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Personal Details

Nationality Austrian

Age 64

Languages Native German, fluent in spoken and written English. Μιλάει άθλια ελληνικά. LATINAE IAM OBLITUS EST.

Education

Location	Date	Secondary College for Chemical Engineering Educational focus: Technical Chemistry	Academic subject	hours
Vienna	Sep 1973 – May 1979			
			Stoichiometry	225
			Inorganic Chemistry	675
			Inorganic Technology and Examination Methods	270
			Inorganic-technological Laboratory	540
			Analytical Chemistry	675
			Analytical Laboratory	1,890
			Physical Chemistry	450
			Physical-chemical Laboratory	270
			Organic Chemistry	540
			Organic-preparative Laboratory	225
			Organic Technology and Examination Methods	225
			Organic-technological Laboratory	540
			Physics and Applied Physics	315
			Mathematics and Applied Mathematics	765
			Information Technology	90
			Descriptive Geometry and Technical Drawing	225
			Mechanical and Process Engineering	720
			Biology	90
			Microbiology	45
			Business Administration and Legal Theory	270
			Geography and Economic Studies	225
			Commodity Science	180
			Political Economy	45
			Civic Education	45
			Industrial Hygiene and Accident Prevention	45
			English	585
			German	540
			Creative Reading	90
				11,070
Vienna	Jun 8, 1979	Final examination passed with distinction		
Vienna	Mar 23, 1983	Standesbezeichnung „Ingenieur” (Professional Designation ‘Engineer’)		

Continuing Education

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
1	 Vienna	Dec 8, 1980	Introduction to Multidimensional Gas Chromatography	Siemens AG	varia
2	 Vienna	Dec 1981	Evaluation of bioavailability studies	Pharmakologische Untersuchungsgesellschaft	V. Nitsche
3	 Vienna	Feb 1–5, 1982	Rocky Mountain BASIC I/9000	Hewlett Packard	R. Gruber
4	 Vienna	Feb 25, 1982	Derivatization in Gas Chromatography	Kurt Bartelt GmbH	N. Zash
5	 Vienna	Apr 1, 1982	Analysis of illicit drugs	Kurt Bartelt GmbH	N. Zash
6	 Vienna	Sep 6, 1984	Symposium on Sample Preparation and Isolation Techniques using Bonded Silica	ICT GmbH	R. Kupferschmidt
7	 Vienna	May 28/29, 1985	Biogenic amines and their metabolites	Ludwig Boltzmann Institut für Klinische Neurobiologie	P. Riederer
8	 Würzburg	Feb 9–11, 1987	Bioavailability/Bioequivalence, Pharmaceutical and Therapeutic Equivalence	Arbeitsgemeinschaft Pharmazeutische Verfahrenstechnik, Arbeitsgruppe „Biopharmazie“	varia
9	 Freiburg	Apr 21–24, 1987	3 rd European Congress of Biopharmaceutics and Pharmacokinetics	FIP, Albert-Ludwig-Universität	varia
10	 Vienna	Nov 9–11, 1987	Pascal Operating System for HP9000 Series 200/300	Hewlett Packard	M. Makrandreou
11	 Vienna	Nov 12/13, 1987	Programming in Pascal	Hewlett Packard	M. Makrandreou
12	 Vienna	Jan 18–20, 1988	5. Forum Analytik	Hewlett Packard	varia
13	 Vienna	Jan 23–26, 1989	6. Forum Analytik	Hewlett Packard	varia
14	 Uppsala	Oct 26/27, 1988	International Symposium on Coupled Column Separations	The Swedish Chemical Society	varia
15	 Graz	Oct 26–28, 1989	VIII. Scientific Meeting	Österreichische Pharmazeutische Gesellschaft	varia
16	 London	Feb 15/16, 1990	Background – Design – Analysis & Interpretation of Bioavailability/Bioequivalence Studies	The Royal Society of Medicine	A. Pidgen
17	 Geneva	Apr 17–19, 1990	4 th European Congress of Biopharmaceutics and Pharmacokinetics	FIP	varia
18	 Amsterdam	May 15–17, 1990	Bioavailability of Drugs & Pharmacokinetics	The Center for Professional Advancement	varia
19	 Graz	Nov 5/6, 1990	Modern Methods for Drug Monitoring and their Significance for Clinical Practice	Österreichische Pharmazeutische Gesellschaft	W. Lindner
20	 Arlington	Dec 3–5, 1990	Analytical Methods Validation: Bioavailability, Bioequivalence and Pharmacokinetic Studies Conference	AAPS, FDA, FIP, HPB, AOAC	varia
21	 Vienna	Jan 21–24, 1991	8. Forum Analytik	Hewlett Packard	varia
22	 Palo Alto	Oct 21–23, 1991	Pharmacokinetic Modeling Workshop	Statistical Consultants Inc	C. Metzler, D. Weiner
23	 Palo Alto	Oct 24/25, 1991	Workshop on Bioavailability / Bioequivalence	Statistical Consultants Inc	C. Metzler, D. Weiner
24	 Vienna	Jan 20–23, 1992	9. Forum Analytik	Hewlett Packard	varia












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25	 Linz	Apr 28–30, 1992	LIMS – Laboratory Information Management Systems	Austrian Association for Analytical Chemistry	W. Landvoigt
26	 Vienna	Jun 9, 1992	Supercritical Fluid Extraction Workshop	Hewlett Packard	V. Weigang
27	 Toronto	Jun 15–18, 1992	International Open Conference on dissolution, bioavailability, bioequivalence	Canadian Health Protection Branch, U.S. FDA, USP	varia
28	 Stockholm	Sep 2–4, 1992	Oral Modified-Release Dosage Forms: Biopharmaceutical Challenges and Clinical Implications	Drug Information Association	varia
29	 Vienna	Sep 24, 1992	Quality assurance in the chemical laboratory	Hewlett Packard	varia
30	 Graz	Nov 9/10, 1992	Modified Release Formulations in Clinical Practice, Pharmaceutical Technology and Registration	Österreichische Pharmazeutische Gesellschaft	W. Lindner
31	 Vienna	Nov 17, 1992	Millennium 2010 Chromatography Manager	Waters Millipore	W. Fleschurz
32	 Bingen	Nov 24/25, 1992	GLP module Good Laboratory Practice. Basic training	Pharma Training Service	A. Burt, F. Gloggen- gießer
33	 Vienna	Jan 25–27, 1993	10. Forum Analytik	Hewlett Packard	varia
34	 Vienna	Feb 2, 1993	Shimadzu HPLC	ICT GmbH	R. Kupfer- schmidt
35	 Neu-Ulm	Mar 10/11, 1993	Computerized Data Handling – Current Trends in Pharmaceutical and Clinical Research	LAB, FAW, AGAH, University of Ulm	varia
36	 Vienna	Mar 17, 1993	Chromatography meeting	Austrian Association for Analytical Chemistry	varia
37	 Brussels	Apr 20–22, 1993	5 th European Congress of Biopharmaceutics and Pharmacokinetics	FIP	varia
38	 Korneuburg	Jun 23–25, 1993	Advanced HPLC seminar	inChrom	C. Wolf
39	 Frankfurt	Nov 26, 1993	The Main Issue is Significance – Typical Pitfalls in Clinical Trials	Colloquium Pharmaceuticum	varia
40	 Vienna	Jan 15, 1994	Generics in Comparison: Bioavailability, Bioequivalence	Österreichische Pharmazeutische Gesellschaft	H.W. Schramm
41	 Vienna	Jan/Feb 1994	HP-UX System Administration	Rauscher IT	H. Rauscher
42	 Munich	Jun 14–18, 1994	Bio-International '94	FIP	varia
43	 Vienna	Sep 1994	Introduction to LAB / UX 2.0 LIMS	Rauscher IT	H. Rauscher
44	 Vienna	Mar 23, 1995	BackOffice	Microsoft	varia
45	 Vienna	Mai 24, 1995	Criteria of Bioequivalence	Biokinet	varia
46	 Nuremberg	Dec 8/9, 1995	Symposium on Quality and Interchangeability of Topical Products for Local Action	EUFEPS	varia
47	 Vienna	May 24, 1996	Current Developments in the Testing of Topical Medicinal Products with Local Effect	Biokinet	varia
48	 Vienna	Nov 27, 1996	HP-Focus „ErfolgsAnalysen“	Hewlett Packard	varia
49	 Munich	Jan 20/21, 1997	Clinical Research Seminar Series: Biometrics in Europe	Colloquium Pharmaceuticum	varia
50	 Vienna	May 20, 1999	The Path of a Drug through the Body: Bioavailability – Pharmacokinetics	Gesellschaft für Chemiewirtschaft	H. Mascher

