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Personal Details

Nationality: Austrian
 Age: 63
 Place of Birth: Vienna

Education

1974 – 1979

Secondary College for Chemical Engineering
Vienna

Educational Focus: Technical Chemistry, Final Examination passed with Distinction.
 Degree 'Ingenieur' (Chemical Engineer).

1983

Language Skills

Native German, fluent in spoken and written English. Τραβλίζει στα ελληνικά.

Activities

1980

Gerot Pharmazeutika GesmbH
Vienna

Syntheses of NCEs (β -blockers, benzodiazepines).

1980 – 1984

Pharmakologische Untersuchungsgesellschaft mbH
Vienna

Trace Analysis (GC/HPLC).
 Development of Software, Evaluation of Bioequivalence and Pharmacokinetic Studies.

1984 – 2004

Biokinet GmbH
Vienna

1984 – 1987

Manager of the Analytical Laboratory.
 Development and Validation of Bioanalytical Methods for the Determination of Drugs in Biological Matrices.

1987 – 2004

Manager of the Department of Biostatistics and Data Management.
 Design, Implementation, Administration of a Laboratory Information Management System (LIMS) according to the rules of GALP (Good Automated Laboratory Practices).
 Design and Evaluation of more than 500 BA/BE Studies.
 Assessment of about 50 Phase I Studies of external Contract Research Organizations (CROs).

2004 – current

BEBAC
Consultancy Services for Bioequivalence and Bioavailability Studies
Vienna

Independent Consultant in the Domain of Bioavailability and Bioequivalence Studies.
 Biostatistical Services (Design, Evaluation and Assessment of Studies; Lectures, Workshops).
 Support at Regulatory Meetings.
 Maintainer of the Bioequivalence and Bioavailability Forum.

Memberships

1992 – 2014

DIA Drug Information Association

2004 +

WKO Wirtschaftskammer Österreichs (The Austrian Federal Economic Chamber)

2004 +

FI Fachverband Ingenieurbüros (Austrian Association of Consulting Engineers)

2005 +

ROeS Region Austria-Switzerland of the IBS (International Biometric Society)

2005 +

ÖPhG Österreichische Pharmazeutische Gesellschaft (Austrian Pharmaceutical Association)

2005 +

ENBIS European Network for Business and Industrial Statistics

2010 +

FIP International Pharmaceutical Federation

2014 +

AAPS American Association of Pharmaceutical Scientists

2015 +	EUFEPS European Federation for Pharmaceutical Sciences
2018 +	AGAH Arbeitsgemeinschaft für Angewandte Humanpharmakologie (Association for Applied Human Pharmacology)
2015 +	Editorial Board of <i>Drugs in R&D</i> .

