

### **Panos Macheras: POSTERS AND TALKS 2013-2023**

1. *Drug development. Making a scientific discovery marketable.* Invited lecture. World Hellenic Biomedical Association-2<sup>nd</sup> summer school in biomedical research and management, Sparta, Greece June 3, 2013.
2. *From the assessment of bioequivalence of generics to the modern era of biosimilars.* Invited lecture. World Hellenic Biomedical Association-2<sup>nd</sup> summer school in biomedical research and management, Sparta, Greece, June 4, 2013.
3. V. KARALIS, P. MACHERAS. On the Properties of a Two-Stage Design for Bioequivalence Studies. 22<sup>nd</sup> Population Approach Group in Europe (PAGE) meeting Glasgow 11-14 June 2013.
4. **Keynote Speaker.** *Modeling oral drug absorption: The scientific basis of regulations.* 5<sup>th</sup> BBBB International conference Athens, Greece, September 26-28, 2013.
5. *Biosimilars: pharmaceutical, immunological and regulatory aspects.* Invited lecture. 5<sup>th</sup> BBBB International conference Athens, Greece, September 26-28, 2013
6. *Biotechnology in Greece: Possibilities and Perspectives.* Invited lecture. 2<sup>nd</sup> International Forum, Biosciences and cancer: From prevention to therapy. Athens, 11<sup>th</sup> October 2013.
7. Organiser, speaker and moderator of sunrise session "Poorly explored issues in Bioequivalence assessment". Talk: *An insight into the problem of interchangeability: Narrow and non-narrow therapeutic range drugs.* 13<sup>th</sup> November 2013. 28<sup>th</sup> Annual Meeting of the A.A.P.S., San Antonio, TX, November 10-14, 2013.
8. V. KARALIS, A. ILIADIS, P. MACHERAS. An application of stochastic compartmental modeling to the anomalous amiodarone pharmacokinetics. 28<sup>th</sup> Annual Meeting of the A.A.P.S., San Antonio, TX, November 10-14, 2013.
9. V. KARALIS, P. MACHERAS. Assessing the performance of a two-stage design in bioequivalence studies. 28<sup>th</sup> Annual Meeting of the A.A.P.S., San Antonio, TX, November 10-14, 2013.
10. V. KARALIS, P. MACHERAS, M. BIALER. On the bioequivalence and switchability of generic products of antiepileptic drugs. 28<sup>th</sup> Annual Meeting of the A.A.P.S., San Antonio, TX, November 10-14, 2013.
11. V. KARALIS, M. BIALER, P. MACHERAS. Quantitative assessment of the interchangeability of generic products. 28<sup>th</sup> Annual Meeting of the A.A.P.S., San Antonio, TX, November 10-14, 2013.

12. V. KARALIS, M. SYMILLIDES, P. MACHERAS. The impact of test and reference products' variability on scaled average bioequivalence acceptance. 28<sup>th</sup> Annual Meeting of the A.A.P.S., San Antonio, TX, November 10-14, 2013.
13. G. CHARKOFTAKI, V. KARALIS, P. MACHERAS. Is there any relationship between pharmacokinetic parameters and BCS/BDDCS classification? 28<sup>th</sup> Annual Meeting of the A.A.P.S., San Antonio, TX, November 10-14, 2013.
14. P. MACHERAS, V. KARALIS. Non-binary biopharmaceutics classification system (NB-BCS) 28<sup>th</sup> Annual Meeting of the A.A.P.S., San Antonio, TX, November 10-14, 2013.
15. *From binary to non-binary biopharmaceutic classification of drugs*. Invited lecture. Manchester Pharmacy School, The University of Manchester UK. Manchester, March 19, 2014.
16. *Oral drug absorption: Science and regulation*. Invited lecture. 4<sup>th</sup> International regulatory workshop on A to Z bioequivalence: bioanalysis, dissolution and biosimilarity. Budapest, May 19-21, 2014.
17. K. SOULELE, P. MACHERAS, V. KARALIS. A population pharmacokinetic study of fluticasone/salmeterol in healthy subjects using two different dry powder inhalers. 23<sup>rd</sup> Population Approach Group in Europe (PAGE) meeting, Alicante. Spain June 10-13, 2014.
18. *Milk as a medium for paediatric formulations: experimental findings and regulatory aspects*, Invited lecture. 6<sup>th</sup> European Pediatric Formulation Initiative, Athens, 17-18 September 2014.
19. *On the dynamic character of biopharmaceutic classification of drugs: Implications for biowaivers*. Invited lecture. Second Congress of Pharmaceutical Sciences in Greece: from research to society. University of Patras, Patras, October 9-11, 2014.
20. C. DAOUSANI, P. MACHERAS. Scientific considerations concerning the EMA change in the definition of "Dose" of the BCS-based Biowaiver Guideline. 29<sup>th</sup> Annual Meeting of the A.A.P.S., San Diego, CA, November 2-6, 2014.
21. C. DAOUSANI, V. KARALIS, P. MACHERAS. On the Properties of the New Biopharmaceutic Classification System AB $\Gamma$ : Application to Actual Data. 29<sup>th</sup> Annual Meeting of the A.A.P.S., San Diego, CA, November 2-6, 2014.
22. K. SOULELE, P. MACHERAS, V. KARALIS. A population pharmacokinetic analysis using data from dry powder inhalers: the case of fluticasone/salmeterol. 29<sup>th</sup> Annual Meeting of the A.A.P.S., San Diego, CA, November 2-6, 2014.

