EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

PERSONAL INFORMATION

Paulo Paixao

WORK EXPERIENCE

December 2019- Present
Assistant Professor
Pharmacy Faculty of Lisbon University (Portugal)

July 2018-July 2019
National Expert on Secondment
European Medicines Agency (Netherlands)

September 2012-November 2019
Invited Assistant Professor
Pharmacy Faculty of Lisbon University (Portugal)

October 2013- Present
Member of the Medicines Evaluation Board
INFARMED (Portugal)

September 2001-July 2018
Assistant Professor
Pharmacy Faculty of Universidade Lusófona de Humanidades e Tecnologias (Portugal)

June 2016-September 2016
Invited Assistant Researcher
College of Pharmacy, University of Michigan (United States)

October 2003-September 2013
PK assessor
INFARMED (Portugal)

September 2002-December 2010
Assistant Professor
Health School of Escola Superior de Saúde Ribeiro Sanches (Portugal)

January 1999-September 2001
Scholarship Researcher
Pharmacy Faculty of Lisbon University (Portugal)

September 1997-September 1999
Scholarship Researcher
INETI - Instituto Nacional de Engenharia, Tecnologia e Inovação (Portugal)

EDUCATION AND TRAINING

2006- 2010
PhD in Pharmacy - Pharmacokinetics
Lisbon University ()

1999- 2002
Master in Pharmacokinetics and Biopharmaceutics
Lisbon University ()

1992- 1997
Bachelors in Biochemistry
Lisbon University ()

ADDITIONAL INFORMATION

Expertise

Experience in Pharmacokinetics in the regulatory context.Involved in the assessment of bioequivalence and Clinical pharmacokinetics (including the ADME in healthy subjects and patients, DDIs and special populations) in Centralized, Decentralized, Mutual recognition and National Procedures. Involved in Scientific Advices Procedures in Clinical Pharmacokinetics at both the National and European context. Involvement in Peer-reviews of reports in European Centralised procedures Experience in Teaching of Pharmacokinetics and Biopharmaceutics.As a professor at the under graduation and graduation (master and PhD programs) level at several Universities. As a Supervisor of Masters and PhD students Research interests in PharmacokineticsMain topic of research activity has been related to pharmacokinetics and Therapeutic Drug Monitoring. In particulate, a great deal of work have been done on drug development tools, namely, QSAR, in vitro assays and data integration on PBPK models. On PBPK, have been mainly focusing in oral absorption with several papers with direct implication on present and future topics on bioavailability/bioequivalence regulatory establishment, namely on the establishment of pharmacokinetics metrics for bioequivalence of modified release formulations, and on the evaluation of similarity metrics for dissolution profiles. Latter research interests, related to the collaboration with the University of Michigan, are related to the better understanding of the physiology of the GI tract and its consequences in clinical variability for oral drug products.

Publications

1 Efthymios Manolis, Alfredo Garcia-Arieta, Anders Lindahl, Evangelos Kotzagiorgis, Jobst Limberg, Oyvind Holte, Paulo Paixao, Carolien Versantvoort, Flora Musuamba Tshinanu, Kevin Blake, Michiel Van Den Heuvel. Using mechanistic models to support development of complex generic drug products: European Medicines Agency perspective. CPT Pharmacometrics Syst Pharmacol 2023 Jan 11.

2 Paixao, P.; Silva, N.; Guerreiro, R.B.; Blake, K.; Bonelli, M.; Morais, J.A.G.; Garcia-Arieta, A.; Gouveia, L.F. Evaluation of a Proposed Approach for the Determination of the Bioequivalence Acceptance Range for Narrow Therapeutic Index Drugs in the European Union. Pharmaceutics 2022 Oct 31;14(11):2349.

3 Petric, Z.; Goncalves, J.; Paixao, P. Under the Umbrella of Clinical Pharmacology: Inflammatory Bowel Disease, Infliximab and Adalimumab, and a Bridge to an Era of Biosimilars. Pharmaceutics 2022 Aug 24;14(9):1766.

4 Rosa, G. M. De L. L. D. .; Silva, S. R. B.; Yamada, S. S.; Paixao, P. J. P. A.; Montanha, M. C.; Kimura, E. Amoxicillin dosing and pharmacokinetics in obesity for the treatment of bacterial respiratory infection secondary to COVID-19: a systematic review. Research, Society and Development, [S. l.], v. 11, n. 14, p. e130111436040, 2022.