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51	 London	Sep 29–Oct 1, 1999	Bio-International '99	FIP, Royal Pharmaceutical Society	varia
52	 London	Nov 26, 2001	Ethical considerations in clinical trials	EMA	varia
53	 Athens	Apr 12–14, 2002	International Symposium On Scientific and Regulatory Aspects of Dissolution and Bioequivalence	AFEA	varia
54	 London	Oct 8–10, 2003	BioInternational 2003	FIP, Royal Pharmaceutical Society, AAPS, FDA	varia
55	 Brussels	Nov 18/19, 2004	Dissolution Testing, Bioequivalence & Bioavailability Studies	Barnett International	varia
56	 Amsterdam	Sep 14/15, 2005	Dissolution Testing, Bioavailability & Bioequivalence	IIR Life Sciences	varia
57	 London	Oct 24–26, 2005	Biointernational 2005	FIP, Royal Pharmaceutical Society, AAPS	varia
58	 Budapest	May 22–24, 2006	5 th Annual Conference on Dissolution Testing, Bioavailability & Bioequivalence	IBC Life Sciences	varia
59	 Vienna	Jun 13, 2006	Arzneimittelzulassung in der EU – Regulatorische Rahmenbedingungen und Möglichkeiten der Mitwirkung von nationalen Experten in Beratungs- und Zulassungsverfahren	Viennese Section of the International Biometric Society (IBS)	T. Lang
60	 Budapest	Oct 19/20, 2006	International Regulatory Workshop on Bioequivalence and Dissolution	Hungarian Society for Experimental and Clinical Pharmacology	varia
61	 Vienna	Jan 23, 2007	Blinded sample size reestimation in non-inferiority trials with binary endpoints	Viennese Section of the IBS	T. Friede
62	 Vienna	May 16, 2007	A general approach to two-stage tests	Viennese Section of the IBS	M. Vandemeulebroecke
63	 Budapest	May 23/24, 2007	Dissolution Testing, Bioavailability & Bioequivalence	informa Life Sciences	varia
64	 Athens	Oct 1/2, 2007	Conference on BA/BE	EUFEPS/COST	varia
65	 Lisbon	Oct 23/24, 2007	Workshop on Bioequivalence Study Design, Working to GCP and Interpreting the Guidelines	European Generic medicines Association	varia
66	 Vienna	Nov 7, 2007	Sources of Multiplicity in Adaptive Designs	Viennese Section of the IBS	W. Maurer
67	 Berlin	Nov 19, 2007	Successfully planning and designing a bioequivalence (BE) study	informa Life Sciences	U. Fuhr
68	 Berlin	Nov 20/21, 2007	Dissolution Testing, Bioavailability & Bioequivalence	informa Life Sciences	varia
69	 Berlin	Nov 22, 2007	Introduction to the In Vitro-In Vivo Correlation (IVIVC)	informa Life Sciences	J.-M. Cardot
70	 Budapest	May 14/15, 2008	Dissolution, Bioavailability and Bioequivalence	informa Life Sciences	varia
71	 Bad Homburg	Jun 17/18, 2008	New Regulations in Bioequivalence: Revised European CHMP Note for Guidance	EUFEPS	varia
72	 London	Jun 26/27, 2008	Dissolution Testing, Bioequivalence and Bioavailability Strategies	visiongain	varia
73	 Zeist	Oct 1/2, 2008	Increasing predictability in gastrointestinal simulation	TNO	varia















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74	 Nuremberg	Oct 3/4, 2008	2 nd World Conference on Magic Bullets (Ehrlich II)	German Association of Pharmaceutical Scientists	varia
75	 Prague	Oct 7, 2008	Dissolution, Bioavailability and Bioequivalence	informa Life Sciences	varia
76	 Paris	Oct 8, 2008	Symposium on Bioequivalence	European Generic medicines Association, CMD(h)	varia
77	 London	Oct 22–24, 2008	Bio-International 2008	FIP, Royal Pharmaceutical Society, EUFEPS, AAPS	varia
78	 Ahmedabad	Dec 1–3, 2008	Bioavailability, Bioequivalence, Pharmacokinetics & beyond	Shivrath Center of Excellence in Clinical Research	varia
79	 Bonn	Jan 14/15, 2009	Revised European Guidelines on Bioequivalence	EUFEPS BABP Network	varia
80	 Budapest	May 12/13, 2009	Bioequivalence and Bioavailability	informa Life Sciences	varia
81	 Munich	Jul 1–3, 2009	Phoenix for WinNonlin Version 6.0	Pharsight	S. Davis
82	 Berlin	Mar 9, 2010	Hurdles and Pitfalls in Generic Drug Development	Parexel Germany	varia
83	 Brussels	Apr 15/16, 2010	EMA Draft Guideline on Validation of Bioanalytical Methods	European Bioanalytical Forum, EUFEPS	varia
84	 Ljubljana	May 18/19, 2010	Bioequivalence and Bioavailability	informa Life Sciences	varia
85	 London	Jun 1, 2010	3 rd Symposium on Bioequivalence	European Generic medicines Association, CMD(h)	varia
86	 Budapest	Jun 21/22, 2010	2 nd International Regulatory Workshop on Bioequivalence and Dissolution	Hungarian Society for Experimental and Clinical Pharmacology	varia
87	 Mumbai	Jan 29/30, 2011	Biostatistics: Basic concepts & applicable principles for various designs in BE studies and data analysis	Pharma Edge Centre	varia
88	 Barcelona	Feb 24/25, 2011	Revision of BE Requirements for Modified Release Products	EUFEPS BABP Network	varia
89	 Vienna	Apr 19, 2011	On the efficiency of two-stage adaptive designs	Viennese Section of the IBS	F. Bretz
90	 Budapest	May 16–18, 2011	Bioavailability / Bioequivalence and Dissolution Testing	informa Life Sciences	varia
91	 Kobe	Jun 29–Jul 1, 2011	International Symposium on BA/BE of Oral Drug Products	FIP	varia
92	 Brussels	Sep 20/21, 2011	2 nd Annual Bioequivalence and Bioavailability Studies	Pharma IQ	varia
93	 Berlin	Nov 8/9, 2011	Innovations in Modified Release	informa Life Sciences	varia
94	 Mumbai	Jan 27–29, 2012	<i>In vitro in vivo</i> Correlation (IVIVC), Biowaivers & Statistical Aspects of Bioequivalence in Drug Product Development	Pharma Edge Centre	varia
95	 Moscow	May 23–25, 2012	Advanced practical training on pharmacokinetics, statistics, and analytics in Bioequivalence Studies towards Russian regulatory requirements	Chemical Diversity Research Institute	varia












