

## Curriculum Vitae

Personal information **Martina Weise**

### Work experience

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1. Employer: Federal Institute for Drugs and Medical Devices (BfArM)
  - Start date: 072016
  - End date:
  - Position: Head, Licensing Division 2
  - Activities: The position includes scientific and personnel responsibility for three multidisciplinary units, one unit on special toxicology and an administration unit.
  - Country: Germany
2. Employer: Federal Institute for Drugs and Medical Devices (BfArM)
  - Start date: 102011
  - End date: 062016
  - Position: Head, Unit on Diabetes/Cardiovascular Disorders
  - Activities: The position included scientific and personnel responsibility for a multidisciplinary team consisting of quality, non\_clinical and clinical assessors, and secretaries.
  - Country: Germany
3. Employer: Federal Institute for Drugs and Medical Devices (BfArM)
  - Start date: 072005
  - End date: 092011
  - Position: Head, Unit on Endocrinology/Gynecology
  - Activities: The position included scientific and personnel responsibility for a multidisciplinary team consisting of quality, non\_clinical and clinical assessors, and secretaries.
  - Country: Germany
4. Employer: Federal Institute for Drugs and Medical Devices (BfArM)
  - Start date: 102001
  - End date: 062005
  - Position: Head, Unit on Endocrinology/Diabetes
  - Activities: The position included scientific and personnel responsibility for a clinical assessor team and secretaries.
  - Country: Germany
5. Employer: Developmental Endocrinology Branch, National Institute of Child Health and Human Development, National Institutes of Health
  - Start date: 071997
  - End date: 092001
  - Position: Clinical Fellow
  - Activities: Fellowship in paediatric endocrinology including inpatient and outpatient care, mainly in children but also adults. Clinical, animal and laboratory research on epiphyseal, bone and adrenal disorders.
  - 1997 Permanent ECFMG certification (USA).
  - Country: United States
6. Employer: Developmental Endocrinology Branch, National Institute of Child Health and Human Development, National Institutes of Health
  - Start date: 011997
  - End date: 061997
  - Position: Adjunct Scientist
  - Activities: Animal and laboratory research on epiphyseal and bone disorders
  - Country: United States
7. Employer: Department of Paediatrics, Johann Wolfgang Goethe\_University, Frankfurt am Main
  - Start date: 021988
  - End date: 071989
  - Position: Clinical Fellow
  - Activities: Outpatient care in children with endocrinological disorders. Clinical research.
  - Country: Germany

### Education and training

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1. Department of Paediatrics, Johann Wolfgang Goethe\_University, Frankfurt am Main
  - Start date: 081989
  - End date: 061995
  - Qualification: Board Certificate in Paediatrics
  - Training in all subspecialties of Paediatrics according to curriculum. Board Certification in Paediatrics in June 1995. Doctoral thesis with doctor's degree in 1992.
  - Country: Germany
2. Johann Wolfgang Goethe\_University, Frankfurt am Main
  - Start date: 041980
  - End date: 121986
  - Qualification: Medical doctor (MD)
  - Medical training including one year of internship.
  - Country: Germany