23. (A). *Milk based formulations for everyone: neonates, children, adults and elderly.* (B). *The dynamic character of biopharmaceutic classification of drugs: Implications for biowaivers.* (C). *From non-classical modeling in Biopharmaceutics-Pharmacokinetics to Population PK-PD approaches.* Invited seminar. Clinical Pharmacology, Phizer, La Jolla, CA, November 6, 2014.
24. *Oral drug absorption: Science and regulation.* Invited lecture. 1st International Congress: From drug discovery to drug delivery. 13-15 November 2014, Royal Olympic Hotel, Athens, Greece.
25. *Milk as a medium for paediatric formulations: experimental findings and regulatory aspects.* Invited lecture. 1st International Congress of Controlled Release Society-Greek local chapter Athens, 27-28 May 2015.
26. *Modeling approaches supporting biowaiver applications.* Invited lecture. MD Pharmacon Pharmaceutical Services workshop on “Advances in scientific-regulatory issues in drug development and authorization processes” May 29, 2015, Aegli Zappeiou, Athens, Greece.
27. *Biosimilars.* Invited lecture. MD Pharmacon Pharmaceutical Services workshop on “Advances in scientific-regulatory issues in drug development and authorization processes” May 29, 2015, Aegli Zappeiou, Athens, Greece.
28. *Modeling approaches for the biopharmaceutic classification of drugs and the biowaiver status.* Invited lecture. MD Pharmacon Pharmaceutical Services satellite workshop to 24th Population Approach Group in Europe (PAGE) meeting on “Kinetic and Dynamic Complexity in Drug Transit-Response in the Human Body”. Creta Maris Convention Center, June 2-5, 2015, Hersonissos, Crete.
29. *Fractals and fractal kinetics in drug release and drug disposition.* Invited lecture. MD Pharmacon Pharmaceutical Services satellite workshop to 24th Population Approach Group in Europe (PAGE) meeting on “Kinetic and Dynamic Complexity in Drug Transit-Response in the Human Body”. Creta Maris Convention Center, June 2-5, 2015, Hersonissos, Crete.
30. V. KARALIS, A. DOKOUMETZIDIS, P. MACHERAS. A computational methodology for the validation of the terminal slope estimate. 24th Population Approach Group in Europe (PAGE) meeting, Creta Maris Convention Center, June 2-5, 2015, Hersonissos, Crete.
31. *Biopharmaceutic classification of drugs revisited.* Invited lecture. 6th BBBB International conference “Strategies to Improve the Quality and Performance of Modern Drug Delivery Systems” Helsinki, Finland, September 10-12, 2015.
32. P. MACHERAS. Biopharmaceutic classification of drugs using a heterogeneous-dynamic pseudo steady-state model of gastrointestinal absorption. 30th Annual Meeting of the A.A.P.S., Orlando, FL, October 25-29, 2015.