IT-Proficiency

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

Presentations / Continuing Education

Introduction to Multidimensional Gas Chromatography (Vienna  1980)
 Rocky Mountain BASIC I/9000 (Vienna  1982)
 Derivatization in GC (Vienna  1982)
 Symposium on Sample Preparation and Isolation Techniques using Bonded Silica (Vienna  1984)
 Biogenic Amines and their Metabolites (Vienna  1985)
 Bioavailability/Bioequivalence, Pharmaceutical and Therapeutic Equivalence (Würzburg  1987)
 European Congress of Biopharmaceutics and Pharmacokinetics (Freiburg  1987, Geneva  1990, Brussels  1993)
 Pascal Operating System for HP9000 Series 200/300 (Vienna  1987)
 Programming in Pascal (Vienna  1987)
 Forum Analytik (Vienna  1988, 1989, 1991, 1992, 1993)
 International Symposium on Coupled Column Separation (Uppsala  1988)
 Background – Design – Analysis & Interpretation of Bioavailability / Bioequivalence Studies (London  1990)
 Bioavailability of Drugs & Pharmacokinetics (Amsterdam  1990)
 Modern Methods for Drug Monitoring and their Significance for Clinical Practice (Graz  1990)
 Analytical Methods Validation: Bioavailability, Bioequivalence and Pharmacokinetic Studies Conference (Arlington  1990)
 Workshop in Pharmacokinetic Modeling (Palo Alto  1991)
 Workshop in Bioavailability/Bioequivalence (Palo Alto  1991)
 LIMS Workshop (Linz  1992)
 Supercritical Fluid Extraction Workshop (Vienna  1992)
 International Open Conference on Dissolution, Bioavailability, Bioequivalence (Toronto  1992)
 Oral Modified-Release Dosage Forms: Biopharmaceutical Challenges and Clinical Implications (Stockholm  1992)
 Quality Assurance in the Analytical Laboratory (Vienna  1992)
 Modified Release Formulations in Clinical Practice, Pharmaceutical Technology and Registration (Graz  1992)
 Millennium 2010 Chromatography Manager (Vienna  1992)
 GLP Module: Good Laboratory Practice, Basic Training (Bingen  1992)
 Shimadzu HPLC (Vienna  1993)
 Computerized Data Handling – Current Trends in Pharmaceutical and Clinical Research (Neu-Ulm  1993)
 Chromatography Meeting (Vienna  1993)
 HPLC Seminar for Professionals (Korneuburg  1993)
 The Main Issue is Significance – Typical Pitfalls in Clinical Trials (Frankfurt  1993)
 Generics in Comparison: Bioavailability, Bioequivalence (Vienna  1994)
 HP-UX System Administration (Vienna  1994)
 Bio-International Conference (Munich  1994, London  1999, 2003, 2005, 2008)
 Introduction to LAB / UX 2.0 LIMS (Vienna  1994)
 Microsoft BackOffice (Vienna  1995)
 BIODINET 95: Criteria of Bioequivalence (Vienna  1995)

2nd EUFEPS Nuremberg Conference: Symposium on Quality and Interchangeability of Topical Products for Local Action (🇩🇪 Nuremberg 1995)

BIOKINET 96: Current Developments in the Testing of Topical Medicinal Products with Local Effect (Vienna 🇦🇹 1996)

Clinical Research Seminar Series: Biometrics in Europe (Munich 🇩🇪 1997)

The Path of a Drug through the Body: Bioavailability – Pharmacokinetics (Vienna 🇦🇹 1999)

Dissolution Testing, Bioequivalence & Bioavailability Studies: Maximizing Scientific and Technological Advancements (🇧🇪 Brussels 2004)

Dissolution, Bioavailability & Bioequivalence: Finding Alternatives to BA/BE Testing (Amsterdam 🇳🇱 2005)

Dissolution Testing, Bioavailability & Bioequivalence (Budapest 🇭🇺 2006, 2007, Berlin 🇩🇪 2007)

International Regulatory Workshop on Bioequivalence and Dissolution (Budapest 🇭🇺 2006)

EGA Workshop on Bioequivalence Study Design, Working to GCP and Interpreting the Guidelines (Lisbon 🇵🇹 2007)

Dissolution, Bioavailability and Bioequivalence (🇭🇺 Budapest 2008, 🇨🇪 Prague 2008)

Dissolution Testing, Bioequivalence and Bioavailability Strategies (London 🇬🇧 2008)

Increasing Predictability in Gastrointestinal Simulation (Zeist 🇳🇱 2008)

2nd World Conference on Magic Bullets – Ehrlich II (🇩🇪 Nuremberg 2008)

CMD(h)-EGA Symposia on Bioequivalence (Paris 🇫🇷 2008, London 🇬🇧 2010)

Bioavailability, Bioequivalence, Pharmacokinetics & Beyond (Ahmedabad 🇮🇳 2008)

EUFEPS BABP Open Discussion Forum (Bonn 🇩🇪 2009, Barcelona 🇪🇸 2011)

Bioequivalence and Bioavailability (Budapest 🇭🇺 2009, Ljubljana 🇸🇯 2010)

Introduction to Phoenix WinNonlin 6.0 (Munich 🇩🇪 2009)

EBF & EUFEPS Workshop: EMEA Draft Guideline on Validation of Bioanalytical Methods (Brussels 🇧🇪 2010)