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96	 Budapest	Jun 4–6, 2012	3 rd International Regulatory Workshop on Bioequivalence and Dissolution	Hungarian Society for Experimental and Clinical Pharmacology	varia
97	 Moscow	Oct 30, 2012	Drug development and registration: «Pharma-2020» Implementation Strategy	I.M. Sechenov First Moscow State Medical University	varia
98	 Mumbai	Jan 25–27, 2013	Advanced concepts of <i>IVIVC</i> through case studies; Biostatistical aspects of Reference-scaled & Two stage designs: A regulatory perspective	Pharma Edge Centre	varia
99	 Bucharest	Mar 19, 2013	Bioequivalence workshop	3S Pharmacological Consultation & Research	L. Endrényi
100	 Budapest	May 15/16, 2013	Bioavailability/Bioequivalence, Dissolution and Biowaivers	informa Life Sciences	varia
101	 Leuven	Jun 5/6, 2013	Bioequivalence Assessment of Oral Dosage Forms: Basic Concepts and Practical Applications	RKV Consultancy	varia
102	 Bonn	Jun 17/18, 2013	Open Discussion Forum on the Revised European Guideline on Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms	EUFEPS	varia
103	 Amman	Sep 24, 2013	1 st MENA Regulatory Conference on Bioequivalence, Biowaivers, Bioanalysis and Dissolution	International Pharmaceutical Research Center	varia
104	 Athens	Sep 26–28, 2013	5 th BBBB International Conference	EUFEPS, AAPS	varia
105	 Munich	Apr 7/8, 2014	Haemophilia Master Class: Personalized Treatment and Care	Ludwig-Maximilians-Universität München	varia
106	 London	Apr 30, 2014	Workshop on the impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms	EMA, EGA	varia
107	 Munich	Apr 16/17, 2014	Introduction to Phoenix [®] for WinNonlin [®] Version 6.2.x & 6.3	Certara	S. Davis
108	 Moscow	Apr 23–25, 2014	Bioequivalence Studies in Russia: Pharmacokinetics, Statistics and Analytics	Zentiva	varia
109	 Budapest	May 14/15, 2014	Bioavailability/Bioequivalence, Dissolution and Biowaivers	informa Life Sciences	varia
110	 Budapest	May 19–21, 2014	4 th International Regulatory Workshop on Bioequivalence and Dissolution	Hungarian Society for Experimental and Clinical Pharmacology	varia
111	 Frankfurt	Jul 3, 2014	Advisory Board on Haemophilia	Baxter	varia
112	 Vienna	Dec 2, 2014	Innovative Statistical Approaches in Drug Development	Viennese Section of the IBS	S. Senn
113	 Barcelona	Jan 27, 2015	XII Congreso	Sociedad Española de Farmacia Industrial y Galénica	varia
114	 Munich	Jan 30, 2015	Interactive Workshop PK Dosing in Haemophilia A	Baxter	varia
115	 Amsterdam	Mar 23/24, 2015	International Conference of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network	varia












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116	 London	Apr 30, 2015	Joint workshop on the impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms	European Medicines Agency, European Generic medicines Association	varia
117	 Prague	May 19/20, 2015	Bioavailability, Bioequivalence, Dissolution and Biowaivers	informa Life Sciences	varia
118	 Budapest	Nov 14, 2015	International Conference on Advances in the Area of Bioequivalence	Hungarian Society for Pharmaceutical Science, EUFEPS	varia
119	 Kyiv	Nov 19, 2015	5 th Scientific Conference “Clinical Trials of Medicines in Ukraine”	State Expert Center of the Ministry of Health of Ukraine	varia
120	 Lisbon	Jun 6, 2016	Scientific and Regulatory Issues in Drug Development and Bioequivalence	Sociedade Portuguesa de Ciências Farmacêuticas	varia
121	 Lisbon	Jun 7–10, 2016	25 th Meeting	Population Approach Group Europe	varia
122	 Rockville	Sep 15/16, 2016	2 nd International Conference of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network, AAPS	varia
123	 Prague	Sep 22/23, 2016	BioBridges 2016	Institute of Pharmacology, 1 st Faculty of Medicine, Charles University	varia
124	 Budapest	Oct 10/11, 2016	2 nd International Symposium on Scientific and Regulatory Advances in Complex Drugs	Hungarian Society for Pharmaceutical Science, EUFEPS	varia
125	 Berlin	Nov 14–16, 2016	Bioequivalence, Dissolution & IVIVC	Fleming Training	M. Ross
126	 Vienna	Jun 12–14, 2017	Bioequivalence, Dissolution & IVIVC	Fleming Training	M. Ross
127	 Prague	Sep 21, 2017	BioBridges 2017	Institute of Pharmacology, 1 st Faculty of Medicine, Charles University	varia
128	 Budapest	Oct 5/6, 2017	2 nd Annual Biosimilars Forum	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	varia
129	 Yaroslavl	Oct 19/20, 2017	2 nd International Conference «Studies of medicinal products: Simple and complex tasks»	Yaroslavl State Medical University	varia
130	 Léon	Nov 20/21, 2017	Bioequivalence, Dissolution & IVIVC	Fleming Training	M. Ross
131	 Barcelona	Mar 19–21, 2018	Bioequivalence, Dissolution & IVIVC	Fleming Training	M. Ross
132	 Amsterdam	Apr 12, 2018	3 rd International Conference of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network	varia
133	 Oberursel	Jun 5/6, 2018	Introduction into Basic Principles of Pharmacokinetics	Association for Applied Human Pharmacology	T. Arnhold, S. Glund, R. Heinig, W. Mück, R.-S. Wedemeyer
134	 Amman	Sep 24/25, 2018	3 rd MENA Regulatory Conference On Bioequivalence, Biowaivers, Bioanalysis and Dissolution	International Pharmaceutical Research Center	varia
135	 Prague	Sep 26/27, 2018	BioBridges 2018	Institute of Pharmacology, 1 st Faculty of Medicine, Charles University	varia

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136	 Budapest	Oct 25, 2018	Univariate and multivariate Bioequivalence of PK parameters	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	T. Jaki, P. Pallmann
137	 Budapest	Oct 26, 2018	3 rd Annual Biosimilars Forum	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	varia
138	 Athens	Nov 7–9, 2018	Bioequivalence, Dissolution & IVIVC	Fleming Training	varia
139	 Vienna	May 13, 2019	Adaptive Multi-arm Multi-stage Group Sequential Design	Viennese Section of the IBS	C.M. Mehta
140	 Vienna	Oct 8/9, 2019	Transforming Data to Insights	Viennese Section of the IBS	D. Spiegelhalter
141	 Budapest	Oct 17, 2019	Robust methods for assessment of average and scaled average bioequivalence	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	R. Schall, D. Burger
142	 Budapest	Oct 18, 2019	4 th Annual Biosimilars Forum	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	varia
143	 Athens	Nov 4–6, 2019	Bioequivalence, Dissolution & Biowaivers	Fleming Training	M. Ross
144	 Bethesda	Dec 12/13, 2019	4 th International Conference of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network, AAPS	varia
145	 Campinas	Feb 11–13, 2020	Network of Scientific Excellence	Sanofi	varia
146	 Vienna	Oct 14, 2020	Some possibly useful thoughts on bioequivalence assessments in the case of sparse sampling	Viennese Section of the IBS	M. Wolfsegger
147	 São Paulo	Apr 29, 2021	Seminário Internacional: Estudos em doses múltiplas para medicamentos genéricos e similares de liberação modificada – Contexto nacional e internacional	Sindusfarma	varia
148	 Vienna	Jun 9, 2021	Platform Trials: The potentials and the caveats of adding arms	Viennese Section of the IBS	K.M. Lee
149	 Yaroslavl	Oct 22, 2021	3 rd International Conference «Studies of medicinal products: Simple and complex tasks»	Yaroslavl State Medical University	varia
150	 Paris	Mar 22–24, 2022	Non-compartmental Analysis, Bioequivalence & Beyond. Spring School with PKanalix™	Lixoft	varia
151	 Vienna	Jun 22, 2022	Symmetric graphs for equally weighted tests, with application to the Hochberg procedure	Viennese Section of the IBS	F. Bretz
152	 Prague	Sep 23, 2022	BioBridges 2022	Institute of Pharmacology, 1 st Faculty of Medicine, Charles University	varia
153	 Amsterdam	Sep 28/29, 2022	5 th International Conference of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network	varia
154	 Oberursel	Oct 6/7, 2022	Introduction into Basic Principles of Pharmacokinetics	Association for Applied Human Pharmacology	T. Arnhold, S. Glund, R. Heinig, J. Höchel, R.-S. Wedemeyer














