

PERSONAL INFORMATION **Frauke Naumann-Winter**

WORK EXPERIENCE

- 1999–2003 **PhD student/PostDoc**
University of Cologne (Germany)
- 2004–2005 **PostDoc**
Institut Pasteur (France)
- 2005–2007 **Research associate**
University of Cologne (Germany)
Member of the editorial base of the Cochrane Haematological Malignancies Group
- 2007–Present **Clinical assessor**
Federal Institute for Drugs and Medical Devices (BfArM) (Germany)
Clinical assessor for oncology
COMP member since 2013

EDUCATION AND TRAINING

- 2003 **PhD Molecular Biology**
University of Cologne (Germany)
- 2010 **European M.Sc. Epidemiology**
University of Mainz (Germany)

ADDITIONAL INFORMATION

- Expertise** Orphan medicines, epidemiology, molecular biology, oncology
- Publications** 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.
- Demonstrating significant benefit of orphan medicines: analysis of 15 years of experience in Europe. Fregonese L., Greene L., Hofer M., Magrelli A., Naumann-Winter F., Larsson K., Sheean M., Stoyanova-Beninska V., Tsigkos S., Westermark K., Sepodes B. *Drug Discov Today.* 2018 Jan;23(1):90-100. doi: 10.1016/j.drudis.2017.09.010.
- Establishing medical plausibility in the context of orphan medicines designation in the European

Union. Tsigkos S., Mariz S., Llinares J., Fregonese F., Aarum S., Naumann-Winter F, Westermark K. and Sepodes B. (2014) Orphanet Journal of Rare Diseases. Orphanet J Rare Dis. 2014 Dec 5;9:175. doi: 10.1186/s13023-014-0175-8.

Clinical pharmacology of tyrosine kinase inhibitors becoming generic drugs: the regulatory perspective. Eckstein N., Röper L., Haas B., Potthast H., Hermes U., Unkrig C., Naumann-Winter F., Enzmann H. J Exp Clin Cancer Res. (2014);33:15. doi: 10.1186/1756-9966-33-15.

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). Naumann-Winter F., Greb A., Borchmann P., Bohlius J., Engert A., Schnell R., Cochrane Database Syst Rev. (2012) Oct 17; 10:CD004626. doi: 10.1002 / 14651858.CD004626.pub3.

Projects

Memberships Member of the steering group of ENCePP (since 2019)

Other Relevant Information