### Additional information

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## Publications

1. Groll A, Meiser A, Weise M, Rettwitz\_Volk W, v.Loewenich V, Gussetis ES, Kornhuber B. Interleukin-6 as early mediator in neonatal sepsis. *Pediatr Infect Dis J* 1992; 11: 496\_8 2. Groll A, Wildfeuer A, Weise M, Gussetis ES, Schwabe D, Gerein V, Kornhuber B. Pharmacokinetics of fluconazole in a pediatric subgroup. In: Adam D, Lode H, Rubinstein E (eds.). *Recent Advances in Chemotherapy*. Futuramed Publishers, Munich 1992: 526\_527E 3. Weise M, James D, Leitner CH, Hartmann KKP, Boehles HJ, Attanasio A and the German Lilly UTS Study Group. Glucose metabolism in Ullrich Turner\_Syndrome: Long term effects of therapy with Human Growth Hormone. *Horm Res* 1993; 39: 36\_41 4. Weise M, James D, Hartmann KH, Reinhardt D, Leitner CH, Boehles HJ, Attanasio A and the German Lilly UTS Study Group. Dose\_dependent effect of growth hormone therapy on glucose metabolism in subjects with Turner Syndrome. *Horm Res* 1993; 39(Suppl 2): 25\_9 5. Groll A, Nowak\_Goettl U, Wildfeuer A, Weise M, Schwabe D, Gerein V, Kornhuber B. Fluconazole treatment of oropharyngeal candidosis in pediatric cancer patients with severe mucositis following antineoplastic chemotherapy. *Mycoses* 1993; 35 (Suppl 1): 35\_40 6. Weise M, Abad V, Considine RV, Nieman LK, Rother KI. Leptin secretion in Cushing's syndrome: Preservation of diurnal rhythm and absent response to Corticotropin\_Releasing Hormone. *J Clin Endocrinol Metab* 1999; 84(6):2075\_9 7. Merke DP, Chrousos GP, Eisenhofer G, Weise M, Keil MF, Rogol AD, Van Wyk JJ, Bornstein SR. Adrenomedullary dysplasia and hypofunction in patients with classic 21\_hydroxylase deficiency. *New Engl J Med* 2000; 343(19):1362\_8 8. Weise M, De\_Levi S, Barnes KM, Gafni RI, Abad V, Baron J. Effects of estrogen on growth plate senescence ad epiphyseal fusion. *Proc Natl Acad Sci USA* 2001; 98(12):6871\_6 9. Gafni RI, Weise M, Robrecht DT, Meyers JL, Barnes KM, De\_Levi S, Baron J. Catch\_up growth is associated with delayed senescence of the growth plate in rabbits. *Pediatr Res*. 2001; 50(5):618\_23 10. Abad, V., Meyers, J.L., Weise, M., Gafni, R.I., Barnes, K.M., Nilsson, O., Bacher, J.D., Baron, J. The role of the resting zone in growth plate chondrogenesis. *Endocrinology* 2002, 143(5):1851\_7 11. Gafni RI, McCarthy EF, Hatcher T, Meyers JL, Inoue N, Reddy C, Weise M, Barnes KM, Abad V, Baron J. Recovery from osteoporosis through skeletal growth: early bone mass acquisition has little effect on adult bone density. *FASEB J*. 2002, 16(7):736\_8 12. Weise M, Merke DP, Pacak K, Walthers MM, Eisenhofer G. Utility of plasma free metanephrines for detecting childhood pheochromocytoma. *J Clin Endocrinol Metab* 2002, 87(5):1955\_60 13. Charmandari E, Weise M, Bornstein SR, Eisenhofer G, Keil MF, Chrousos GP, Merke DP. Children with classic congenital adrenal hyperplasia have elevated serum leptin concentrations and insulin resistance: potential clinical implications. *J Clin Endocrinol Metab* 2002, 87(5):2114\_20 14. Weise M, Eisenhofer G, Merke DP. Pubertal and gender\_related changes in the sympathoadrenal system in healthy children. *J Clin Endocrinol Metab* 2002, 87(11):5038\_43 15. Pacak K, Weise M, Eisenhofer G, Brouwers FM, Koch CA. Disorders of the adrenal medulla: Catecholamine\_Producing Tumors in Childhood. In *Pediatric Endocrinology*, 4th ed, New York: Marcel Dekker; ed F Lifshitz, 2003 16. Weise M, Flor A, Barnes KM, Cutler Jr. GP, Baron J. Determinants of growth during GnRH analog therapy for precocious puberty. *J Clin Endocrinol Metab* 2004, 89(1):103\_7 17. Weise M, Mehlinger SL, Drinkard B, Charmandari E, Hiroi M, Eisenhofer G, Yanovski J, Chrousos GP, Merke DP. Patients with classic congenital adrenal hyperplasia have decreased catecholamine reserve and defective glucose elevation in response to high intensity exercise. *J Clin Endocrinol Metab* 2004, 89(2):591\_7 18. Weise M, Drinkard B, Mehlinger SL, Rawson E, Charmandari E, Hiroi M, Eisenhofer G, Chrousos GP, Merke D. Stress dose of hydrocortisone is not beneficial in patients with classic congenital adrenal hyperplasia undergoing short\_term high\_intensity exercise. *J Clin Endocrinol Metab* 2004, 89(8):3679\_84. (Editorial pp. 3677\_78) 19. Liza Green\_Golan, Catherine Yates, Bart Drinkard, Carol VanRyzin, Graeme Eisenhofer, Martina Weise, Deborah P. Merke. Patients with Classic Congenital Adrenal Hyperplasia Have Decreased Epinephrine Reserve and Defective Glycemic Control During Prolonged Moderate\_Intensity Exercise. *J Clin Endocrinol Metab* 2007, 92: 3019\_3024 20. Kathleen Coyle, Kristina I.Rother, Martina Weise, Alaa Ahmed, Frederick W. Miller, Lisa G. Rider. Metabolic Abnormalities and Cardiovascular Risk Factors in Children with Myositis. *J Pediatr* 2009, 155(6): 882\_7 21. Martina Weise, Christian K Schneider. Biosimilars in the EU: