



**Joint FMS/DSBS Meeting**  
***Statistical analysis of risks and safety data***  
**November 1, 2016**  
**Radisson Blu Hotel, Malmö**

**Programme**

<b>08.00 – 09.00</b>	<b>Registration and Breakfast</b>
<b>09.00 – 09.10</b>	<b>Welcome and Opening of Meeting</b> <i>Paul Dickman, President of FMS</i> <i>Charlotte Hindsberger, President of DSBS</i>
<b>09.10 – 10.00</b>	<b>Application of extreme value modelling to safety data from clinical trials</b> <i>Harry Southworth, Data Clarity Consulting Ltd., UK</i>
<b>10.00 – 10.20</b>	<b>Coffee</b>
<b>10.20 – 11.10</b>	<b>Use of survival analysis methods in the assessment of safety</b> <i>Per Kragh Andersen, Biostatistics, University of Copenhagen</i>
<b>11.10 – 12.00</b>	<b>Recent regulatory considerations on summarising safety data from clinical trials</b> <i>Andrew Thomson, European Medicines Agency, UK</i>
<b>12.00 – 13.00</b>	<b>Lunch</b>
<b>13.00 – 13.30</b>	<b>Drug safety during pregnancies – Evaluation with register based pharmacoepidemiology</b> <i>Pär Karlsson, Centre for Pharmacoepidemiology, Karolinska Institutet, Stockholm</i>
<b>13.30 – 14.00</b>	<b>Liraglutide and Cardiovascular Outcomes in Type 2 Diabetes</b> <i>Søren Rasmussen, Novo Nordisk, Copenhagen</i>
<b>14.00 – 14.30</b>	<b>Modelling duration of diabetes in a design with matched controls</b> <i>Stefan Franzén, Centre of Registers Västra Götaland, Gothenburg</i>
<b>14.30 – 14.50</b>	<b>Coffee</b>
<b>14.50 – 15.20</b>	<b>Statistical analysis of recurrent events, based on simple frailty models, and extensions</b> <i>Philip Hougaard, Lundbeck, Denmark</i>
<b>15.20 – 15.50</b>	<b>Latent class analysis for more effective exploration of suspected adverse drug reactions</b> <i>Niklas Norén, Uppsala Monitoring Centre</i> <i>WHO Collaborating Centre for International Drug Monitoring, Uppsala</i>
<b>15.50 – 16.00</b>	<b>Closing Remarks</b> <i>Paul Dickman, President of FMS</i> <i>Charlotte Hindsberger, President of DSBS</i>

Register for the meeting at the latest October 17 at:

<https://viceversaeventmanagement.nemtilmeld.dk/14/at-bmafhlr8/>

Conference fee: 1500/750 DKK for industry/academia employees. The fee includes breakfast, lunch and coffee.

