Curriculum Vitae

Personal information

Frauke Naumann-Winter

Work experience

1. Employer: Federal Institute for Drugs and Medical Devices (BfArM)
   - Start date: 2007
   - End date:
   - Position: Clinical assessor
   - Activities: Clinical assessor for oncology, COMP member since 2013, Vice Chair since 2024
   - Country: Germany
2. Employer: University of Cologne
   - Start date: 2005
   - End date: 2007
   - Position: PostDoc
   - Activities: Editorial base of Cochrane Haematological malignancies group
   - Country: Germany
3. Employer: Institut Pasteur
   - Start date: 2004
   - End date: 2005
   - Position: PostDoc
   - Activities: Postdoctoral research
   - Country: France

Education and training

1. Subject: Epidemiology
   - Start date: 2006
   - End date: 2010
   - Qualification: European M.Sc. Epidemiology
   - Organisation: University of Mainz
   - Country: Germany
2. PhD Biology (Genetics)
   - Start date: 1999
   - End date: 2003
   - Qualification: PhD Molecular Biology
   - Organisation: University of Cologne
   - Country: Germany
3. Diploma (Biology)
   - Start date: 1991
   - End date 1998
   - Qualification: Diploma in Biology
   - Organisation: Universities of Düsseldorf and Cologne
   - Country: Germany

Additional information

Publications

Palomo G.M., Pose-Boirazian T., Naumann-Winter F., Costa E., Duarte D.M., Kalland M.E., Malikova E., Matusevicius D., Vitezic D., Larsson K., Magrelli A., Stoyanova-Beninska V., Mariz S. Navigating the orphan medicinal product designation: Evidence requirements for gene therapies in Europe. Mol Ther. 2025 Jun 4;33(6):2834-2841. doi: 10.1016/j.ymthe.2024.10.015. Epub 2024 Oct 28. PMID: 39489919; PMCID: PMC12172177.

Prilla S., Groeneveld S., Pacurariu A., Restrepo-Méndez M.C., Verpillat P., Torre C., Gartner C., Mol P., Naumann-Winter F., Breen K., Gault N., Gross-Martirosyan L., Benchetrit S., Aylward B., Stoyanova-Beninska V., O'Donovan M., Straus S., Kjaer J., and Arlett P. Real-world evidence to support EU regulatory decision-making - Results from a pilot of regulatory use cases. Clinical Pharmacology & Therapeutics, 2024 Jul 4. doi: 10.1002/cpt.3355.

Kalland M.E., Pose-Boirazian T., Palomo G.M., Naumann-Winter F., Costa E., Matusevicius D., Duarte D.M., Malikova E., Vitezic D., Larsson K., Magrelli A., Stoyanova-Beninska V., Mariz S. Advancing rare disease treatment: EMA's decade-long insights into engineered adoptive cell therapy for rare cancers and orphan designation. Gene Ther. 2024 Mar 14. doi: 10.1038/s41434-024-00446-0.

Palomo G.M., Pose-Boirazian T., Naumann-Winter F., Costa E., Duarte D.M., Kalland M.E., Malikova E., Matusevicius D., Vitezic D., Larsson K., Magrelli. A, Stoyanova-Beninska V., Mariz S. The European landscape for gene therapies in orphan diseases: 6-year experience with the EMA Committee for Orphan Medicinal Products. Mol Ther. 2023 Oct 4:S1525-0016(23)00540-3. doi: 10.1016/j.ymthe.2023.09.020.

Naumann-Winter F., Kaiser T., Behring A. [Evidence-based health care with pharmaceuticals for rare diseases: the role of digitalisation] Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2022 Oct 20. doi: 10.1007/s00103-022-03605-z.

Naumann_Winter F, Wolter F, Hermes U, Malikova E, Lilienthal N, Meier T, Kalland ME, Magrelli A. Licensing of Orphan Medicinal Products_Use of Real_World Data and Other External Data on Efficacy Aspects in Marketing Authorization Applications Concluded at the European Medicines Agency Between 2019 and 2021. Front Pharmacol. 2022 Aug 11;13:920336. doi: 10.3389/fphar.2022.920336. PMID: 36034814; PMCID: PMC9413272.