International Regulatory Workshops on Bioequivalence, Bioanalysis, Dissolution and Biosimilarity (Budapest 🇭🇺 2010, 2012, 2014)

Bioequivalence and Bioavailability Studies (Munich 🇩🇪 2010, Brussels 🇧🇪 2011)

Biostatistics: Basic concepts & applicable principles for various designs in bioequivalence studies and data analysis (Mumbai 🇮🇳 2011)

Bioavailability/Bioequivalence and Dissolution Testing (Budapest 🇭🇺 2011)

International Symposium on BA/BE of Oral Drug Products (Kobe 🇯🇵 2011)

Innovations in Modified Release (Berlin 🇩🇪 2011)

In vitro in vivo Correlation (IVIVC), Biowaivers & Statistical Aspects of Bioequivalence in Drug Product Development (Mumbai 🇮🇳 2012)

Drug development and registration «Pharma-2020» Implementation Strategy (Moscow 🇷🇺 2012)

Advanced concepts of *IVIVC* through case studies; Biostatistical aspects of Reference-scaled & Two stage designs (Mumbai 🇮🇳 2013)

Bioavailability / Bioequivalence, Dissolution and Biowaivers (Budapest 🇭🇺 2013, 2014, Prague 🇨🇪 2015)

EUFEPS BABP Open Discussion Forum on the Revised European Guideline on Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms (Bonn 🇩🇪 2013)

Bioequivalence Assessment of Oral Dosage Forms (Leuven 🇧🇪 2013)

MENA Regulatory Conference on Bioequivalence, Biowaiver, Bioanalysis and Dissolution (Amman 🇯🇴 2013, 2018)

5th BBBB International Conference. From Drug Discovery and Formulation Strategies to Pharmacokinetics and Pharmacodynamics (Athens 🇬🇷 2013)

Clinical Development Workshop (Prague 🇨🇪 2013)

Haemophilia Master Class: Personalized Treatment and Care (Munich 🇩🇪 2014, Frankfurt 🇩🇪 2014)

Innovative Statistical Approaches in Drug Development (Vienna 🇦🇹 2014)

Spanish Congress of Pharmacy and Pharmaceutical Technology (Barcelona 🇪🇸 2015)

Interaktiver Workshop PK-Dosing in der Hämophilie A (Munich 🇩🇪 2015)

EUFEPS BABP Network: Global Bioequivalence Harmonisation Initiative (Amsterdam 🇳🇱 2015, Rockville 🇺🇸 2016, Amsterdam 🇳🇱 2018, Bethesda 🇺🇸 2019)

EMA / EGA joint workshop on the impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms (London 🇬🇧 2015)

International Symposium on Scientific and Regulatory Advances in Complex Drugs (Budapest 🇭🇺 2015, 2016)

5th Scientific Conference “Clinical Trials of Medicines in Ukraine” (Kiev 🇺🇦 2015)

Scientific and Regulatory Issues in Drug Development and Bioequivalence (Lisbon 🇵🇹 2016)

25th PAGE meeting (Lisbon 🇵🇹 2016)

To New Shores in Drug Development Implementing Statistical Innovation (Vienna 🇦🇹 2016)





BE Workshop (Moscow 🇷🇺 2016)

BioBridges (Prague 🇨🇪 2016, 2017, 2018, 2019)







































Annual Biosimilars Forum (Budapest 🇭🇺 2017, 2018, 2019)

IInd International Conference «Studies of medicinal products: Simple and complex tasks» (Yaroslavl 🇷🇺 2017)

Transforming Data to Insights (Vienna 🇦🇹 2019)

Network of Scientific Excellence (Campinas  2020)
 Estudos em doses múltiplas para medicamentos genéricos e similares de liberação modificada – Contexto nacional e internacional (São Paulo  2021)
 IIIrd International Conference «The life cycle of medicines: simple and complex tasks» (Yaroslavl  2021)
 Bioequivalence. An Old Area with some Uncharted Territories (Vienna  2021)

