



## Curriculum Vitae

Personal information **Laszlo Tothfalusi**

### Work experience

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- **Nov 2024 – Present:** Clinical Pharmacology Assessor, National Center for Public Health and Pharmacy (formerly National Institute of Pharmacy)
- **1999 – Oct 2024:** Contracted Clinical Pharmacology Assessor, National Institute of Pharmacy
- **1997 – 1998:** Visiting Scholar, Department of Pharmacology, University of Toronto, Canada
- **1993 – 1996:** Research Fellow, Department of Pharmacology, University of Toronto, Canada

**1981 – Present:** Various positions, currently Professor, Department of Pharmacodynamics

### Education and training

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#### University Degrees:

- **1990 – 1993:** MSc in Computational Mathematics, Faculty of Science, Eötvös Loránd University (ELTE), Grade: Excellent
- **1986 – 1990:** BSc in Computational Mathematics, Faculty of Science, Eötvös Loránd University (ELTE), Grade: Distinction
- **1975 – 1981:** Pharmacy Degree, Faculty of Pharmaceutical Sciences, Semmelweis University, Grade: Distinction

### Additional information

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#### Publications

#### Relevant Publications

1. Endrenyi L, Tothfalusi L, Zha J. Metrics assessing absorption rates: principles, and determination of bioequivalence in the steady state. In: Henning H. Blume, Kamal K Midha editors. *Bioavailability, Bioequivalence and Pharmacokinetic Studies*. International Conference of FIP "Bio-International '94" Munich, Germany: FIP; 1994. p. 77-87.
2. Zha J, Tothfalusi L, Endrenyi L. Properties of metrics applied for the evaluation of bioequivalence. *Drug Information Journal*. 1995;29(3):989-996.

3. Tothfalusi L, Endrenyi L. Without extrapolation, C<sub>max</sub>/AUC is an effective metric in investigations of bioequivalence. *Pharmaceutical Research*. 1995;12(6):937-942.
4. Tothfalusi L, Endrenyi L. Algorithms for robust nonlinear regression with heteroscedastic errors. *International Journal of Biomedical Computing*. 1996;42(3):181-190.
5. Endrenyi L, Tothfalusi L. Secondary metrics for the assessment of bioequivalence. *Journal of Pharmaceutical Sciences*. 1997;86(3):401-402.
6. Endrenyi L, Tothfalusi L. Truncated AUC evaluates effectively the bioequivalence of drugs with long half-lives. *International Journal of Clinical Pharmacology and Therapeutics*. 1997;35(4):142-150.
7. Endrenyi L, Csizmadia F, Tothfalusi L, Chen ML. Metrics comparing simulated early concentration profiles for the determination of bioequivalence. *Pharmaceutical Research*. 1998;15(8):1292-1299.
8. Endrenyi L, Tothfalusi L. Subject-by-formulation interaction in determinations of individual bioequivalence: bias and prevalence. *Pharmaceutical Research*. 1999;16(2):186-190.
9. Kalow W, Ozdemir V, Tang BK, Tothfalusi L, Endrenyi L. The science of pharmacological variability: an essay. *Clinical Pharmacology & Therapeutics*. 1999;66(5):445-447.
10. Ring A, Tothfalusi L, Endrenyi L, Weiss M. Sensitivity of empirical metrics of rate of absorption in bioequivalence studies. *Pharmaceutical Research*. 2000;17(5):583-588.
11. Endrenyi L, Taback N, Tothfalusi L. Properties of the estimated variance component for subject-by-formulation interaction in studies of individual bioequivalence. *Statistics in Medicine*. 2000;19(20):2867-2878.
12. Tothfalusi L, Endrenyi L. Evaluation of some properties of individual bioequivalence (IBE) from replicate-design studies. *International Journal of Clinical Pharmacology and Therapeutics*. 2001;39(4):162-166.
13. Kalow W, Ozdemir V, Tothfalusi L. Multigenic traits and risk assessment in pharmacology: a population approach. *Pharmacogenomics Journal*. 2001;1(4):234-236.
14. Tothfalusi L, Endrenyi L, Midha KK, Rawson MJ, Hubbard JW. Evaluation of the bioequivalence of highly-variable drugs and drug products. *Pharmaceutical Research*. 2001;18(6):728-733.
15. Tóthfalusi L, Borvendég J. Bioekvivalencia vizsgálatok kiértékelésének néhány problémája a nemzetközi szabályozás tükrében vizsgálva. *Gyógyszereink*. 2002;53:168-170.

16. Tothfalusi L, Endrenyi L. Estimation of Cmax and Tmax in populations after single and multiple drug administrations. *Journal of Pharmacokinetics and Pharmacodynamics*. 2003;30(5):363-385.
17. Tothfalusi L, Endrenyi L. Limits for the scaled average bioequivalence of highly variable drugs and drug products. *Pharmaceutical Research*. 2003;20(3):382-389.
18. Tothfalusi L, Endrenyi L, Midha KK. Scaling or wider bioequivalence limits for highly variable drugs and for the special case of Cmax. *International Journal of Clinical Pharmacology and Therapeutics*. 2003;41(5):217-225.
19. Ehmann F, Sakai-Kato K, Duncan R, de la Ossa DHP, Pita R, Vidal JM, Kohli A, Tothfalusi L, Sanh A, Tinton S, Robert JL, Lima BS, Amati MP. Next-generation nanomedicines and nanosimilars: EU regulators' initiatives relating to the development and evaluation of nanomedicines. *Nanomedicine: Nanotechnology, Biology, and Medicine*. 2013;8(5):849-856.
20. Endrenyi L, Chang C, Chow SC, Tothfalusi L. On the interchangeability of biologic drug products. *Statistics in Medicine*. 2013;32(3):434-441.
21. Tothfalusi L, Endrenyi L, Chow SC. Statistical and regulatory considerations in assessments of interchangeability of biological drug products. *European Journal of Health Economics*. 2014;15:S5-S11.
22. Tothfalusi L, Endrenyi L. An exact procedure for the evaluation of reference-scaled average bioequivalence. *AAPS Journal*. 2016;18(2):476-489.
23. Brodszky V, Biro A, Szekanecz Z, Soos B, Baji P, Rencz F, Tothfalusi L, Gulacsi L, Pentek M. Determinants of biological drug survival in rheumatoid arthritis: evidence from a Hungarian rheumatology center over 8 years of retrospective data. *ClinicoEconomics and Outcomes Research*. 2017;9:139-147.
24. Endrenyi L, Blume HH, Tothfalusi L. The two main goals of bioequivalence studies. *AAPS Journal*. 2017;19(4):885-890.
25. Tothfalusi L, Endrenyi L. Algorithms for evaluating reference-scaled average bioequivalence: Power, bias, and consumer risk. *Statistics in Medicine*. 2017;36(27):4378-4390.

#### Projects

Methodology development for bioequivalence assessment of highly-variable drugs  
 Consultant statistician for several Ph.D projects on many different fields

#### Memberships

International Society of Clinical Biostatistics.

#### Other Relevant Information