Presentations

#	Location	Date	Conference / Workshop / Training	Title (number)
1	 Vienna	May 24, 1995	Criteria of Bioequivalence	<ul style="list-style-type: none"> • The role of biometrics
2	 Brussels	Nov 19, 2004	Dissolution Testing, Bioequivalence & Bioavailability Studies	<ul style="list-style-type: none"> • Pitfalls in BA/BE-Studies
10	 Istanbul	Mar 7/8, 2006	Regulatory Update and Overview of BE and BA Testing with an Industry Perspective	<ul style="list-style-type: none"> • Overview of Dissolution for BA / BE • Bioavailability / Bioequivalence (9)
11	 Budapest	May 24, 2006	5 th Annual Conference on Dissolution Testing, Bioavailability & Bioequivalence	<ul style="list-style-type: none"> • Pitfalls in BA/BE-Studies
12	 Berlin	Nov 21, 2007	Dissolution Testing, Bioavailability & Bioequivalence	<ul style="list-style-type: none"> • Getting to grips with statistical aspects of BE studies
13	 Budapest	May 14, 2008	Dissolution, Bioavailability and Bioequivalence	<ul style="list-style-type: none"> • Ensuring bioanalytical compliance of your BA/BE study
14	 London	Jun 27, 2008	Dissolution Testing, Bioequivalence and Bioavailability Strategies	<ul style="list-style-type: none"> • Considerations for planning and designing a bioequivalence (BE) study
15	 Zeist	Oct 2, 2008	Increasing predictability in gastrointestinal simulation	<ul style="list-style-type: none"> • View of BEBAC on <i>in vitro</i> studies
17	 Nuremberg	Oct 3/4, 2008	2 nd World Conference on Magic Bullets (Ehrlich II)	<ul style="list-style-type: none"> • Bioequivalence – Still an Applied Science or already a ‘Cookbook’? (2)
18	 Prague	Oct 7, 2008	Dissolution, Bioavailability and Bioequivalence	<ul style="list-style-type: none"> • BA/BE design versus ‘job creation scheme’
22	 Ahmedabad	Dec 1–3, 2008	Bioavailability, Bioequivalence, Pharmacokinetics & beyond	<ul style="list-style-type: none"> • Analytical Development and Validation • Clinical Part of Phase I Studies • Statistical Design and Analysis • Q&A Session: Examples
29	 Aesch	Dec 15, 2008	Workshop on Bioequivalence Basics	<ul style="list-style-type: none"> • Overview and Introduction • Analytical Development and Validation • Clinical Part of BA/BE Studies • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (3)
36	 Budapest	May 11, 2009	Bioequivalence and Bioavailability	<ul style="list-style-type: none"> • Best Design of BE Studies: Overview and Introduction • Analytical Development and Validation • Clinical Part of BA/BE Studies • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (3)
44	 Prague	Oct 8/9, 2009	Workshop on Statistics for Bioequivalence	<ul style="list-style-type: none"> • Overview and Introduction • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (2) • Outliers in cross-over BE Studies • Replicate Designs • Sequential Designs • Sample Size Estimation
















#	Location	Date	Conference / Workshop / Training	Title (number)
58	 Ljubljana	Feb 4, 2010	Workshop on bioequivalence	<ul style="list-style-type: none"> • History of BE • Study Types • Simulations • Bioanalytics • Common Problems and Solutions • GCP Issues • Ethical Issues • Study Planning • Special Designs • Pilot Studies • Pitfalls in NCA • Sample Sizes • Biostatistics for BE (2)
59	 Berlin	Mar 9, 2010	Hurdles and Pitfalls in Generic Drug Development	<ul style="list-style-type: none"> • Design and Interpretation of BE Studies – Current and Future Issues
63	 Holz-kirchen	Apr 21, 2010	Bioequivalence workshop	<ul style="list-style-type: none"> • Noncompartmental Analysis in PK, PK-based Design
66	 Munich	Apr 22, 2010	Bioequivalence workshop	<ul style="list-style-type: none"> • Statistical Design and Analysis (3) • Noncompartmental Analysis in PK, PK-based Design
73	 Ljubljana	May 17–19, 2010	Bioequivalence and Bioavailability	<ul style="list-style-type: none"> • Statistical Design and Analysis (2) • Design and Evaluation of BE Studies: Overview and Introduction • Analytical Development and Validation • Clinical Part of BA/BE Studies • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (2) • Successfully Overcoming Sample Size Challenges in BE Studies
75	 Nijmegen	Jun 17, 2010	Bioequivalence workshop	<ul style="list-style-type: none"> • Biostatistical Aspects of Bioequivalence Studies • Sample Size Issues in BE Studies
77	 Prague	Oct 14, 2010	Workshop on Bioanalytics for BE Studies	<ul style="list-style-type: none"> • Basics of Bioanalytics • Validation of Bioanalytical Methods
81	 Munich	Oct 25–27, 2010	Bioequivalence and Bioavailability Studies	<ul style="list-style-type: none"> • Taking a Biostatistical Approach to Designing a BE Study: Ensuring Success through Effective Planning (3) • Sample Size Challenges in BE Studies and the Myth of Power
87	 Mumbai	Jan 29/30, 2011	Biostatistics: Basic concepts & applicable principles for various designs in BE studies and data analysis	<ul style="list-style-type: none"> • Background and History of BE • Basic Concepts • Basic Designs for BE Studies • Advanced Designs • Sample Size Calculations • Add-On and Sequential Designs
88	 Barcelona	Feb 24, 2011	Revision of BE Requirements for Modified Release Products	<ul style="list-style-type: none"> • Assessment of bioequivalence of implants: Appropriate study design, metrics, and acceptance criteria
93	 Budapest	May 16–18, 2011	Bioavailability / Bioequivalence and Dissolution Testing	<ul style="list-style-type: none"> • Design and Evaluation of BE Studies: Overview and Introduction • Noncompartmental Analysis in PK, PK based Design • Statistical Design and Analysis (2) • Determining Optimal Sample Size