33. *Biopharmaceutic classification of drugs: an ever evolving field.* Invited lecture. The International Conference on Advances in the Area of Bioequivalence (ICAB 2015) Margaret Island, Hotel Danubius, Budapest, Hungary. November 14, 2015.
34. K. SOULELE, V. KARALIS, P. MACHERAS. A population pharmacokinetic study of salmeterol in asthmatic patients using two dry powder inhalers. 25<sup>th</sup> Population Approach Group in Europe (PAGE) meeting Lisbon, Portugal, June 7-10, 2016.
35. *BCS: Then and now.* Invited lecture. MDPharmacon Pharmaceutical Services- Portuguese Society of Pharmaceutical Sciences, Satellite workshop to 25<sup>th</sup> PAGE meeting on Scientific and regulatory issues in drug development and bioequivalence. Faculty of Pharmacy, University of Lisbon, Lisbon, Portugal, June 6-9, 2016.
36. *Drug Dissolution and Release: Current and future modeling and biopharmaceutical aspects.* Invited lecture. MDPharmacon Pharmaceutical Services- Portuguese Society of Pharmaceutical Sciences, Satellite workshop to 25<sup>th</sup> PAGE meeting on Scientific and regulatory issues in drug development and bioequivalence. Faculty of Pharmacy, University of Lisbon, Lisbon, Portugal June 6-9, 2016.
37. *Drug Dissolution and Release: Modeling and Biopharmaceutical Aspects.* Invited lecture. 27<sup>th</sup> Symposium of Pharmaceutical Technology, University of Ljubljana, Faculty of Pharmacy, Ljubljana, Slovenia, June 16, 2016.
38. *Reaction-limited model of drug dissolution: Important...but of low status in pharmaceuticals/biopharmaceuticals.* 2<sup>nd</sup> International congress of Greek local chapter of Controlled Release Society (CRS), Athens, 22-24 June 2016.
39. *Modeling and simulation in biopharmaceutics, pharmacokinetics and pharmacodynamics: Science and Regulation.* Invited lecture. MIT, Boston, USA, November 7, 2016.
40. *Milk based formulations.* Invited lecture. Bill & Melinda Gates Foundation. Seattle, USA, November 9, 2016.
41. *BCS, BDDCS: Then, now and beyond.* Invited lecture. University of California San Francisco, San Francisco, USA, November 10 (morning talk) 2016.
42. *Getting a license without a clinical study: Science and Regulation.* Invited lecture. University of Stanford, Palo Alto, USA, November 10 (afternoon talk) 2016.
43. K. SOULELE, V. KARALIS, P. MACHERAS. A comparison of the pharmacokinetics of inhaled salmeterol in healthy and asthmatic subjects: A population pharmacokinetic analysis. 31<sup>st</sup> Annual Meeting of the A.A.P.S., Denver, CO, November 13-17, 2016.
44. C. DAOUSANI, P. MACHERAS, V. KARALIS. Understanding the Linkage between Pharmacokinetic Properties and the Two Classification Systems: BCS and BDDCS. 31<sup>st</sup> Annual Meeting of the A.A.P.S., Denver, CO, November 13-17, 2016.

45. *Overcoming regulatory challenges: dissolution criterion F2 and BCS based biowaiver.*1<sup>st</sup> meeting of Pharminformatics Unit of the ATHENA research and innovation center. Athens, 13 February 2017.
46. *Model dependent and model independent approaches for the biopharmaceutical classification of drugs.* Invited lecture. The cutting edge in pharmaceutical sciences (50 Years of progress-Celebrating Les Benet's 80<sup>th</sup> birthday), Stockholm, Sweden, May 20, 2017.
47. K. SOULELE, P. MACHERAS, V. KARALIS. Population pharmacokinetic analysis of inhaled budesonide in asthma patients.26<sup>th</sup>Population Approach Group in Europe(PAGE) meeting Budapest Hungary, June 6-9, 2017.
48. P. MACHERAS, J. LUKAS, F. de TONI UCHOA. Order in patch absorption rates? 26<sup>th</sup> Population Approach Group in Europe (PAGE) meeting Budapest, Hungary, June 6-9, 2017.
49. D. BONIFAZI ET AL. EPTRI – European Paediatric Translational Research Infrastructure to promote technology-driven Paediatric research.16<sup>th</sup> European Society for Developmental Perinatal and Pediatric Pharmacology Congress, Leuven, Belgium,20-23 June 2017.
50. D. HERSEG, S. NTOUSKAS, P. SOPASAKIS, A. DOKOUMETZIDIS, P. MACHERAS, H. SARIMVEIS, P. PATRINOS. Modeling and administration scheduling of fractional-order pharmacokinetic systems. The 20<sup>th</sup> world congress of the international federation of automatic control, Toulouse, France, July9-14, 2017.
51. *Advances in regulatory science: Drugs are classified according to their biopharmaceutical properties and liposomes are considered as non-biological complex drugs.* Invited lecture. ILS Liposome Advances/Liposome Research Days Combined Conference: 16-18 September 2017, Royal Olympic Hotel, Athens.
52. K. SOULELE, P. MACHERAS, V. KARALIS. A study on the enterohepatic recirculation of inhaled formoterol using population pharmacokinetic modeling. 32<sup>nd</sup>Annual Meeting of the A.A.P.S., San Diego, CA, November 12-15, 2017.
53. K. SOULELE, P. MACHERAS, V. KARALIS. On the parallel (fast and slow) absorption of inhaledbudesonide.32<sup>nd</sup>Annual Meeting of the A.A.P.S., San Diego, CA, November 12-15, 2017.
54. N. PILLAI, P. MACHERAS, R. BIES. Some irreproducible results in cell, animal or clinical studies may originate from a lurking dynamical system: The Kuznetsov's tumor model case 32<sup>nd</sup> Annual Meeting of the A.A.P.S., San Diego, CA, November 12-15, 2017.
55. *A random walk in the modeling of drug absorption and PK-PD processes.* Invited lecture. School of pharmacy and pharmaceutical sciences, The State University of New York (SUNY), Buffalo, 17<sup>th</sup> November 2017 (part of the nomination for adjunct professorship).
56. Kick-off Meeting of EPTRI (European Paediatric Translational Research Infrastructure).Representative of Pharma informatics Unit, ATHENA Research Center. Rome, Italy, 15-16 January 2018.

