

## Symposium on clinical Pharmacology strategies for small molecules and antibodies

### Programme

- 09.30      **Registration with coffee/tea and sandwich**
- 10.00      **Clinical Pharmacology Strategy from TPP to SmPC:  
Framing the Small Molecule and monoclonal antibody (mAb) Tracks**  
*Angelica Quartino, AstraZeneca*
- 10.15      **Designing Early Phase Studies for Small Molecules**  
*Mia Lundblad, NovoNordisk*
- 11.00      **ADME Foundations and Special Populations for Small Molecules**  
*Anna Nordmark, Clin Pharm Consulting*
- 11.45      **Lunch**
- 12.30      **Small Molecule Drug–drug interactions Strategy:  
From In Vitro Risk Assessment to Clinical Studies and Labeling**  
*Eva Berglund, Certara*
- 13.15      **Managing Formulation Changes for small molecules and design of  
relative bioavailability/bioequivalence studies**  
*Susanne Proton, AstraZeneca*
- 13.45      **Designing Early Phase Studies for mAbs**  
*René Bouw*
- 14.15      **Drug–drug interactions Strategy for biologics**  
*Carolina Säll (NovoNordisk)*





- 14.45      **Coffee break**
- 15.15      **Immunogenicity risk assessment and evaluation of clinical consequence of ADA**  
*Cecilia Arfvidsson, AstraZeneca*
- 15.45      **Managing formulation and device changes for mAbs and consideration for BA/BE studies**  
*Scott Roberts, NovoNordisk*
- 16.15      **Translating clinical pharmacology data into the SmPC: Posology, Interactions, Clinical Pharmacology, and Special Populations**  
*Erika Fredriksson, Läkemedelsverket*
- 17.00      **Wrap up and key takeaways**

**Organizers:**

*Anna Nordmark, Mia Lundblad and Angelica Quartino, together with the Section for Pharmacokinetics and Drug Metabolism.*