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94	 Vienna	Jul 11, 2011	Workshop on GCP and Logistics for Bioequivalence Studies	<ul style="list-style-type: none"> • Theory and Practice
99	 Aesch	Aug 8–10, 2011	Advanced Workshop on Bioequivalence	<ul style="list-style-type: none"> • Overview • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (2) • Determining Optimal Sample Size
103	 Aesch	Aug 11–12, 2011	Workshop on Statistics for Bioanalysis and Bioequivalence	<ul style="list-style-type: none"> • Regression & Calibration • Basic Concepts of BE • Basic Designs for Bioequivalence Studies • Advanced Designs for Bioequivalence Studies
106	 Brussels	Sep 19–21, 2011	2 nd Annual Bioequivalence and Bioavailability Studies	<ul style="list-style-type: none"> • Setting up a BE study: from design to approval • Power and intra-subject variability in 2 stage approaches • ‘Perfecting’ the two stage study design
107	 Berlin	Nov 8, 2011	Innovations in Modified Release	<ul style="list-style-type: none"> • Practically meeting modified release BE requirements
112	 Mumbai	Jan 27–29, 2012	<i>In vitro in vivo</i> Correlation (IVIVC), Biowaivers & Statistical Aspects of Bioequivalence in Drug Product Development	<ul style="list-style-type: none"> • Design and Conduct of Bioequivalence Studies and Current Regulatory Trends • Sample Size Calculations • Sample Size Calculations Examples • Statistical aspects of two-way cross-over studies • Statistical aspects of reference-scaled studies
120	 Nyon	Mar 12, 2012	Seminar on BABE Studies	<ul style="list-style-type: none"> • Design and Conduct of BE Studies and Current Regulatory Trends • Clinical part of BABE studies • Specific designs (3) • Focus on PK topics currently being debated (2) • Ensuring bioanalytical compliance of BABE studies
125	 Moscow	May 23–25, 2012	Advanced practical training on pharmacokinetics, statistics, and analytics in Bioequivalence Studies towards Russian regulatory requirements	<ul style="list-style-type: none"> • Introduction to Bioequivalence • PK–NCA, PK based Design, Biostatistics (2) • Development of Bioanalytical Methods for BE Studies • Validation of Bioanalytical Methods for BE Studies
126	 Moscow	Oct 30, 2012	Drug development and registration: «Pharma-2020» Implementation Strategy	<ul style="list-style-type: none"> • Sample Size Estimation in BE Studies including Studies with Highly Variable Drugs – Comparison of Russian and EU Guidelines
127	 Moscow	Oct 31, 2012	Statistics for Bioequivalence Studies	<ul style="list-style-type: none"> • Sample Size Estimation, Two-Stage Sequential Designs, Reference-scaling (HVDs/HVDPs)
129	 Prague	Dec 13, 2012	Seminar on Bioequivalence Studies	<ul style="list-style-type: none"> • Bioequivalence Studies of Highly Variable Drugs / Drug Products (HVDs/HVDPs) • Statistics of Two Stage Study Designs

#	Location	Date	Conference / Workshop / Training	Title (number)
132	 Mumbai	Jan 25–27, 2013	Advanced concepts of <i>IVIVC</i> through case studies; biostatistical aspects of Reference-scaled & Two stage designs: A regulatory perspective	<ul style="list-style-type: none"> • Reference-Scaled Average Bioequivalence (HVDs/HVDPs) • Two-Stage Designs • RSABE (NTIDs)
136	 Bucharest	Mar 19, 2013	Bioequivalence workshop	<ul style="list-style-type: none"> • Integration in Chromatography • Sample Size Estimation • Sequential Designs • Introduction to Population PK
137	 Budapest	May 16, 2013	Bioavailability/Bioequivalence, Dissolution and Biowaivers	<ul style="list-style-type: none"> • Experiences in Implementing Two-Stage Designs in Europe: Tricks and Traps
139	 Leuven	Jun 5/6, 2013	Bioequivalence Assessment of Oral Dosage Forms: Basic Concepts and Practical Applications	<ul style="list-style-type: none"> • Pharmacokinetic Analysis of BE Data • Statistical Analysis of BE Data
145	 Ulm	Jul 18/19, 2013	Workshop in Biostatistics for Bioequivalence	<ul style="list-style-type: none"> • Introduction to Biostatistics • Statistical Basics of Bioequivalence • Sample Size Estimation • Adaptive Designs • Highly Variable Drugs / Drug Products • Group Effects in Bioequivalence
146	 Amman	Sep 24, 2013	1 st MENA Regulatory Conference on Bioequivalence, Biowaivers, Bioanalysis and Dissolution	<ul style="list-style-type: none"> • Pharmacokinetic and Statistical Analysis of BE Data
149	 Prague	Oct 16, 2013	Clinical Development Workshop	<ul style="list-style-type: none"> • Partial AUCs • Two-Stage Designs in BE-Studies • Modified Release: $C_{min} - C_{\tau}$
155	 Zagreb	Oct 23/24, 2013	Biostatistics workshop	<ul style="list-style-type: none"> • Introduction to Biostatistics • Statistical Basics of Bioequivalence • Sample Size Estimation • Adaptive Designs • Highly Variable Drugs / Drug Products • Group Effects in Bioequivalence
156	 Munich	Apr 7, 2014	Haemophilia Master Class: Personalized Treatment and Care	<ul style="list-style-type: none"> • Pharmacokinetic Issues: A Basic Refresher
160	 Moscow	Apr 24, 2014	Bioequivalence Studies in Russia: Pharmacokinetics, Statistics and Analytics	<ul style="list-style-type: none"> • Basic Designs for BE Studies • Sample Size Estimation for BE Studies • Two-Stage Sequential Designs • Outliers in BE Studies
161	 Budapest	May 14, 2014	Bioavailability/Bioequivalence, Dissolution and Biowaivers	<ul style="list-style-type: none"> • Practical Advice for Implementing Two-Stage Designs
162	 Frankfurt	Jul 3, 2014	Advisory Board on Haemophilia	<ul style="list-style-type: none"> • Pharmacokinetic Issues: A Basic Refresher
169	 Barcelona	Sep 17/18, 2014	Design and Evaluation of Bioequivalence Studies	<ul style="list-style-type: none"> • Issues in Bioanalytical Method Validation (EMA vs. FDA) • Introduction to Biostatistics for Bioequivalence • Evaluation of Parallel and Cross-over Designs • Two-Stage Designs • Replicate Designs with Adaptation of Acceptance Criteria for HVDs / HVDPs • Some Ideas about Pilot Studies • Sample Size Estimation for BE Studies
170	 Barcelona	Jan 27, 2015	XII Congreso de la Sociedad Española de Farmacia Industrial y Galénica	<ul style="list-style-type: none"> • Two-Stage Sequential Designs in Bioequivalence

#	Location	Date	Conference / Workshop / Training	Title (number)
171	 Munich	Jan 30, 2015	Interactive Workshop PK Dosing in Haemophilia A	<ul style="list-style-type: none"> • Pharmacokinetic Issues: A Basic Refresher
172	 Prague	May 19, 2015	Bioavailability, Bioequivalence, Dissolution and Biowaivers	<ul style="list-style-type: none"> • Statistical Software for Bioequivalence
174	 Kyiv	Nov 19, 2015	5 th Scientific Conference “Clinical Trials of Medicines in Ukraine”	<ul style="list-style-type: none"> • Designs for Bioequivalence Studies • Sample Size Estimation for Bioequivalence Studies
175	 Bilbao	Mar 11, 2016	Drug Modeling & Consulting – Group Meeting	<ul style="list-style-type: none"> • Reference-Scaled Average Bioequivalence
176	 Lisbon	Jun 6, 2016	Scientific and Regulatory Issues in Drug Development and Bioequivalence	<ul style="list-style-type: none"> • Statistical Planning and Evaluation of Bioequivalence Studies
177	 Vienna	Jun 16, 2016	Pharmacometrics & Biostatistics Meeting	<ul style="list-style-type: none"> • Inflation of the Type I Error in Reference-scaled Average Bioequivalence
180	 Prague	Sep 22, 2016	BioBridges 2016	<ul style="list-style-type: none"> • Two-Stage Sequential Designs (2) • Inflation of the Type I Error in Reference-scaled Average Bioequivalence
185	 Moscow	Oct 6, 2016	BE Workshop	<ul style="list-style-type: none"> • Sample Size Estimation • Two Stage Designs • Reference-scaling • Software Validation • Case Studies
193	 Berlin	Nov 14–16, 2016	Bioequivalence, Dissolution & IVIVC	<ul style="list-style-type: none"> • The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • Pilot Studies • Similarity, Comparability and Correlation • Software Validation • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
194	 Prague	Dec 9, 2016	Zentiva	<ul style="list-style-type: none"> • Inflation of the Type I Error in Reference-scaled Average Bioequivalence
202	 Budapest	May 3/4, 2017	Course on Pharmacokinetics and Bioequivalence	<ul style="list-style-type: none"> • (L)ADME / Basics of Pharmacokinetics • PK and statistical background of BE studies • Clinical study design (5) • Regulatory requirements
210	 Vienna	Jun 12–14, 2017	Bioequivalence, Dissolution & IVIVC	<ul style="list-style-type: none"> • The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
211	 Prague	Sep 21, 2017	BioBridges 2017	<ul style="list-style-type: none"> • How to design a pilot study – extrapolation of results

