

PopSim Meeting

March 14, 2019 at 14.30-17.00
Ferring Pharmaceuticals A/S, Kay Fiskers Plads 11, Copenhagen

Updated EMA guideline Background and implications for design of First-In-Man trials

An update of the EMA guideline on strategies to identify and mitigate risks for first-in-man and early clinical trials came into effect on February 1st, 2018. This update was directly motivated by a serious accident occurring during a first-in-man trial conducted for the pharmaceutical company Bial.

At this PopSim meeting we will have a close look at the trial that has influenced how early clinical trials are conducted today and learn about the implications for the design of these trials. In the second half of the meeting, participants will be applying these principles for designing a first-in-man trial based on available nonclinical data for a hypothetical compound.



Please feel free to forward this invitation to any colleagues with an interest in first-in-man trial design, as the meeting will be relevant also for those without a background in modelling.

Meeting Programme

14:30 Welcome

14:35 Reason for guideline update: The Bial case (Trine Høyer Rose, Novo Nordisk)

15:00 Implications of the revised EMA guideline for early clinical trials (Mia Lundblad, Ferring Pharmaceuticals)

15:45 Coffee break and networking

16:15 Workshop

- Interactive discussion in small groups: hands-on design of first-in-man trials
- Discussion of pros and cons of proposed trial designs

16:55 Closing remarks

Registration

Please register for the event at our website:

<http://farmaceutisk-selskab.dk/arrangementer/popsim-meeting-first-in-man-trials/>

PopSim Membership

Participation is free of charge. However, if you value PopSim as a place to develop your network and scientific horizon within quantitative pharmacology, please support us by getting a membership (275kr/year) for our organisation within the Danish Pharmaceutical Society.

<http://farmaceutisk-selskab.dk/en/indmeldelse/>

Best regards,

Stine Timmermann Ottesen, Lene Alifrangis and Daniël Jonker