



## Curriculum Vitae

Personal information **Irene Nowotny**

### Work experience

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1. Employer: Paul\_Ehrlich\_Institut
  - Start date: 062022
  - End date:
  - Position: Clinical Assessor
  - Activities: Assessments of Clinical Trial Applications Scientific Advices
  - Country: Germany
2. Employer: Sanofi\_Aventis Deutschland GmbH, Frankfurt
  - Start date: 052006
  - End date: 062020
  - Position: Clinical Research Director
  - Activities: Translational medical lead for diabetes/obesity preclinical to Phase III Projects, planning, execution, data evaluation and interpretation of clinical studies
  - Country: Germany
3. Employer: Sanofi\_Aventis Deutschland GmbH, Frankfurt
  - Start date: 032005
  - End date: 042006
  - Position: Departmental Manager Thrombosis and Angiogenesis
  - Activities: Quality Management, review of alliances and renewal of contracts, budget planning
  - Country: Germany
4. Employer: Aventis Pharma
  - Start date: 012000
  - End date: 022005
  - Position: Project Manager
  - Activities: Management of projects from candidate identification to end of Phase II in the area of cardiovascular and thrombosis
  - Country: Germany
5. Employer: Hoechst AG
  - Start date: 011993
  - End date: 121999
  - Position: Study Manager
  - Activities: Management of Phase III studies
  - Country: Germany

### Education and training

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1. Subject: Johannes\_Gutenberg University Mainz
  - Start date: Dec 1989
  - End date: Nov 1992
  - Qualification: PhD (Dr. rer. nat)
  - Organisation: Plant physiology
  - Country: Germany

### Additional information

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#### Publications

1. Geddes A, Thaler M, Schonwald S, Härkönen M, Jacobs F, Nowotny I. Levofloxacin in the empirical treatment of patients with suspected bacteraemia/sepsis: comparison with imipenem/cilastatin in an open, randomized trial. *Journal of Antimicrobial Chemotherapy*, 1999; 44: 799–810
2. Becker R, Nowotny I, Teichert L, Bergmann K, Kapitza C. Low within - and between - day variability in exposure to new insulin glargine 300 U/ml. *Diabetes Obes Metab*, 2015; 17: 261\_267
3. Becker R, Nowotny I, Teichert L, Bergmann K, Kapitza C. Reproduzierbar Schwankungsarme Blutspiegel beim Neuen Insulin Glargin 300 E/ml. *Diabetologie und Stoffwechsel* 2015; 10 \_ P226
4. Kapitza C, Nowotny I, Lehmann A, Bergmann K, Rotthaeuser B, Nosek L, Becker RHA. Similar pharmacokinetics and pharmacodynamics of rapid - acting insulin lispro products SAR342434 and US - and EU - approved Humalog in subjects with type 1 diabetes. *Diabetes Obes Metab*. 2017; 19: 622– 627
5. Pohlmeier H, Berard L, Brulle\_Wohlhueter C, Wu J, Dahmen R, Nowotny I, Klonoff D. Ease of Use of the Insulin Glargine 300 U/ml Pen Injector in Insulin\_Naïve People With Type 2 Diabetes. *J Diabetes Sci Technol*. 2017; 11: 263\_269.
6. Thrasher J, Surks H, Nowotny I, Pierre S, Rotthaeuser B, Wernicke\_Panten K, Garg S. Safety of Insulin Lispro and a Biosimilar Insulin Lispro When Administered Through an Insulin Pump. *J Diabetes Sci Technol*. 2018 May;12(3):680\_686
7. Kapitza C, Nosek L, Schmider W, Teichert L, Nowotny I. Single\_Dose Euglycemic Clamp Study Demonstrating Pharmacokinetic and Pharmacodynamic Similarity Between SAR341402 Insulin Aspart and US\_ and EU\_ Approved Versions of Insulin Aspart in Subjects. *Diabetes Technology & Therapeutics* 2020; 22: 278\_284
8. Thrasher J, Polsky S, Hovsepian L, Nowotny I, Pierre S, Bois De Fer B, Bhargava A, Mukherjee B, Garg SK. Safety and Tolerability of Insulin Aspart Biosimilar SAR341402 Versus Originator Insulin Aspart (NovoLog) When Used in Insulin Pumps in Adults with Type 1 Diabetes: A Randomized, Open\_Label Clinical Trial. *Diabetes Technol Ther*. 2020 Sep;22(9):666\_673
9. Kapitza C, Nosek L, Schmider W, Teichert L, Mukherjee B, Nowotny I. A single - dose euglycaemic clamp study in two cohorts to compare the exposure of SAR341402 (insulin aspart) Mix 70/30 with US - and European - approved versions of insulin aspart Mix 70/30 and SAR341402 rapid - acting solution in subjects with type 1 diabetes. *Diabetes, Obesity and Metabolism* 2021, 23(3): 674\_ 681.
10. Shiramoto M, Yoshihara T, Schmider W, Takagi H, Nowotny I, Kajiwara M, Muto H. Pharmacokinetic and pharmacodynamic similarity between SAR341402 insulin aspart and

Japan\_approved NovoRapid in healthy Japanese subjects. *Sci Rep* 2021, 11: 1\_7 11. Shiramoto, M., Yoshihara, T., Schmider, W., Takahashi, Y., Nowotny, I., Kajiwara, M., & Muto, H. Similar Pharmacokinetics and Pharmacodynamics of Biosimilar SAR342434 Insulin Lispro and Japan - Approved Humalog Insulin Lispro in Healthy Japanese Subjects. *Clin Pharmacol Drug Dev.* 2022 Jun;11(6):754\_760 12. Bossart M, Wagner M, Elvert R, Evers A, Hübschle T, Kloeckener T, Lorenz K, Moessinger C, Eriksson O, Velikyan I, Pierrou S, Johansson L, Dietert G, Dietz\_Baum Y, Kissner T, Nowotny I, Einig V, Jan C, Rharbaoui F, Gassenhuber J, Prochnow H, Agueusop I, Porksen N, Smith W, Nitsche A, Konkar A. Effects on weight loss and glycemic control with SAR441255, a potent unimolecular peptide GLP\_1/GIP/GCG receptor triagonist. *Cell Metabolism* 2022; 34: 59–74 13. Stechl J, Nowotny I, Pfeiffer C, Pinquier JL, Msihid J. Glp\_1 agonist for use in the treatment of stenosis or/and obstruction in the biliary tract. <https://patents.google.com/patent/WO2013050379A1/en>

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