

3 July 2018
EMA/457607/2018
Human Medicines Evaluation Division

EMA stakeholder interaction on the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH)

Invitation for expressions of interest

The European Medicines Agency (EMA) announces a one-day workshop on the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH). The workshop will be held at the EMA, in London, UK on 3 December 2018.

Objectives of the planned workshop

- Discuss the difficulties and opportunities for drug development in the field of chronic liver disease (PBC, PSC, NASH), which should include:
 - Identification of appropriate endpoints including validation of adequate surrogate endpoints/biomarkers
 - Suitable study populations
 - Potentially adequate trial designs
- Discuss similarities and differences of the disease entities and their impact on regulatory requirements.
- Specify needs and anticipated problems of Paediatric drug development

Expressions of interest

We invite interested experts and stakeholders to send an expression of interest to attend this workshop by 31 October to CNILD_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 13th November 2018.