57. *Από την έρευνα στη μοντελοποίηση και προσομοίωση των in vitro και in vivo πορειών / φαινομένων των φαρμάκων στη Μονάδα Φαρμακοπληροφορικής του Ερευνητικού Κέντρου ATHENA.* Invited lecture. Σχολή Χημικών Μηχανικών, Εθνικό Μετσόβιο Πολυτεχνείο, 21 Μαρτίου 2018, Athens, Greece.
58. P. MACHERAS, K. Kosmidis. Fractal or fractional kinetics in drug release studies: A comparative study of the Weibull and Mittag-Leffler functions. EUFEPS Annual Meeting 2018: Crossing Barriers for Future Medicines, Athens, Greece, 24-26 May 2018.
59. P. MACHERAS, A. ILIADIS, G. MELAGRAKI. Exploring a reaction limited dissolution model for drug absorption and its implications for biopharmaceutic classification of drugs. EUFEPS Annual Meeting 2018: Crossing Barriers for Future Medicines, Athens, Greece, 24-26 May 2018.
60. D. BONIFAZI ET AL. EPTRI – European Paediatric Translational Research Infrastructure. Mapping the research units active in the field of paediatrics in the EU. EUFEPS Annual Meeting 2018: Crossing Barriers for Future Medicines, Athens, Greece, 24-26 May 2018.
61. 27<sup>th</sup> Population Approach Group in Europe (PAGE) meeting Montreux, Switzerland, May 29- June 1, 2018. (Organising Committee Meeting).
62. *Regulatory science of oral drug absorption.* Invited lecture. University of Ljubljana, Faculty of Pharmacy, October 26, 2018.
63. K. KOSMIDIS, P. MACHERAS. Fractal or fractional kinetics in drug release 33<sup>rd</sup> Annual Meeting of the A.A.P.S., Washington, DC, November 4-7, 2018.
64. *The role of Modeling & Simulation in pediatric drug development and approval.* Invited lecture. US WorldMeds LLC. Louisville, KY, USA, November 8, 2018.
65. S. SHWARTZ, N. PILLAI, P. MACHERAS, T. HO, R. BIES. The conundrum of reproducibility. A role for causal determinism. 8<sup>th</sup> Annual Indiana CTSI Symposium on Disease and Therapeutic Response Modeling and Simulation, Indianapolis, IN, USA, November 12,13, 2018.
66. *A reaction limited in vivo dissolution model for the study of drug absorption: Implications for the biopharmaceutic classification of drugs.* Invited lecture. 3<sup>rd</sup> International symposium on scientific and regulatory advances in biological and non-biological complex drugs: A to Z in bioequivalence .Budapest, Hungary, 12-14 November 2018.
67. P. MACHERAS, E. ANDRIOTIS, D.G. FATOUROS. Solubility studies of BCS II class drug X in UHT milk. EUFEPS Annual Meeting 2019, 6-8 March 2019, Frankfurt, Germany.
68. *Drug delivery using nature's emulsion: milk.* Invited lecture. EUFEPS Annual Meeting 2019, 6-8 March 2019, Frankfurt, Germany.
69. *Requirements for the approval of paediatric medicines in EMA and FDA.* Invited lecture. 12<sup>th</sup> Congress on paediatric guidelines, Montana hotel, Karpenisi, Greece, 29-31 March 2019.