Sheean ME, Naumann_Winter F, Capovilla G, Kalland ME, Malikova E, Mariz S, Matusevicius D, Nistico R, Schwarzer_Daum B, Tsigkos S, Tzogani K, Larsson K, Magrelli A, Stoyanova_Beninska V. Defining Satisfactory Methods of Treatment in Rare Diseases When Evaluating Significant Benefit_The EU Regulator's Perspective. Front Med (Lausanne). 2021 Aug 27;8:744625. doi: 10.3389/fmed.2021.744625. PMID: 34513895; PMCID: PMC8429787.

Vreman R.A., de Ruijter A.S., Zawada A., Tafuri G., Stoyanova_Beninska V., O'Connor D.J. Naumann_Winter F., Wolter F., Mantel_Teeuwisse A.K., Leufkens H.G.M, Sidiropoulos I., Larsson K. Goettsch W.G. Assessment of significant benefit for orphan medicinal products by European regulators may support subsequent relative effectiveness assessments by health technology assessment organizations. Drug Discov Today 2020 Jul;25(7):1223_1231.doi: 10.1016/j.drudis.2020.04.012.

O'Connor D.J., Sheean M.E., Hofer M.P., Tsigkos S., Mariz S., Fregonese L., Larsson K., Hivert V., Westermark K., Naumann_Winter F., Stoyanova_Beninska V., Barišić I., Capovilla G., Magrelli A., Sepodes B. Defining orphan conditions in the context of the European orphan regulation: challenges and evolution. Nat Rev Drug Disc. 2018/09/12/online. doi.org/10.1038/nrd.2018.128

Ecker A., Mariz S., Naumann_Winter F., Norga K., Barisic I., Girard T., Tomasi P., Mentzer D., Sepodes B. Comparative analysis of the scope of European Union paediatric investigation plans with corresponding orphan designations. Arch Dis Child. 2018 May;103(5):427_430. doi: 10.1136/archdischild_2017_313352.

Tsigkos S., Hofer M.P., Sheean M.E., Mariz S., Larsson K., Naumann_Winter F., Fregonese L., Sepodes B. Establishing rarity in the context of orphan medicinal product designation in the European Union. Drug Discov Today. 2018 Mar;23(3):681_686. doi: 10.1016/j.drudis.2017.06.003.

Polsinelli B., Tsigkos S., Naumann_Winter F., Mariz S., Sepodes B. Evolving prevalence of haematological malignancies in orphan designation procedures in the European Union. Orphanet J Rare Dis. 2017 Jan 21;12(1):17. doi:10.1186/s13023_017_0567_7.

Fregonese L., Greene L., Hofer M., Magrelli A., Naumann_Winter F., Larsson K., Sheean M., Stoyanova_Beninska V., Tsigkos S., Westermark K., Sepodes B. Demonstrating significant benefit of orphan medicines: analysis of 15 years of experience in Europe. Drug Discov Today. 2018 Jan;23(1):90_100. doi: 10.1016/j.drudis.2017.09.010.

Tsigkos S., Mariz S., Llinares J., Fregonese F., Aarum S., Naumann_Winter F, Westermark K. and Sepodes B. Establishing medical plausibility in the context of orphan medicines designation in the European Union. Orphanet Journal of Rare Diseases. Orphanet J Rare Dis. 2014 Dec 5;9:175. doi: 10.1186/s13023_014_0175_8.

Naumann_Winter F., Greb A., Borchmann P., Bohlius J., Engert A. ,Schnell R. First_line double high_dose chemotherapy and autologous stem cell transplantation versus single high_dose chemotherapy and autologous stem cell transplantation in multiple myeloma (Review)., Cochrane Database Syst Rev. (2012) Oct 17; 10:CD004626. doi: 10.1002 / 14651858.CD004626.pub3.

Projects

Memberships

COMP representative in the steering group of ENCePP (since 2019)

Advisory board of EU-funded Real4Reg project

ESEC Oncology

ESEC Methodology

Other Relevant Information