

PERSONAL INFORMATION

Brigitte Schwarzer-Daum

WORK EXPERIENCE

- January 2003–Present **Vice Chair, Department of Clinical Pharmacology**
Medical University of Vienna (Austria)
- January 1996–January 2000 **Vice Chair, Department of Clinical Pharmacology**
Medical University of Vienna (Austria)
- August 1992–July 1996 **Consultant, Department of Clinical Pharmacology, Vienna**
Medical University of Vienna (Austria)

EDUCATION AND TRAINING

- June 1996–Present **Professor of Clinical Pharmacology**
- June 1996–Present **Registered Consultant in Clinical Pharmacology**
- August 1992–Present **Registered Consultant in Internal Medicine**
- August 1988–August 1992 **Resident**
Vienna University Hospital (Austria)
Department of Internal Medicine (Oncology, Gastroenterology, Endocrinology, Cardiology),
- September 1986–August 1988 **Senior House Officer**
Auckland University Hospital, (New Zealand)
Depts. of Surgery, Accident and Emergency, Orthopaedics, Internal Medicine, Paediatrics,
Gynaecology & Obstetrics
- September 1985–August 1986 **Resident**
Vienna University Hospital (Austria)
Department of Chemotherapy
- October 1978–June 1985 **Doctor of Medicine**
Medical University of Vienna (Austria)

ADDITIONAL INFORMATION

- Expertise** Clinical Pharmacology
Drug Development
Trial Design
Orphan Medicinal Products
Internal Medicine
Oncology

- Publications** Selected Publications

Low risk pragmatic trials do not always require participants' informed consent

Rafael Dal-Ré, Cristina Avendaño-Solà, Brigitte Bloechl-Daum, Anthonius de Boer, Stefan Eriksson, Uwe Fuhr, Søren Holm, Stefan K James, Robert J Mentz, Emilio Perucca, Frits R Rosendaal professor Shaun Treweek:

BRITISH MEDICAL JOURNAL 2019;364:l1092 doi: 10.1136/bmj.l1092 (Published 27 March 2019)

"Data rich, information poor; can we use health records to create a learning healthcare system for pharmaceuticals?" Hans-Georg Eichler, Brigitte Bloechl-Daum, Karl Broich, Paul Kyrle, Jillian Oderkirk, Guido Rasi, Rui Ivo, Ad Schuurman, Thomas Senderovitz, Luke Slawomirski, Martin Wenzl, and Valerie Paris [Paper #2018-0405CR]: CLINICAL PHARMACOLOGY & THERAPEUTICS. 2018 Sep 4. doi: 10.1002/cpt.1226

'Threshold-crossing': a useful way to establish the counterfactual in clinical trials?" by Hans-Georg Eichler*, Brigitte Bloechl-Daum*, Peter Bauer, Frank Bretz, Jeffrey Brown, Lisa Hampson, Peter Honig, Michael Krams, Hubert Leufkens, Robyn Lim, Murray Lumpkin, Martin Murphy, Francesco Pignatti, Martin Posch, Sebastian Schneeweiss, Mark Trusheim, and Franz Koenig: CLINICAL PHARMACOLOGY & THERAPEUTICS. 19. October 2016 100: 699–712. doi:10.1002/cpt.515

* Shared First Author

Hans-Georg Eichler, Lynn G Baird, Richard Barker, Brigitte Bloechl-Daum et al. From adaptive licensing to adaptive pathways: Delivering a flexible life-span approach to bring new drugs to patients Clinical Pharmacology & Therapeutics Volume 97,3, 234–246, (2015) DOI: 10.1002/cpt.59

Hans-Georg Eichler, Brigitte Bloechl-Daum*, Daniel Brasseur, Alasdair Breckenridge, Hubert Leufkens, June Raine, Tomas Salmonson, Christian K. Schneider and Guido Rasi: The risks of risk aversion in drug regulation. Nature Reviews Drug Discovery 12, 907–916 (2013) doi:10.1038/nrd4129

*Corresponding Author and Shared First Author

Hans-Georg Eichler, Eric Abadie, Alasdair Breckenridge, Bruno Flamion, Lars L. Gustafsson, Hubert Leufkens, Malcolm Rowland, Christian K. Schneider and Brigitte Bloechl-Daum*: Bridging the efficacy–effectiveness gap: a regulator's perspective on addressing variability of drug response: Nature Reviews Drug Discovery Volume 10, July 2011, 495-506

