



## Curriculum Vitae

Personal information **Brigitte Schwarzer-Daum**

### Work experience

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1. Employer: Medical University of Vienna
  - Start date: 012003
  - End date:
  - Position: Vice Chair, Department of Clinical Pharmacology
  - Activities:
  - Country: Austria
2. Employer: Medical University of Vienna
  - Start date: 011996
  - End date: 012000
  - Position: Vice Chair, Department of Clinical Pharmacology
  - Activities:
  - Country: Austria
3. Employer: Medical University of Vienna
  - Start date: 081992
  - End date: 071996
  - Position: Consultant, Department of Clinical Pharmacology, Vienna
  - Activities:
  - Country: Austria

### Education and training

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1. Subject:
  - Start date: 061996
  - End date:
  - Qualification: Professor of Clinical Pharmacology
  - Organisation:
  - Country:
2. Subject:
  - Start date: 061996
  - End date:
  - Qualification: Registered Consultant in Clinical Pharmacology
  - Organisation:
  - Country:
3. Subject:
  - Start date: 081992
  - End date:
  - Qualification: Registered Consultant in Internal Medicine
  - Organisation:
  - Country:
4. Subject: Vienna University Hospital
  - Start date: 081988
  - End date: 081992
  - Qualification: Resident
  - Organisation: Department of Internal Medicine (Oncology, Gastroenterology, Endocrinology, Cardiology),
  - Country: Austria
5. Subject: Auckland University Hospital,
  - Start date: 091986
  - End date: 081988
  - Qualification: Senior House Officer
  - Organisation: Depts. of Surgery, Accident and Emergency, Orthopaedics, Internal Medicine, Paediatrics, Gynaecology & Obstetrics
  - Country: New Zealand
6. Subject: Vienna University Hospital
  - Start date: 091985
  - End date: 081986
  - Qualification: Resident
  - Organisation: Department of Chemotherapy
  - Country: Austria
7. Subject: Medical University of Vienna
  - Start date: 101978
  - End date: 061985
  - Qualification: Doctor of Medicine
  - Organisation:
  - Country: Austria

### Additional information

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#### Publications

##### **Selected Publications:**

Dal-Ré R, Bottieau E, Launay O, Rosendaal FR, Schwarzer-Daum B.  
**Challenges in conducting efficacy trials for new COVID-19 vaccines in developed countries.** CLINICAL TRIALS. 2024; March 29.  
<https://journals.sagepub.com/doi/10.1177/17407745241238925>

Hans-Georg Eichler, Michael Kossmeier, Markus Zeitlinger, and Brigitte Schwarzer-Daum\*. "Orphan drugs' clinical uncertainty and prices: addressing allocative and technical inefficiencies in orphan drug reimbursement." FRONTIERS IN PHARMACOLOGY 14: 60. 26 January 2023 <https://doi.org/10.3389/fphar.2023.1074512>  
\*Corresponding Author

Rafael Dal-Ré, MD, Prof Raphaël Porcher, PhD, Prof Frits R. Rosendaal, MD, Prof Brigitte Schwarzer-Daum, MD **Regulatory agencies disregard real-world effectiveness evidence on product labels beyond what is reasonable** JOURNAL OF CLINICAL EPIDEMIOLOGY November 09, 2022  
<https://doi.org/10.1016/j.jclinepi.2022.11.007>

Hans-Georg Eichler, Mark Trusheim, Brigitte Schwarzer-Daum, Kay Larholt, Markus Zeitlinger, Martin Brunninger, Michael Sherman, David Strutton, Gigi Hirsch: **Precision reimbursement for precision medicine: using real-world evidence to evolve from trial-and-project to track-and-pay to learn-and-predict** CLINICAL PHARMACOLOGY & THERAPEUTICS 2022 Jan;111(1):52-62. Epub 2021 Nov 17, 111(1):  
<https://doi.org/10.1002/cpt.2471>

Rafael Dal-Ré, Raphaël Porcher, Frits R Rosendaal, Brigitte Schwarzer-Daum: **It is time to include real-world effectiveness data on medicinal product labels** THE LANCET RESPIRATORY MEDICINE Published: January 10, 2022  
DOI: [https://doi.org/10.1016/S2213-2600\(22\)00003-0](https://doi.org/10.1016/S2213-2600(22)00003-0)

Maria E. Sheean, Frauke Naumann-Winter, Giuseppe Capovilla, Maria Elisabeth Kalland, Eva Malikova, Segundo Mariz, Darius Matusevicius, Robert Nistico, Brigitte Schwarzer-Daum, Stelios Tsigkos, Kyriaki Tzogani, Kristina Larsson, Armando Magrelli and Violeta Stoyanova-Beninska: **Defining Satisfactory Methods of Treatment in Rare Diseases When Evaluating Significant Benefit–The EU Regulator's Perspective** FRONTIERS IN MEDICINE, 27 August 2021  
<https://doi.org/10.3389/fmed.2021.744625>