Workshops / in-house Trainings

Regulatory Update and Overview of BE and BA Testing with an Industry Perspective (Istanbul  2006)
 Bioequivalence (Aesch  2008, 2011, Nijmegen  2010, Ljubljana  2010, Munich  2010, Holzkirchen  2010, Vienna  2011, Nyon  2012, Bucharest  2013, Kaunas  2017)
 Workshop on Statistics for Bioequivalence Studies (Prague  2009, Moscow  2012)
 Design and Interpretation of Bioequivalence Studies – Current and Future Issues (Berlin  2010)
 Workshop on Bioanalytics (Prague  2010)
 Advanced training on pharmacokinetics, statistics and analytics in Bioequivalence Studies in Russia (Moscow  2012, 2014)
 Seminar on BE Studies (Prague  2012)
 Workshop in Biostatistics for Bioequivalence (Ulm  2013, Zagreb  2013)
 Design and Evaluation of Bioequivalence Studies (Barcelona  2014)
 PK-NCA, PK-based Design, Biostatistics (Prague  2015)
 Drug Modeling & Consulting (Bilbao  2016)
 Bioequivalence, Dissolution & IVIVC (Berlin  2016, Barcelona  2017, Vienna  2017, León  2017, Barcelona  2018, Athens  2018)
 Inflation of the Type I Error in Reference-Scaled Average Bioequivalence (Vienna  2016, Prague  2016)
 Course on Pharmacokinetics and Bioequivalence (Budapest  2017)
 Open Issues in the Assessment of Bioequivalence and Biosimilarity (Budapest  2017)
 Basic Statistical Concepts behind BE Testing (Pamplona  2018)
 Introduction into Basic Principles of Pharmacokinetics (Oberursel  2018)
 Sample Size Estimation for Bioequivalence (Amman  2018)
 Statistical Assessment of Bioequivalence Studies (Gdańsk  2019)
 Dissolution, Bioequivalence & Biowaivers (Athens  2019)
 BE Course (Bilbao  2021)
 Methodenseminar Statistik (Vienna  2022)

Posters

Eichinger A, Schütz H, Nitsche V. *Development and Application of an HPLC Determination of Buspirone in Plasma by Solid-Phase Extraction and On-Line Precolumn Trace Enrichment*. International Symposium on Coupled Column Separations (Uppsala  1988, Oct 26–27). Poster 7.
 Eichinger A, Schütz H, Nitsche V. *Determination of Buspirone in Plasma by HPLC with Solid-Phase Extraction and On-Line Precolumn Trace Enrichment and its Application to a Pharmacokinetic Study*. 4th European Congress of Biopharmaceutics and Pharmacokinetics (Geneva  1990, Apr 17–19). *Europ J Drug Metabol Pharmacokin*. 1990; 15(1): P234.
 Schütz H, Eichinger A, Nitsche V. *Determination of Amoxicillin and Ampicillin using a new HPLC Method with Post-Column Derivatization and its Application to Bioavailability Studies*. 4th European Congress of Biopharmaceutics and Pharmacokinetics (Geneva  1990, Apr 17–19). *Europ J Drug Metabol Pharmacokin*. 1990; 15(1): P235.
 Schütz H, Eichinger A, Krenauer J, Kaspar A, Wolf C, Nitsche V. *Implementierung der GLP in einem Auftragsforschungslabor mit 6 Mitarbeitern*. 10. Forum Analytik (Vienna  1993, Jan 25–27).
 Henry A, Schütz H, Hughes L, Davis S. *Performing Reference-Scaled Average Bioequivalence (RSABE) in Phoenix[®] WinNonlin[®]*. AAPS Annual Meeting and Exposition (San Antonio  2013, Nov 10–14). Poster T2350. doi:10.13140/RG.2.1.1008.0800.
 König F, Wolfsegger MJ, Jaki T, Schütz H, Wassmer G. *Adaptive two-stage bioequivalence trials with early stopping and sample size re-estimation*. 35th Annual Conference of the International Society for Clinical Biostatistics (Vienna  2014, Aug 24–28). Poster P1.2.88. doi:10.13140/RG.2.1.5190.0967.
 König F, Wolfsegger MJ, Jaki T, Schütz H, Wassmer G. *Adaptive two-stage bioequivalence trials with early stopping and sample size re-estimation*. 3rd International Clinical Trials Methodology Conference (Glasgow  2015, Nov 16–17) Poster 218. *Trials* 16(Suppl 2): P218. doi:10.1186/1745-6215-16-S2-P218.
 Booth J, Schütz H, Steinitz-Trost K, Lee H-Y, Bauer A, Wolfsegger M. *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*. XXVI Congress of the International Society on Thrombosis and Haemostasis and 63rd Annual Scientific and Standardization Committee Meeting (Berlin  2017, Jul 8–13) PB 1131.