*Corresponding Author

The Committee for Orphan Medicinal Products and the European Medicines Agency Scientific Secretariat: Outlook: European regulation on orphan medicinal products: 10 years of experience and future perspectives. European regulation on orphan medicinal products: 10 years of experience and future perspectives.: Westermarck K, Holm BB, Söderholm M, Llinares-Garcia J, Rivière F, Aarum S, Butlen-Ducuing F, Tsigkos S, Wilk-Kachlicka A, N'Diamoi C, Borvendég J, Lyons D, Sepodes B, Bloechl-Daum B, et al. Nature Reviews Drug Discovery 10, 341-349 (May 2011) | doi:10.1038/nrd3445

Hans-Georg Eichler, Brigitte Bloechl-Daum*, Eric Abadie, David Barnett, Franz König & Steven Pearson: Relative efficacy of drugs: an emerging issue between regulatory agencies and third-party payers. Nature Reviews Drug Discovery 9, (April 2010) 277-291

*Corresponding Author and Shared First Author

Pieter Stolk, Harald E Heemstra, Hubert GM Leufkens, Brigitte Bloechl-Daum, Eibert R Heerdink: No difference in between-country variability in use of newly approved orphan and non- orphan medicinal products-a pilot study. Orphanet Journal of Rare Diseases 2009, 4:27

Brigitte Bloechl-Daum, Robert R. Deuson, Panagiotis Mavros, Mogens Hansen, Jørn Herrstedt: Delayed Nausea and Vomiting Continue to Reduce Patients' Quality of Life After Highly and Moderately Emetogenic Chemotherapy Despite Antiemetic Treatment J Clin Oncol 2006 24:4472-4478.

Müller M, Brunner M, Schmid R, Mader RM, Bockenheimer J, Steger GG, Steiner B, Eichler HG, Blöchl-Daum B: Interstitial methotrexate kinetics in primary breast cancer lesions. Cancer Res 1998, 58: 2982-2985

Müller M, Mader RM, Steiner B, Steger GG, Gnant M, Helbich T, Jakesz R, Eichler HG, Blöchl-Daum B: 5-Fluorouracil kinetics in the extracellular tumour space and clinical response in breast cancer patients. Cancer Res 1997, 57:2598-2601

Dorner GT, Pehamberger H, Kornek G, Steger G, Müller M, Kletter K, James P, Breiteneder H, Eichler HG, Blöchl-Daum B: Cisplatin-induced renal effects and thromboxane A2 receptor blockade: Evidence against a major role of thromboxane A2. Eur J Clin Invest 1997, 27:836-839

Blöchl-Daum B, Müller M, Meisinger V, Eichler HG, Fassolt A, Pehamberger H: Measurement of extracellular fluid carboplatin kinetics in melanoma metastases with microdialysis. Brit J Cancer 1996,

73:920-924

Blöchl-Daum B, Mader R, Millesi W, Lang S, Rainer H, Eglmeier R, Müller M, Zanaschka G, Eichler HG: First pass uptake of intra-arterial methotrexate in head and neck cancers. *Eur J Clin Invest* 1996, 26:371-375

Blöchl-Daum B, Pehamberger H, Kurz C, Kyrle PA, Wagner O, Müller M, Monitzer B, Eichler HG: Effects of Cisplatin on urinary thromboxane B2 excretion. *Clin Pharmacol Ther* 1995, 58:418-24

Blöchl-Daum B, Vierhapper H, Eichler HG, Waldhäusl W: Endothelin-induced vasoconstriction is unaffected by type 2 diabetes: in vivo effect of histamine on endothelin action on veins. *Arch Int Pharmacodyn Ther* 1992, 316:90-96

Wagner B, Eichler HG, Schneider B, Blöchl-Daum B, Brenner B, Gasic S, Lechner K, Kyrle PA,: Studies on the effect of two angiotensin-converting enzyme inhibitors, captopril and cilazapril, on platelet and vascular prostaglandin metabolism in vivo. *Naunyn-Schmiedeberg's Arch Pharmacol* 1992, 346:453-456

Eichler HG, Blaschke TF, Kraemer FB, Ford GA, Blöchl-Daum B, Hoffman BB: Responsiveness of superficial hand veins to alpha-adrenergic agonists in insulin-dependent diabetic patients. *Clin Sci* 1992, 82: 163-8

