Dansk Selskab for Biofarmaceutisk Statistik
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EMA draft guideline on the investigation of subgroups in confirmatory clinical trials

Thursday 10 April 2014 at 09:00 – 10:30

Dear DSBS member,

You are hereby invited to a discussion meeting on the new EMA draft guideline on the investigation of subgroups in confirmatory clinical trials. This should be of interest to all of you given the challenges of differentiation of our new products, both at the regulatory approval level and at the HTA level. We plan to provide consolidated DSBS comments to the draft guideline and feed those back via EFSPI. This is an excellent opportunity for you to participate in the process.

The meeting will take place at

H. Lundbeck A/S, Ottiliavej 9, 2500 Valby

Please sign in at the reception at the northern gate (from Ottiliavej) where someone will pick you up.

Agenda:

09:00-10:30:: *Presentation and discussion of the draft guideline*
Kristian Windfeld, Lead Specialist, Biometrics
H. Lundbeck A/S

The intention is for this to be an interactive session with active participation from you so please read the guideline before the meeting and come prepared to share your views.

Don't miss this opportunity to discuss this important new draft guideline and meet your colleagues from other companies in the area.

Please send an email to krwi@lundbeck.com to register for the meeting.

Kind regards,

DSBS board