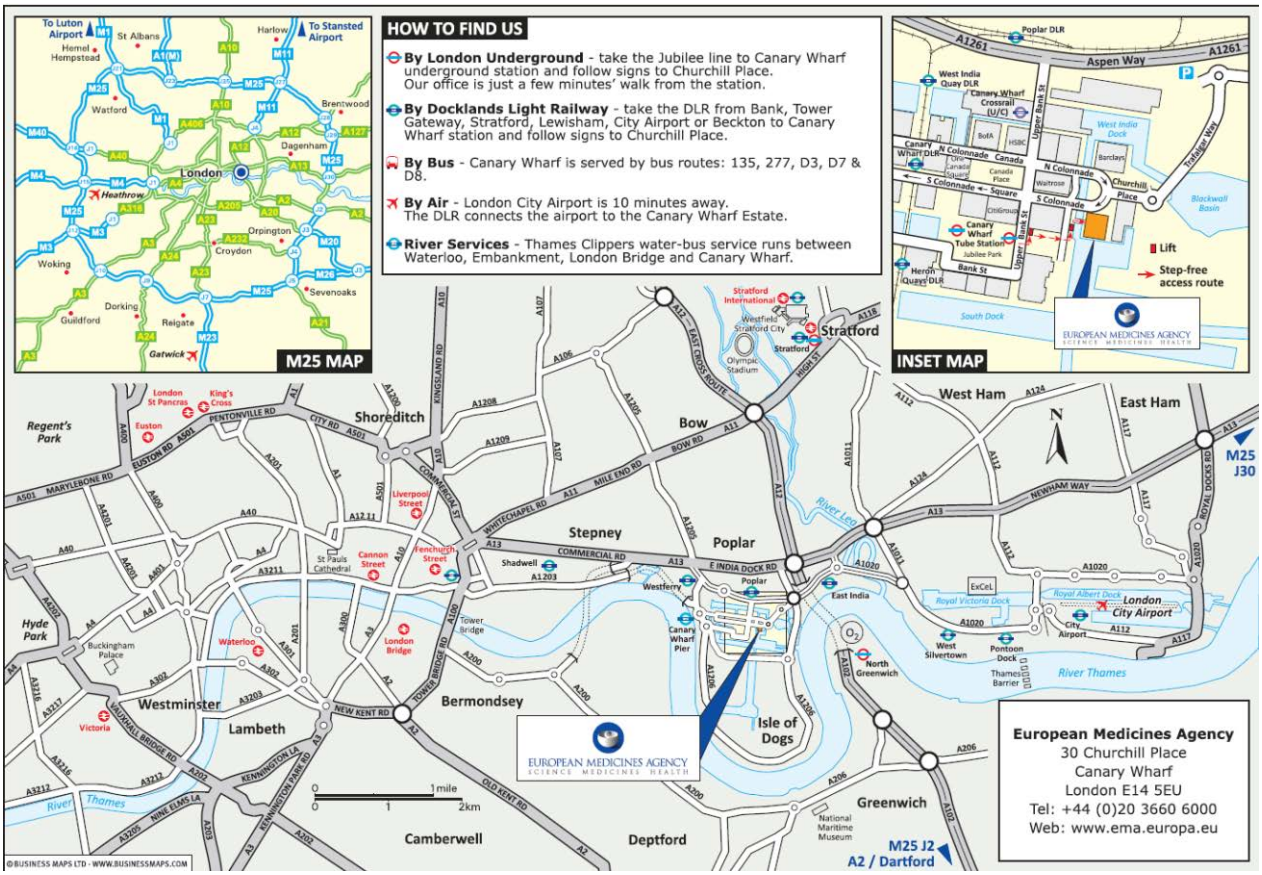
Recording and Photography

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on the European Union. The conference will be recorded. By attending these events you consent to any photographing, recording, broadcast and publication of presentations on the EMA website.

Contact

Should you have any questions, please contact Monica Simeoni or Joachim Masaus via IBD_Workshop@ema.europa.eu

Directions to European Medicines Agency and map of the area



By Docklands Light Railway (DLR)

Both venues are a short walk from Canary Wharf or Heron Quays station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.

By Underground

The nearest stop for both venues is Canary Wharf station on the Jubilee Line.

By Bus

Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.

River services

River services run between Embankment, London Bridge and Canary Wharf throughout the day. Canary Wharf pier is roughly a 15-minute walk from the European Medicines Agency.

From London City Airport

Take a taxi to Canary Wharf, or catch the DLR to Westferry station then change to the DLR to Canary Wharf.

Useful links

http://www.tfl.gov.uk/

National Rail

Gatwick Express

Heathorw Express

Stansted Express

Eurostar

Heathrow airport

Gatwick airport

London City

London Stansted

Hillgate travel