- Booth J, Schütz H, Steinitz-Trost K, Lee H-Y, Bauer A, Wolfsegger M. *Minimum half-life extension ratio model for reduced dosing frequency of extended half-life recombinant FVIII products*. HAA Annual Scientific Meeting (Sydney 🇦🇺 2017, Oct 29–Nov 01). P223.
- Mehl C, Henry A, Hughes L, Schütz H. *Reference-Scaled Average Bioequivalence (RSABE) Approach For Compounds With A Narrow Therapeutic Index (NTID) Using Phoenix™ WinNonlin®*. AAPS Annual Meeting and Exposition (San Diego 🇺🇸 2017, Nov 12–16). Poster W2087. doi:10.13140/RG.2.2.35361.30564.
- Booth J, Schütz H, Steinitz-Trost K, Lee H-Y, Bauer A, Wolfsegger M. *A Model of the Minimum Half-life Extension Ratio Needed to Reduce the Dosing Frequency of Extended Half-life (EHL) Recombinant FVIII (rFVIII) Products*. 62nd Annual Meeting of the Society of Thrombosis and Haemostasis Research (Vienna 🇦🇹 2018, Feb 20–23). P160.
- Ring A, Lang B, Kazaroho C, Labes D, Awounvo JS, Schütz H. *Assurance (expected power) for planning crossover bioequivalence trials*. Pharmacology (London 🇬🇧, 2018, Dec 18–20). P79. Br J Clin Pharmacol. 2019; 85: 1622. doi:10.1111/bcp.13937.