Rafael Dal-Ré, Linda-Gail Bekker, Christian Gluud, Søren Holm, Vivekanand Jha, Gregory A Poland, Frits R Rosendaal, Brigitte Schwarzer-Daum, Esperança Sevens, Halidou Tinto, Teck Chuan Voo, Nadarajah Sreeharan: **Ongoing and future COVID-19 vaccine clinical trials: challenges and opportunities** LANCET INFECT DISEASES 2021 Published Online May 18, 2021  
[https://doi.org/10.1016/S1473-3099\(21\)00263](https://doi.org/10.1016/S1473-3099(21)00263)

Hans-Georg Eichler, Francesco Pignatti, Brigitte Schwarzer-Daum, Ana Hidalgo-Simon, Irmgard Eichler, Peter Arlett, Anthony Humphreys, Spiros Vamvakas, Nikolai Brun and Guido Rasi: **Randomized Controlled Trials Versus Real World Evidence: Neither Magic Nor Myth** CLINICAL PHARMACOLOGY & THERAPEUTICS Received August 21, 2020; First published: 16 October 2020 <https://doi.org/10.1002/cpt.2083>

Eichler H G, Koenig F, Arlett P, Enzmann H, Humphreys A, Pétavy F, [Schwarzer - Daum B](#), Sepodes B, Vamvakas S, Rasi G **Are novel, non - randomised analytic methods fit for decision - making? The need for prospective, controlled and transparent validation** [CLINICAL PHARMACOLOGY & THERAPEUTICS](#), 2020, 107(4): 773-779 .doi:10.1002/cpt.1638

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: **Low risk pragmatic trials do not always require participants' informed consent** [BRITISH MEDICAL JOURNAL](#) 2019;364:11092 doi: 10.1136/bmj.11092 (Published 27 March 2019)

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]: "**Data rich, information poor; can we use health records to create a learning healthcare system for pharmaceuticals?**" [CLINICAL PHARMACOLOGY & THERAPEUTICS](#). 2018 Sep 4. doi: 10.1002/cpt.1226

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: **Threshold-crossing': a useful way to establish the counterfactual in clinical trials?"** [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](#) 12 DEC 2014 DOI: 10.1002/cpt.59

Hans-Georg Eichler, [Brigitte Bloechl-Daum](#)\*, Daniel Basseur, 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

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.: **European regulation on orphan medicinal products: 10 years of experience and future perspectives.** European regulation on orphan medicinal products.

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.

[B Bloechl-Daum](#): " **Me-too drugs**" und das Konzept des Klasseneffekts [WMW](#) Wiener Medizinische Wochenschrift, 2006

Müller M, Brunner M, Schmid R, Mader RM, Bockenheimer J, Steger GG, Steiner B, Eichler HG, [Bloechl-Daum B](#): **Interstitial methotrexate kinetics in primary breast cancer lesions.** [CANCER RESEARCH](#) 1998, 58: 2982-2985

Müller M, Mader RM, Steiner B, Steger GG, Gnant M, Helbich T, Jakesz R, Eichler HG, [Bloechl-Daum B](#): **5-Fluorouracil kinetics in the extracellular tumour space and clinical response in breast cancer patients.** [CANCER RESEARCH](#) 1997, 57:2598-2601

Dorner GT, Pehamberger H, Kornek G, Steger G, Müller M, Kletter K, James P, Breiteneder H, Eichler HG, [Bloechl-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

[Bloechl-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

[Bloechl-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

[Bloechl-Daum B](#), Pehamberger H, Kurz C, Kyrle PA, Wagner O, Müller M, Monitzer B, Eichler HG: **Effects of Cisplatin on urinary thromboxane B2 excretion:** [CLINICAL PHARMACOLOGY & THERAPEUTICS](#). 1995, 58:418-24

Schütz W, Freissmuth M, Tuisl E, [Bloechl-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

Eichler HG, Blaschke TF, Kraemer FB, Ford GA, [Bloechl-Daum B](#), Hoffman BB: **Responsiveness of superficial hand veins to alpha-adrenergic agonists in insulin-dependent diabetic patients.**

[CLIN SCI](#) 1992, 82: 163-8

Wagner B, Eichler HG, Schneider B, [Bloechl-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

[Bloechl-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, Schneider B, [Bloechl-Daum B](#), Speiser W, Brenner B, Eichler HG, Lechner K, Kyrle PA: **Effect of ritanserin - a 5- hydroxytryptamine<sub>2</sub> receptor antagonist - on platelet function and thrombin generation at the site of plug formation in vivo.**

[CLINICAL PHARMACOLOGY & THERAPEUTICS](#) 1990, 48: 419-23

[Bloechl-Daum B](#), Schuller-Petrovic S, Wolzt M, Korn A, Böhler K, Eichler HG: **Primary defect in alpha-adrenergic responsiveness in patients with varicose veins.**

[CLINICAL PHARMACOLOGY & THERAPEUTICS](#) 1991,49:49-52

[Bloechl-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

Eichler HG, [Bloechl-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, [Bloechl-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

[Bloechl-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, [Bloechl-Daum B](#), Steger G, Rainer H: **Poly(I).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, [Bloechl-Daum B](#), Mader R, Rainer H, Steger G, Dittrich C. Moser K, Ehninger G: **Coupling of mitoxantrone to poly(I).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 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))