the interplay of regulators, treating physicians and pharmacists. *Hospital Pharmacy Europe* 2009, 43: 31\_35 22. Somya Verma, Liza Green\_Golan, Carol VanRyzin, Bart Drinkard, MSPT, Martina Weise, Graeme Eisenhofer, Deborah Merke. Adrenomedullary Function in Patients with Nonclassic Congenital Adrenal Hyperplasia. *Horm Metab Res* 2010, 42(8):607\_612 23. Büttel IC, Chamberlain P, Chowen Y, Ehmann F, Greinacher A, Jefferis R, Kramer D, Kropshofer H, Lloyd P, Lubiniecki A, Krause R, Mire\_Sluis A, Platts\_Mills T, Ragheb JA, Reipert BM, Schellekens H, Seitz R, Stas P, Subramanyam M, Thorpe R, Trouvin JH, Weise M, Windisch J, Schneider CK. Taking immunogenicity assessment of therapeutic proteins to the next level. *Biologicals* 2011, 39(2):100\_9 24. Harald G. Enzmann, Martina Weise. Current European Regulatory Perspectives on Insulin Analogues. *Diabetol Metab Syndr* 2011, 3:14 25. Martina Weise, Marie\_Christine Bielsky, Karen De Smet, Falk Ehmann, Niklas Ekman, Narayanan Gopalan, Hans\_Karl Heim, Esa Heinonen, Kowid Ho, Robin Thorpe, Camille Vlemminckx, Meenu Wadhwa, and Christian K Schneider. Biosimilars – Why terminology matters. *Nature Biotechnol* 2011, 29(8):690\_3 26. Schneider CK, Borg JJ, Ehmann F, Ekman N, Heinonen E, Ho K, Hoefnagel MH, van der Plas RM, Ruiz S, van der Stappen AJ, Thorpe R, Tiitso K, Tsiftoglou AS, Vlemminckx C, Waxenecker G, Welin M, Weise M, Trouvin JH; Working Party on Similar Biological (Biosimilar) Medicinal Products (BMWP); Biologicals Working Party (BWP) of the Committee for Medicinal Products for Human Use (CHMP). In support of the European Union biosimilar framework. *Nature Biotechnol* 2012, 30:745\_8 27. Martina Weise, Marie\_Christine Bielsky, Karen De Smet, Falk Ehmann, Niklas Ekman, Thijs J Giezen, Iordanis Gravanis, Hans\_Karl Heim, Esa Heinonen, Kowid Ho, Alexandre Moreau, Gopalan Narayanan, Nanna A Kruse, Gabriele Reichmann, Robin Thorpe, Leon van Aerts, Camille Vlemminckx, Meenu Wadhwa, and Christian K Schneider. Biosimilars: what clinicians should know. *Blood* 2012, 120(26):5111\_7 28. Schneider CK, Vlemminckx C, Gravanis I, Ehmann F, Trouvin JH, Weise M, Thirstrup S. Setting the stage for biosimilar monoclonal antibodies. *Nat Biotechnol*. 2012, 30(12):1179\_85 29. Nilsson O\*, Weise M\*, Landman EB, Meyers JL, Barnes KM, Baron J. Evidence that estrogen hastens epiphyseal fusion and cessation of longitudinal bone growth by irreversibly depleting the number of resting zone progenitor cells in female rabbits. *Endocrinology* 2014, 155(8):2892\_9. \*shared first authorship 30. Weise M, Kurki P, Wolff\_Holz E, Bielsky MC, Schneider CK. Biosimilars: the science of extrapolation. *Blood* 2014, 20(22):3191\_6 31. Manuel Haas, Viktor Vleck, Pavel Balabanov, Tomas Salmonson, Serge Bakchine, Greg Markey, Martina Weise, Gabriele Schlosser\_Weber, Henning Brohmann, Concepcion Prieto Yerro, Macarena Rodriguez Mendizabal, Violeta Stoyanova\_Beninska, Hans L. Hillege. European Medicines Agency review of ataluren for the treatment of ambulant patients aged 5 years and older with Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene. *Neuromuscular Disorders* 2015, 25(1):5\_13 32. Schneider CK, Weise M. Regulatory aspects of biosimilars: Myths and facts. *Z Rheumatol* 2015, 74(8):695\_700 33. Lemery SJ, Esteva FJ, Weise M. Biosimilars: Here and Now. *AM Soc Clin Oncol Educ Book* 2016, 35:e151\_7 34. Weise M, Wolff\_Holz E. Opportunities and challenges of extrapolation for biosimilars. *Z Gastroenterol* 2016 Nov;54(11):1211\_1216 35. Anton R, Haas M, Arlett P, Weise M, Balabanov P, Mazzaglia G, Prieto L, Keller\_Stanislawski B, Raine J. Drug\_induced progressive multifocal leukoencephalopathy in multiple sclerosis: European regulators' perspective. *Clin Pharmacol Ther* 2017, 102(2):283\_289 36. Kurki P, van Aerts L, Wolff\_Holz E, Giezen T, Skibeli V, Weise M. Interchangeability of Biosimilars: A European Perspective. *BioDrugs*. 2017, 31(2):83\_91 37. Weise M. From bioequivalence to biosimilars: How much to regulators dare? *Z Evid Fortbild Qual Gesundhwes*. 2019, 140:58\_62 38. Wolff\_Holz E, Tiitso K, Vlemminckx C, Weise M. Evolution of the EU Biosimilar Framework: Past and Future. *BioDrugs* 2019; 33(6):621\_634 39. Pinheiro LC, Giezen TJ, Wolff\_Holz E, Weise M, Laslop A, Hidalgo\_Simon A. Identifiability of Biologicals: An Analysis Using EudraVigilance, the European Union's Database of Reports of Suspected Adverse Drug Reactions. *Clin Pharmacol Ther* 2021, 110:1311\_1317 40. Kurki P, Kang H\_N, Ekman N, Knezevic I, Weise M, Wolff\_Holz E. Regulatory Evaluation of Biosimilars: Refinement of Principles Based on the Scientific Evidence and Clinical Experience. *BioDrugs* 2022, 36:359\_371 41. Guillen E, Ekman N, Barry S, Weise M, Wolff\_Holz E. A Data Driven Approach to Support Tailored Clinical Programs for Biosimilar Monoclonal Antibodies. *Clin Pharmacol Ther* 2023, 113:108\_123