#	Location	Date	Conference / Workshop / Training	Title (number)
215	 Budapest	Oct 5, 2017	2 nd Annual Biosimilars Forum	<ul style="list-style-type: none"> • Open Issues in the Assessment of Bioequivalence and Biosimilarity: Unequal carry-over – “solved” in BE but still an Issue in Assessing Biosimilarity? • Multi-Group and Multi-Site Studies. To pool or not to pool? • Group-Sequential and Two-Stage Designs • Reference-scaling and Control of the Type I Error
216	 Yaroslavl	Oct 19/20, 2017	II nd International Conference «Studies of medicinal products: Simple and complex tasks»	<ul style="list-style-type: none"> • Multi-Group Studies in BE. To pool or not to pool?
220	 León	Nov 20/21, 2017	Bioequivalence, Dissolution & IVIVC	<ul style="list-style-type: none"> • The General Requirements for Biostudies • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues • Bioanalytical Method Validation • Dissolution / Biowaivers / IVIVC • (L)ADME / Basics of Pharmacokinetics / NCA • Calculation of PK Metrics • The Concept of Bioavailability and Bioequivalence • Types of Study Designs • Sample Size Estimation • Group-Sequential and Two-Stage Designs • Reference-scaling and Control of the Type I Error
230	 Kaunas	Dec 5/6, 2017	Training on Bioequivalence	<ul style="list-style-type: none"> • Protocol & Report, Risks, Case Studies • The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
238	 Barcelona	Mar 19–21, 2018	Bioequivalence, Dissolution & IVIVC	<ul style="list-style-type: none"> • How to measure what happens in pharmacokinetics: PK metrics of relevance! • Primary and secondary PK metrics for evaluation of steady state studies, C_{min} vs. C_{τ}, relevance of C_{min}/C_{τ} or fluctuation for BE assessment
239	 Vienna	Apr 6, 2018	Shire	<ul style="list-style-type: none"> • Basic Statistics for BE • Sample Size Estimation • Group-Sequential and Two-Stage Designs • Reference-scaling and Control of the Type I Error • Nonparametric Statistics (t_{max}, t_{lag}) • Special Topics
240	 Amsterdam	Apr 12, 2018	3 rd International Conference of the Global Bioequivalence Harmonisation Initiative	
246	 Pamp-lona	Apr 24, 2018	Basic Statistical Concepts Behind BE Testing	

#	Location	Date	Conference / Workshop / Training	Title (number)
248	 Ober- ursel	Jun 5/6, 2018	AGAH-Workshop “Introduction into Basic Principles of Pharmacokinetics”	<ul style="list-style-type: none"> • How to measure what happens in pharmacokinetics: PK metrics of relevance! • Pitfalls in BA/BE
249	 Amman	Sep 24, 2018	3 rd MENA Regulatory Conference On Bioequivalence, Biowaivers, Bioanalysis and Dissolution	<ul style="list-style-type: none"> • Multi-Group Studies in BE. To pool or not to pool?
250	 Prague	Sep 26, 2018	BioBridges 2018	<ul style="list-style-type: none"> • Multi-Group Studies in BE. To pool or not to pool?
251	 Budapest	Oct 26, 2018	3 rd Annual Biosimilars Forum	<ul style="list-style-type: none"> • Roundtable Moderation
259	 Athens	Nov 7–9, 2018	Bioequivalence, Dissolution & IVIVC	<ul style="list-style-type: none"> • The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
263	 Gdańsk	Sep 3, 2019	Statistical Assessment of Bioequivalence Studies	<ul style="list-style-type: none"> • Design of Comparative Bioavailability Studies • Noncompartmental Analysis, Statistical Evaluation • Pitfalls in Bioequivalence • Bioanalytical Method Development and Validation
289	 Campi- nas	Feb 11–13, 2020	Network of Scientific Excellence	<ul style="list-style-type: none"> • Steady-state Studies • Pilot Studies • Two-Stage Designs • Replicate Designs • Outliers in BE
290	 São Paulo	Apr 29, 2021	Seminário Internacional: Estudos em doses múltiplas para medicamentos genéricos e similares de liberação modificada – Contexto nacional e internacional	<ul style="list-style-type: none"> • Steady-State Studies: Scientific Background, Regulatory Requirements, Current Discussions / Open Issues
291	 Vienna	Oct 1, 2021	Takeda	<ul style="list-style-type: none"> • Bioequivalence. An Old Area with some Uncharted Territories
295	 Bilbao	Oct 18, 2021	BE course	<ul style="list-style-type: none"> • Biostudy Statistical Design and Evaluation (3) • General Hurdles and Pitfalls in Bioequivalence Studies
296	 Yaroslavl	Oct 22, 2021	3 rd International Conference «Studies of medicinal products: Simple and complex tasks»	<ul style="list-style-type: none"> • Critical Remarks on Reference-Scaled Average Bioequivalence
297	 Vienna	Dec 15, 2021	Biometric Colloquium of the Viennese Section of the IBS	<ul style="list-style-type: none"> • Bioequivalence. An Old Area with some Uncharted Territories
298	 Prague	Sep 23, 2022	BioBridges 2022	<ul style="list-style-type: none"> • t_{\max} Evaluation: Where are we and where will we go...
299	 Amster- dam	Sep 28, 2022	5 th International Conference of the Global Bioequivalence Harmonisation Initiative	<ul style="list-style-type: none"> • Novel approaches in adaptive designs and α adjustment, e.g., with futility criteria and for parallel design studies
301	 Ober- ursel	Oct 6/7, 2022	AGAH-Workshop “Introduction into Basic Principles of Pharmacokinetics”	<ul style="list-style-type: none"> • How to measure what happens in pharmacokinetics: PK metrics of relevance! • Pitfalls in BA/BE





IT Proficiency











- Networks LanManager (Hewlett Packard, Microsoft), Samba (GNU)
- LIMS LAB/UX (Hewlett Packard / Agilent Technologies)
- Operating Systems HP/UX (Hewlett Packard), DOS (Microsoft, Digital Research), OS/2 (IBM), Windows XP | Vista | 7 | 11 (Microsoft)
- GUIs CDE (The Open Group), Windows 3.11 for Workgroups | NT4 | 2000 (Microsoft)
- Scripts, Macros awk (Unix), BAT (Microsoft), JavaScript (Sun)
- Office Microsoft, Apache Software Foundation
- Languages Pascal for Workstations (Hewlett Packard), TurboPascal (Borland), BASIC dialects: Rocky Mountain Basic (Hewlett Packard), HTB (TransEra), GW-Basic | QuickBASIC/VBA (Microsoft), CRA-Basic (Shimadzu)
- Databases dBase (Ashton-Tate), ACCESS (Microsoft), MySQL (Oracle)
- Web (X)HTML | CSS (W3C), php (The PHP Group), APACHE (Apache Software Foundation)
- Software
 - Proprietary
 - Reflection (Micro Focus), BioEvaluat (Biokinet), TOPFIT (Springer), STATISTICA (StatSoft), StatXact (Cyxel), NCSS (NCSS Software), StudySize | Result (CreoSoft), EquivTest | PK (Statistical Solutions), KINETICA (Thermo Scientific), Phoenix WinNonlin | NLME | IVIVC (Certara), Monolix | PKanalix | Simulix (Lixoft)
 - Open source
 - BIOEQV (Wijnand), Boomer (Bourne), WinSAAM (WinSAAM Inc), MONOLIX (The Monolix Group), Berkley Madonna (Macey & Oster), WinBUGS | PKBugs (GNU), Octave (GNU), Maxima (GNU), MikTeX (Schenk), git (GNU), pandoc (GNU), GitHub (Microsoft), R (The R Foundation for Statistical Computing)

