EUFEMED 1st DISCUSSION FORUM

The New FIH EMA Guideline: Disruptive or Constructive?

19 September 2018
KU LEUVEN, BELGIUM

VENUE

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PROGRAMME

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250 € Members
350 € Non-Members
100 € Young Scientists below the age of 30 years

rates valid until the 14th of September 2018 at midnight (CET)

The revised ‚EMA Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products' has been published on 20 July 2017 and came into operation on 01 February 2018. Accordingly, all stakeholders have gathered first experiences with implementation of the required changes.

To collect structured information on these first experiences and any difficulties arising from the updated recommendations on early phase clinical trials, EUFEMED has conducted a survey among stakeholders involved in early medicines development, taking up an initiative from the French Club Phase I.
The results will be presented and discussed with Competent Authority Representatives from EUFEMED countries / EMA as well as with Sponsors, Investigators, and CROs.
Areas of success and fields for further improvement will be identified and resolution of open questions will be sought.

You are most kindly invited to form part of an interactive audience contributing to overcome any remaining challenges.

The meeting will be thoroughly minuted and a final protocol will reflect (i) mutually agreed solutions regarding the implementation of the revised guideline and (ii) points requiring further debate.

The meeting will be thoroughly minuted and a final protocol will reflect (i) the points requiring further clarification as well as (ii) the mutually agreed solutions regarding the implementation of the revised guideline.

H. Sourgens, President EUFEMED
J. de Hoon, Secretary EUFEMED (hosting this meeting at Leuven University)
Y. Donazzolo, President Elect EUFEMED

09:30 Registration

10:30 Welcome note and Introduction

J. de Hoon, Leuven, Belgium

10:40 The revised guideline - disruptive or constructive?

Moderator: H. Sourgens, Y. Donazzolo, J. de Hoon
Minutes: T. Hardman, London, UK

Initial votes taken from the audience

10:45 Results of the EUFEMED Survey as compared with the Club Phase I Survey

H. Sourgens, Munich, Germany
Y. Donazzolo, Grenoble, France

11:25 The European Regulators‘ perspective

- Does the outcome of this survey reflect the impressions from your daily business?
- Do you experience other qualms not addressed in the survey?
- What are the future expectations of the Regulators following the revised guideline regarding the Applications for Clinical Trial Authorisation?

12:00 Collecting pivotal points for the subsequent panel discussion

12:30 Break

13:30 Panel discussion on non-clinical aspects

- Questions from the audience / Case examples
- Areas for potential improvement as identified by the audience and faculty
- Road map for resolutions of any remaining issues

14:15 Panel discussion on clinical aspects

- Questions from the audience / Case examples
- Areas for potential improvement as identified by the audience and faculty
- Road map for resolutions of any remaining issues

15:15 Break

15:35 Panel discussion on regulatory issues and harmonisation between countries

- Do applicants go "shopping" for the country / agency with the perceived lowest hurdles?
- What about harmonisation of Clinical Trial Application Approvals accross EU?
- How to make sure Europe stays attractive for early clinical medicines development

16:10 The revised guideline - disruptive or constructive? Impact of the debate on your opinion
Final votes taken from the audience

16:15 How can EUFEMED support a smooth implementation of the revised EMA FIH guideline?

16:30 Wrap up

16:45 End of the Forum

FACULTY MEMBERS

Prof. Dr. Jan de Hoon	University Leuven, Belgium
Dr. Izaak den Haas	QPS, Groningen, Netherlands
Dr. Yves Donazzolo	Eurofins Optimed, Grenoble, France
Dr. Tim Hardman	Niche Science & Technology, Richmond, UK
Dr. Sarah Heil	BfArM Bonn, Germany
Dr. Mario Iovino	Boehringer Ingelheim, Germany
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