## Projects

Introduction to the Principles and Practice of Clinical Research. WG Magnuson Clinical Center, National Institutes of Health, USA (Oct 1998 \_ March 1999, prerequisite for participation in clinical trials at NIH. Participation in clinical trials (completed) 1. Growth\_hormone treatment in children with Ullrich Turner Syndrome (UTS), a German multicenter, randomized, placebo\_controlled study. 2. Catecholamine Reserve and Exercise Tolerance in Subjects with Congenital Adrenal Hyperplasia and in Healthy Controls (USA). 3. A Double\_Blind, Randomized, Placebo\_Controlled Trial of the Effect of Biosynthetic Growth Hormone and/or Ethinyl Estradiol on Adult Height in Patients with Turner Syndrome (USA). 4. Different endocrine studies in healthy children and in children with congenital adrenal hyperplasia, Cushing's syndrome or pheochromocytoma (USA). Regulatory Guidelines:

Involvement in the drafting and revision of various CHMP guidelines especially in the field of Diabetes and Biosimilars and of WHO guidelines on Biotherapeutic products prepared by Recombinant DNA Technology and on Similar Biotherapeutic Products.

#### Memberships

German member of the CHMP. Member of the Working Party on Similar Biological Medicinal Products (BMWP) of the CHMP. Expert to the WHO regarding biosimilars.

#### Other Relevant Information