R Packages

- 1 Schütz H. AdaptiveBE: Acceptability of Adaptive Bioequivalence Studies. 2018-05-07; Package version 0.8.4.9000. <https://github.com/Helmut01/AdaptiveBE>
- 2 Molins E, Labes D, Schütz H, Ocaña J. betsd: Adjusting significance levels in two-stage adaptive 2×2 crossover designs. 2019-07-03; Package version 0.1.5. <https://github.com/eduard-molins/betsd>
- 3 Schütz H. indirectBE: Adjusted Indirect Comparisons. 2021-06-11; Package version 0.3.0.
- 4 Schütz H, Tomashevskiy M, Labes D. replicateBE: Average Bioequivalence with Expanding Limits (ABEL). 2022-05-02; Package version 1.1.1. <https://cran.r-project.org/package=replicateBE>
- 5 Labes D, Schütz H, Lang B. PowerTOST: Power and Sample Size Based on Two One-Sided *t*-Tests (TOST) for (Bio)Equivalence Studies. 2022-02-21; Package version 1.5-4. <https://cran.r-project.org/package=PowerTOST>
- 6 Labes D, Lang B, Schütz H. Power2Stage: Power and Sample-Size Distribution of 2-Stage Bioequivalence Studies. 2021-11-12; Package version 0.5-4. <https://cran.r-project.org/package=Power2Stage>

Posters

#	Location	Date	Occasion	Title	Co-authors
1	 Uppsala	Oct 26, 1988	International Symposium on Coupled Column Separations	<i>Development and Application of an HPLC Determination of Buspirone in Plasma by Solid-Phase Extraction and On-Line Precolumn Trace Enrichment</i>	A. Eichinger, V. Nitsche
2	 Vienna	Jan 23–25, 1989	6. Forum Analytik	<i>Anwendung von Säulenschaltungen in der HPC anhand von Beispielen.</i>	A. Eichinger, V. Nitsche
3	 Graz	Oct 26–28, 1989	VIII. Wissenschaftliche Tagung der Österreichischen Pharmazeutischen Gesellschaft	<i>Spurenanalytik von Arzneistoffen aus biologischen Matrices</i>	A. Eichinger, V. Nitsche
4	 Geneva	Apr 17–19, 1990	4 th European Congress of Biopharmaceutics and Pharmacokinetics	<i>Determination of buspirone in plasma by HPLC with solid-phase extraction and on-line precolumn trace enrichment and its application to a pharmacokinetic study</i>	A. Eichinger, V. Nitsche

#	Location	Date	Occasion	Title	Co-authors
5	 Geneva	Apr 17–19, 1990	4 th European Congress of Biopharmaceutics and Pharmacokinetics	<i>Determination of amoxicillin and ampicillin using a new HPLC method with post-column derivatization and its application to bioavailability studies</i>	A. Eichinger, V. Nitsche
6	 Vienna	Jan 25–27, 1993	10. Forum Analytik	<i>Implementierung der GLP in einem Auftragsforschungslabor mit 6 Mitarbeitern</i>	A. Eichinger, J. Krenauer, A. Kaspar, C. Wolf, V. Nitsche
7	 San Antonio	Nov 10–14, 2013	AAPS Annual Meeting and Exposition	<i>Performing Reference-Scaled Average Bioequivalence (RSABE) in Phoenix[®] WinNonlin[®]</i> doi:10.13140/RG.2.1.1008.0800	A. Henry, L. Hughes, S. Davis
8	 Vienna	Aug 24–28, 2014	35 th Annual Conference of the International Society for Clinical Biostatistics	<i>Adaptive two-stage bioequivalence trials with early stopping and sample size re-estimation</i> doi:10.13140/RG.2.1.5190.0967	F. König, M.J. Wolfsegger, T. Jaki, G. Wassmer
9	 Glasgow	Nov 16/17, 2015	3 rd International Clinical Trials Methodology Conference	<i>Adaptive two-stage bioequivalence trials with early stopping and sample size re-estimation</i> doi:10.1186/1745-6215-16-S2-P218	F. König, M.J. Wolfsegger, T. Jaki, G. Wassmer
10	 Berlin	Jul 8–13, 2017	XXVI Congress of the International Society on Thrombosis and Haemostasis and 63 rd Annual Scientific and Standardization Committee Meeting	<i>An investigation of the minimum half-life extension needed to make a clinically meaningful impact on dosing frequency of extended half-life recombinant FVIII products</i>	J. Booth, K. Steinitz-Trost, H.Y. Lee, A. Bauer, M. Wolfsegger
11	 Sydney	Oct 29–Nov 1, 2017	HAA Annual Scientific Meeting	<i>Minimum half-life extension ratio model for reduced dosing frequency of extended half-life recombinant FVIII products</i>	J. Booth, K. Steinitz-Trost, H.Y. Lee, A. Bauer, M. Wolfsegger
12	 San Diego	Nov 12–16, 2017	AAPS Annual Meeting and Exposition	<i>Reference-Scaled Average Bioequivalence (RSABE) Approach For Compounds With A Narrow Therapeutic Index (NTID) Using Phoenix[™] Win-Nonlin[®]</i>	C. Mehl, A. Henry, L. Hughes
13	 Vienna	Feb 20–23, 2018	62 nd Annual Meeting of the Society of Thrombosis and Haemostasis Research	<i>A Model of the Minimum Half-life Extension Ratio Needed to Reduce the Dosing Frequency of Extended Half-life (EHL) Recombinant FVIII (rFVIII) Products</i>	J. Booth, K. Steinitz-Trost, H.Y. Lee, A. Bauer, M. Wolfsegger
14	 London	Dec 18–20, 2018	Pharmacology 2018	<i>Assurance (expected power) for planning crossover bioequivalence trials</i> doi:10.1111/bcp.13937	A. Ring, B. Lang, C. Kazaroho, D. Labes, J.S. Awounvo

Publications

- 1 Nitsche V, Mascher H, Schütz H. *Comparative bioavailability of several phenytoin preparations marketed in Austria*. Int J Clin Pharmacol Ther Toxicol. 1984; 22(2): 104–7. <https://www.ncbi.nlm.nih.gov/pubmed/6698663>.
- 2 Mascher H, Nitsche V, Schütz H. *Separation, Isolation and Identification of Optical Isomers of 1,4-Benzodiazepine Glucuronides from Biological Fluids by Reversed-Phase High-Performance Liquid Chromatography*. J Chromatogr Biomed Appl. 1984; 306: 231–9. [https://doi.org/10.1016/S0378-4347\(00\)80885-3](https://doi.org/10.1016/S0378-4347(00)80885-3).
- 3 Nitsche V, Mascher H, Schütz H. *Bioverfügbarkeit von Amilorid-Hydrochlorothiazid-Kombinationspräparaten*. Therapiewoche. 1985; 36(1): 56–60.