Papers

- 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. PMID 6698663.
- 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. doi:10.1016/S0378-4347(00)80885-3.
- Nitsche V, Mascher H, Schütz H. *Bioverfügbarkeit von Amilorid-Hydrochlorothiazid-Kombinationspräparaten*. Therapiewoche. 1985; 36(1): 56–60.
- 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. doi:10.1016/0378-4347(87)80175-5.
- Nitsche V, Lauschner R, Eichinger A, Schütz H. *Absolute Bioverfügbarkeit von Ambroxol-Zäpfchen*. Pharm Ztg. 1988; 133(32): 28–33.
- 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. PMID 9089000.
- Bohner H, Janiak PS, Nitsche V, Eichinger A, Schütz H. *Relative bioavailability of different butamirate citrate preparations after single dose oral administration to 18 healthy volunteers*. Int J Clin Pharmacol Ther. 1997; 35(3): 117–22. PMID 9089001.
- Schütz H. *An extremely strange observation?* [letter]. Eur J Drug Metabol Pharmacokinet. 2004; 29(1): 69–71. doi:10.1007/BF03190576.
- Fischer R, Schütz H, Grossmann M, Leis HJ, Ammer R. *Bioequivalence of methylphenidate hydrochloride of an extended release preparation; comparison of an intact capsule and an opened capsule sprinkled on applesauce*. Int J Clin Pharmacol Ther. 2006; 44(3): 135–41. doi:10.5414/cpp44135.
- 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. doi:10.5414/cpp47761.
- Leis HJ, Schütz H, Windischhofer W. *Quantitative determination of methylphenidate in plasma by gas chromatography negative ion chemical ionisation mass spectrometry using o-(pentafluorobenzoyloxy-carbonyl)-benzoyl derivatives*. Anal Bioanal Chem. 2011; 400(8): 2663–70. doi:10.1007/s00216-011-5048-6.
- Schütz H, Labes D, Fuglsang A. *Reference Datasets for 2-Treatment, 2-Sequence, 2-Period Bioequivalence Studies*. AAPS J. 2014; 16(6): 1292–7. doi:10.1208/s12248-014-9661-0. PMC 4389751.
- 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. doi:10.1208/s12248-014-9680-x. PMC 4287291.
- Schütz H. *Two-stage designs in bioequivalence trials*. Eur J Clin Pharmacol. 2015; 71(3): 271–81. doi:10.1007/s00228-015-1806-2.
- Fuglsang A, Schütz H, Labes D. *Reference Datasets for Bioequivalence Trials in a Two-Group Parallel Design*. AAPS J. 2015; 17(2): 400–4. doi:10.1208/s12248-014-9704-6. PMC 4365103.
- Labes D, Schütz H. *Inflation of Type I Error in the Evaluation of Scaled Average Bioequivalence, and a Method for its Control*. Pharm Res. 2016; 33(11): 2805–14. doi:10.1007/s11095-016-2006-1.
- Cardot J-M, Roudier B, Schütz H. *Dissolution comparisons using a Multivariate Statistical Distance (MSD) test and a comparison of various approaches for calculating the measurements of dissolution profile comparison*. AAPS J. 2017; 19(4): 1091–1101. doi:10.1208/s12248-017-0063-y.
- Hermans C, Mahlangu J, Booth J, Schütz H, Santagostino E, Young G, Lee H-J, Steinitz-Trost KN, Blanchette V, Berntorp E. *Pharmacokinetic modelling and validation of the half-life extension needed to reduce the burden of infusions compared with standard factor VIII*. Haemophilia. 2018; 24(3): 376–84. doi:10.1111/hae.13483.

- Ring A, Lang B, Kazaroho C, Labes D, Schall R, Schütz H. *Sample size determination in bioequivalence studies using statistical assurance*. Br J Clin Pharmacol. 2019; 85(10): 2369–77. doi:10.1111/bcp.14055. PMID 6783617.
- Schütz H, Tomashevskiy M, Labes D, Shitova A, González-de la Parra M, Fuglsang A. *Reference Data-sets for Studies in a Replicate Design intended for Average Bioequivalence with Expanding Limits*. AAPS J. 2020; 22(2): Article 44. doi:10.1208/s12248-020-0427-6.
- Molins E, Ocaña J, Cobo E, Labes D, Schütz H. *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. doi:10.1002/bimj.201900388.
- Wolfsegger JM, 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. doi:10.1002/pst.2074.
- Schütz H, Labes D. (2021). *Critical remarks on reference-scaled average bioequivalence*. Manuscript submitted for publication.
- Schütz H. (2022). *Group-Effects in Bioequivalence Studies*. Manuscript in preparation.

R packages

- Schütz H. *AdaptiveBE: Acceptability of Adaptive Bioequivalence Studies*. 2018; R package version 0.8.4.9000.
- Molins E, Labes D, Schütz H, Ocaña J. *betsd: Adjusting significance levels in two-stage adaptive 2×2 crossover designs*. 2019; R package version 0.1.5.
- Schütz H, Tomashevskiy M, Labes D. *replicateBE: Average Bioequivalence with Expanding Limits (ABEL)*. 2021; R package version 1.1.0.
- Schütz H. *indirectBE: Adjusted Indirect Comparisons*. 2021; R package version 0.3.0.
- Labes D, Schütz H, Lang B. *PowerTOST: Power and Sample Size Based on Two One-Sided t-Tests (TOST) for (Bio)Equivalence Studies*. 2021; R package version 1.5-3.
- Labes D, Lang B, Schütz H. *Power2Stage: Power and Sample-Size Distribution of 2-Stage Bioequivalence Studies*. 2021; R package version 0.5-4.