Schütz W, Freissmuth M, Tuisl E, Blöchl-Daum B, Eichler HG, Loew D: Bioequivalence between two furosemide-spirolactone formulations: a pharmacokinetic and pharmacodynamic approach. *Curr Med Res Opin* 1991, 12: 450-8

Blöchl-Daum B, Korn A, Wolzt M, Eichler HG: In vivo studies on alpha adrenergic receptor subtypes in human veins. *Naunyn-Schmiedeberg's Arch Pharmacol* 1991,344:302-7

Blöchl-Daum B, Schuller-Petrovic S, Wolzt M, Korn A, Böhler K, Eichler HG: Primary defect in alpha-adrenergic responsiveness in patients with varicose veins. *Clin Pharmacol Ther* 1991,49:49-52

Wagner B, Schneider B, Blöchl-Daum B, Speiser W, Brenner B, Eichler HG, Lechner K, Kyrle PA: Effect of ritanserin - a 5- hydroxy-tryptamine2 receptor antagonist - on platelet function and thrombin generation at the site of plug formation in vivo. *Clin Pharmacol Ther* 1990, 48: 419-23

Eichler HG, Blöchl-Daum B, Eichler I, Wolzt M, Korn A, Götz M: Normal responsiveness of superficial hand veins to alpha- and beta-adrenergic stimuli in allergic asthma: Effects of terbutaline and prednisolone on beta adrenergic responsiveness. *J Allergy Clin Immunol* 1990, 86: 714-25

Eichler H, Blöchl-Daum B, Kyrle PA, Gasic S: Cilazapril and enalapril inhibit local angiotensin I conversion in human veins, but lack direct venodilating properties. *J Cardiovasc Pharmacol* 1989, 14: 248-52

Blöchl-Daum B, Eichler HG, Rainer H, Jakesz R, Salzer H, Schüller J, Günther E, Proksch B, Ehninger G: Escalating dose regimen of intraperitoneal mitoxantrone - phase I study - clinical and pharmacokinetic evaluation. *Eur J Cancer* 1988, 24: 1133-8

Eichler HG, Mader R, Blöchl-Daum B, Steger G, Rainer H: Poly(l).poly(C), a potential drug carrier for the antitumor agent mitoxantrone - in vitro drug binding study. *Cancer Chemother Pharmacol* 1987, 20: 81-2

Eichler HG, Blöchl-Daum B, Mader R, Rainer H, Steger G, Dittrich C, Moser K, Ehninger G: Coupling of mitoxantrone to poly(l).poly(C) reduces absorption after intraperitoneal administration. *Chemotherapy* 1987, 33:157-9

Projects

Memberships

2005 - Austrian Delegate to the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMA)

2006 - Member of the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines (EMA)

2006 - Member of the Scientific Committee of the Medicinal Products Advisory Council - Austrian Ministry of Health

1996 - 1998,

2003 - Member of the Ethics Committee of the Medical University of Vienna

2008 - Vice -Chair, Committee on Reimbursement of Drugs of the Austrian Sick Funds and Social Security Association Institutions

2009 - Member of the Committee "Rational Use of Medicinal Products" of the Medicinal Products Advisory Council-Austrian Ministry of Health

2011 - Member Austrian expert group for rare diseases of the Federal Ministry of Health
2005 - 2011 President; Clinical Pharmacology Section of the Austrian Pharmacologic Society
2009 - 2011 Member of the Austrian subcommittee for rare diseases on the Supreme Health Board
2003 - 2012 Senior lecturer at the Vienna School of Clinical Research (VSCR)
2006 - 2012 Member of VSCR Educational Advisory Board
2005 - 2011 Austrian Representative to the European Network of National Programs of the European and Developing Countries Clinical Trials Partnership
2007 – 2008 Member of the Austrian Pharmaceutical Appeals Committee (UHK)
1993 - 1999 Member, Medical Faculty Senate of the University of Vienna
1992 Medical License (Internist), Austria
1992 Diploma, Clinical Investigator, Austrian Medical Association

Other Relevant Information

Marital Status: married to Dr. Christoph Schwarzer (2019)
widowed (married from 1986 to Dr. Ing. Rainer Bloechl (died 2016))
Children: Vivien Cornelia (1997), Colin Herbert (1999)
Maternity Leave: 1997- 2003 (1998-2003 Los Angeles, California USA)