70. P. MAVROUDIS, K. KOSMIDIS, P. MACHERAS. On the unphysical hypotheses in pharmacokinetics and oral drug absorption: Time to utilize instantaneous rate coefficients instead of rate constants. 28<sup>th</sup> Population Approach Group in Europe (PAGE) meeting, Stockholm, Sweden, June 11-14, 2019.
71. N. PILLAI, P. MACHERAS, S.L. SCHWARTZ, T. HO, R. BIES. On the Multilemma of reproducibility: Stochastic or Deterministic or Stochastic and Deterministic. 28<sup>th</sup>Population Approach Group in Europe (PAGE) meeting, Stockholm, Sweden, June 11-14, 2019
72. V.PIGNATARO, F. BRAKO; L. RUGGIERI; J. KINDBLOM, P. MACHERAS, R. MARUSHKO, V. KAZANTSEV, N. DENORA, C. TULEAU, D.BONIFAZI. EPTRI - European Paediatric Translational Research Infrastructure: turning the spotlight on paediatric formulations advancement. 11<sup>th</sup> European Paediatric Formulation Initiative, Malmo, Sweden. September 10- 12 , 2019
73. P. MACHERAS, M.SFOUNI. Reconsideration of flip-flop kinetics under the finite drug absorption concept. 34<sup>th</sup> Annual Meeting of the A.A.P.S., San Antonio, TX , USA November 3-6, 2019.
74. P. CHRYSSAFIDIS. P. MACHERAS. Revising Pharmacokinetics of Oral Drug Absorption. Models Based on Biopharmaceutical Physiological and Finite Absorption Time Concepts. **EUFEPS Annual Meeting 2021 (virtual).**
75. P. CHRYSSAFIDIS, A. A. TSEKOURAS P. MACHERAS. A paradigm shift in oral drug absorption: The rise of physiologically based finite time pharmacokinetic (PBFTPk) models. 29<sup>th</sup> Population Approach Group in Europe (PAGE) meeting (virtual)
76. *Modeling the worldwide COVID-19 spreading.* Webinar on COVID-19. Organizer – Speaker. 16, March 2021. ATHENA Research Center.  
<https://www.youtube.com/watch?v=hUlijp-dvGo&t=2s>.
77. *Improving absorption modeling for biopharmaceutics, pharmacometric and translational pharmacokinetic applications,* Invited lecture. 36<sup>th</sup> Annual Meeting of the A.A.P.S., Philadelphia, PA, USA 17-20 October, 2021.(virtual)
78. ***Drugs are Absorbed in Finite Time: A New Era in Biopharmaceutics and Pharmacokinetics.*** Invited talk. International conference in pharmaceutical drug development, quality control and regulatory science. **DDRS 2021 Budapest, Hungary 15-17 Novemebr 2021.**
79. P. MACHERAS, K. KOSMIDIS, P. CHRYSSAFIDIS. ***Demystifying the spreading of pandemics I: The fractal kinetics SI model quantifies the dynamics of COVID-19.*** *Medrxiv* doi: <https://doi.org/10.1101/2020.11.15.20232132>
80. P. CHRYSSAFIDIS, A. A. TSEKOURAS P. MACHERAS. Re-writing oral pharmacokinetics using physiologically based finite time pharmacokinetic (PBFTPk) models. 30<sup>th</sup> Population Approach Group in Europe (PAGE) meeting, Ljubljana, Slovenia, 28 June- 1 July 2022.

81. N.ALIMPERTIS, A. A. TSEKOURAS P. MACHERAS. Revising the assessment of bioequivalence: The axitinb case. 30<sup>th</sup> Population Approach Group in Europe (PAGE) meeting, Ljubljana, Slovenia, 28 June- 1 July 2022.
82. *Physiologically based finite time pharmacokinetic(PBFTPk) models: the end of the beginning in oral drug absorption. Invited talk .9<sup>th</sup> BBBB International Conference on Pharmaceutical Sciences, Pharma Sciences of Tomorrow. Ljubljana, Slovenia 15-17 September, 2022.*
83. *Revising Oral Pharmacokinetics, Bioavailability and Bioequivalence based on the Finite Absorption Time (FAT) Concept. Invited zoom talk: FDA 9 November 2022*
84. N.ALIMPERTIS, A. A. TSEKOURAS P. MACHERAS. The estimates for the absorption rate constant in pharmacokinetics and pharmacometrics are wrong: A new era based on the finite absorption time concept rises. 31<sup>st</sup> Population Approach Group in Europe (PAGE) meeting, La Coruna, Spain 28-30 June 2023.
85. N.ALIMPERTIS, A. A. TSEKOURAS P. MACHERAS. Software using Physiologically Based Finite Time Pharmacokinetic (PBFTPk) Models 31<sup>st</sup> PAGE meeting La Coruna, Spain 27-30 June, 2023.