- 4 Nitsche V, Schütz H, Eichinger A. *Rapid high-performance liquid chromatographic determination of nifedipine in plasma with on-line precolumn solid-phase extraction*. J Chromatogr, Biomed Appl. 1987; 420: 207–11. [https://doi.org/10.1016/0378-4347\(87\)80175-5](https://doi.org/10.1016/0378-4347(87)80175-5).
- 5 Nitsche V, Lauschner R, Eichinger A, Schütz H. *Absolute Bioverfügbarkeit von Ambroxol-Zäpfchen*. Pharm Ztg. 1988; 133(32): 28–33.
- 6 Schütz H, Eichinger A, Nitsche V, Hofmann R. *Relative bioavailability of 3 different chlormezanone 200 mg preparations after single dose oral administration*. Int J Clin Pharmacol Ther. 1997; 35(3): 112–6. <https://www.ncbi.nlm.nih.gov/pubmed/9089000>.
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- 8 Schütz H. *An extremely strange observation?* [letter]. Eur J Drug Metabol Pharmacokinet. 2004; 29(1): 69–71. <https://doi.org/10.1007/BF03190576>.
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- 10 Schütz H, Fischer R, Grossmann M, Mazur D, Leis HJ, Ammer R. *Lack of bioequivalence between two methylphenidate extended modified release formulations in healthy volunteers*. Int J Clin Pharmacol Ther. 2009; 47(12): 761–9. <https://doi.org/10.5414/cpp47761>.
- 11 Leis HJ, Schütz H, Windischhofer W. *Quantitative determination of methylphenidate in plasma by gas chromatography negative ion chemical ionisation mass spectrometry using o-(pentafluorobenzoyloxycarbonyl)-benzoyl derivatives*. Anal Bioanal Chem. 2011; 400(8): 2663–70. <https://doi.org/10.1007/s00216-011-5048-6>.
- 12 Schütz H, Labes D, Fuglsang A. *Reference Datasets for 2-Treatment, 2-Sequence, 2-Period Bioequivalence Studies*. AAPS J. 2014; 16(6): 1292–7. <https://doi.org/10.1208/s12248-014-9661-0>. [PMC https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389751/pdf/12248_2014_Article_9661.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389751/pdf/12248_2014_Article_9661.pdf).
- 13 Roudier B, Davit B, Schütz H, Cardot J-M. *Impact of Data Base Structure in a Successful In Vitro-In Vivo Correlation for Pharmaceutical Products*. AAPS J. 2015; 17(1): 24–34. <https://doi.org/10.1208/s12248-014-9680-x>. [PMC https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4287291/pdf/12248_2014_Article_9680.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4287291/pdf/12248_2014_Article_9680.pdf).
- 14 Schütz H. *Two-stage designs in bioequivalence trials*. Eur J Clin Pharmacol. 2015; 71(3): 271–81. <https://doi.org/10.1007/s00228-015-1806-2>.
- 15 Fuglsang A, Schütz H, Labes D. *Reference Datasets for Bioequivalence Trials in a Two-Group Parallel Design*. AAPS J. 2015; 17(2): 400–4. <https://doi.org/10.1208/s12248-014-9704-6>. [PMC https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365103/pdf/12248_2014_Article_9704.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365103/pdf/12248_2014_Article_9704.pdf).
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- 21 Molins E, Labes D, Schütz H, Cobo E, Ocaña J. *An iterative method to protect the type I error rate in bioequivalence studies under two-stage adaptive 2×2 crossover designs*. Biom J. 2021; 63(1): 122–33. <https://doi.org/10.1002/bimj.201900388>. *Pearls of Bioequivalence Award 2022* by ‘The Frankfurt Foundation Quality of Medicines’ and the EUFEPS ‘Network Bioavailability and Biopharmaceutics’
- 22 Wolfsegger MJ, Bauer A, Labes D, Schütz H, Vonk R, Lang B, Lehr S, Jaki TF, Engl W, Hale MD. *Assessing goodness-of-fit for evaluation of dose-proportionality*. Pharm Stat. 2021; 20(2): 272–81. <https://doi.org/10.1002/pst.2074>.
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Professional Activities

- | | | |
|---------------------|---|---|
| Jul 1976 | Vinzenz Wagner GmbH
(internship) | <ul style="list-style-type: none"> • Rheology, pycnometry, colorimetry |
| Jul 1977 | Technol GmbH
(internship) | <ul style="list-style-type: none"> • Rheology, flashpoint determinations, pH measurements, UV / VIS spectrometry, IR spectrometry, normal phase HPLC |
| Jan 1980 – Oct 1980 | Gerot Pharmazeutika GmbH | <ul style="list-style-type: none"> • Syntheses of New Chemical Entities (beta blockers, benzodiazepines) |
| Nov 1980 – Jan 1984 | Pharmakologische Untersuchungsgesellschaft mbH | <ul style="list-style-type: none"> • Trace analysis of drugs in biological matrices (GC/HPLC) • Development and validation of software for pharmacokinetics, NCA, and comparative bioavailability • Evaluation of Phase I studies |
| Feb 1984 – May 1987 | Biokinet GmbH | <ul style="list-style-type: none"> • Manager of the Analytical Laboratory • Development and validation of bioanalytical methods for the determination of drugs in biological matrices |
| Jun 1987 – Jul 2004 | Biokinet GmbH | <ul style="list-style-type: none"> • Manager of the Department of Biostatistics and Data Management • Design, implementation, administration of a Laboratory Information Management System (LIMS) according to the rules of Good Automated Laboratory Practices (GALP) • Design and evaluation of more than 500 comparative bioavailability studies • Assessment of about 50 Phase I studies of external CROs |
| Oct 2004 – current | BEBAC – Consultancy
Services for Bioequivalence
and Bioavailability Studies | <ul style="list-style-type: none"> • Consultant in the domain of bioavailability and bioequivalence • Biostatistical services (design, evaluation, and assessment of studies) • Workshops, trainings • Support at regulatory meetings • Maintainer of the Bioequivalence and Bioavailability Forum |
| 2004 – current | Peer reviewer | <ul style="list-style-type: none"> • AAPS J, Chemometr Intell Lab Syst, Clin Pharmacokinet, Clin Res Regul Aff, Comput Meth Prog Biomed, Curr Drug Metab, Drug Metab Lett, Drugs in R&D, Eur J Clin Pharmacol, Eur J Pharm Biopharm, Eur J Pharm Sci, J Bioequivalence Bioavailab, J Biopharm Stat, J Pharm Pharmacol, J Pharmacokinet Pharmacodyn, Pharm Res, Pharm Stat, Stat Med |
| 2016 – current | Co-organiser of the ‘BioBridges’ Conference at the Institute of Pharmacology, 1 st Faculty of Medicine, Charles University, Prague | |
| Feb 2022 – Aug 2022 | Lecturer at the Institute of Medical Statistics, Medical University of Vienna | |

Professional Memberships

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|----------------|--|
| 1992 – 2014 | Drug Information Association (DIA) |
| 2004 – current | The Austrian Federal Economic Chamber |
| 2004 – current | Austrian Association of Consulting Engineers |
| 2005 – current | Region Austria-Switzerland of the International Biometric Society (ROeS-IBS) |
| 2005 – current | Austrian Pharmaceutical Association |
| 2005 – current | European Network for Business and Industrial Statistics |
| 2008 – current | International Society for Clinical Biostatistics (ISCB) |
| 2010 – current | Fédération internationale pharmaceutique (FIP) |
| 2014 – current | American Association of Pharmaceutical Scientists (AAPS) |
| 2015 – current | European Federation for Pharmaceutical Sciences (EUFEPS) |

2015 – current Editorial Board of ‘Drugs in R&D’

2018 – current Association for Applied Human Pharmacology (AGAH)

Certifications

Apr 1980 – current	CMAS	Diver *
Jul 1981 – current		Open Water Scuba Diver
May 1993 – current	PADI	Advanced Open Water Diver
Jul 1995 – Dec 1995		Rescue Diver
Aug 1995 – Dec 2005		Divemaster
		Open Water Scuba Instructor
May 1997 – current	NACD	Cavern Diver
		Introduction to Cave Diving
		Cave Diver
Feb 2002 – current	ProNRC	Nitrox Level I
		Nitrox Level II