5 Paulo Paixao, Rita Bento Guerreiro, Nuno Silva, Kevin Blake, Milton Bonelli, Jose Augusto Guimaraes Morais, Alfredo Garcia Arieta, Luis Filipe Gouveia; "A Proposed Approach for the Determination of the Bioequivalence Acceptance Range for Narrow Therapeutic Index Drugs in the European Union". Clin Pharmacol Ther. 2022 Feb;111(2):470-476. doi: 10.1002/cpt.2451. Online ahead of print.

6 Ana Luiza P P D P Soares, Maiara C Montanha, Conrado D S Alcantara, Sandra R B Silva, Cristina M Kuroda, Sergio S Yamada, Antonio E Nicacio, Liane Maldaner, Jesui V Visentainer, Caroline F Simoes, Joao Carlos Locatelli, Wendell A Lopes, Josmar Mazucheli, Andrea Diniz, Paulo J P A Paixao, Elza Kimura; "Pharmacokinetics of amoxicillin in obese and nonobese subjects". Br J Clin Pharmacol . 2021 Jan 20. doi: 10.1111/bcp.14739. Online ahead of print

7 Augustijns P, Vertzoni M, Reppas C, Langguth P, Lennernas H, Abrahamsson B, Hasler WL, Baker JR, Vanuytsel T, Tack J, Corsetti M, Bermejo M, Paixao P, Amidon GL, Hens B.; "Unraveling the behavior of oral drug products inside the human gastrointestinal tract using the aspiration technique: History, methodology and applications.". Eur J Pharm Sci. 2020 Dec 1;155:105517

8 Bermejo M, Hens B, Dickens J, Mudie D, Paixao P, Tsume Y, Shedden K, Amidon GL.; "A Mechanistic Physiologically-Based Biopharmaceutics Modeling (PBBM) Approach to Assess the In Vivo Performance of an Orally Administered Drug Product: From IVIVC to IVIVP.". Pharmaceutics. 2020 Jan 17;12(1):74.

9 Isca VMS, Andrade J, Fernandes AS, Paixao P, Uriel C, Gomez AM, Duarte N, Rijo P; "In Vitro Antimicrobial Activity of Isopimarane-Type Diterpenoids". Molecules. 2020 Sep 16;25(18):4250.

10 Paixao P; Kawakami K; Bermejo M; Tsume Y; Nuno Silva; Moribe K; Morais JAG; Amidon GL; Yamashita S; "Report from the "3rd International Symposium on BA/BE of Oral Drug Products: Biopharmaceutics meets Galenics"; Journal of Drug Delivery Science and Technology, 2020, Volume 56, Part B, 101274

11 Montanha MC, Diniz A, Silva NMEN, Kimura E, Paixao P.; "Physiologically-Based Pharmacokinetic Model on the Oral Drug Absorption in Roux-en-Y Gastric Bypass Bariatric Patients: Amoxicillin Tablet and Suspension.". Mol Pharm. 2019 Dec 2;16(12):5025-5034

12 Montanha MC, Dos Santos Magon TF, de Souza Alcantara C, Simoes CF, Silva SRB, Kuroda CM, Yamada SS, de Oliveira LES, Nasser D, Junior NN, Mazucheli J, Diniz A, Paixao PJPA, Kimura E.; "Reduced bioavailability of oral amoxicillin tablets compared to suspensions in Roux-en-Y gastric bypass bariatric subjects.". Br J Clin Pharmacol. 2019 Sep;85(9):2118-2125

13 Paixao P, Bermejo M, Hens B, Tsume Y, Dickens J, Shedden K, Salehi N, Koenigsknecht MJ, Baker JR, Hasler WL, Lionberger R, Fan J, Wysocki J, Wen B, Lee A, Frances A, Amidon GE, Yu A, Benninghoff G, Lobenberg R, Talattof A, Sun D, Amidon GL.; "Linking the Gastrointestinal Behavior of Ibuprofen with the Systemic Exposure between and within Humans-Part 2: Fed State". Mol Pharm. Nov 12, 2018

14 Bermejo M, Paixao P, Hens B, Tsume Y, Koenigsknecht MJ, Baker JR, Hasler WL, Lionberger R, Fan J, Dickens J, Shedden K, Wen B, Wysocki J, Lobenberg R, Lee A, Frances A, Amidon GE, Yu A, Salehi N, Talattof A, Benninghoff G, Sun D, Kuminek G, Cavanagh KL, Rodriguez-Hornedo N, Amidon GL; "Linking the Gastrointestinal Behavior of Ibuprofen with the Systemic Exposure between and within Humans-Part 1: Fasted State Conditions". Mol Pharm. Nov 12, 2018

15 Bart Hens, Jozef Al-Gousous, Kai Wang, Niloufar Salehi, Robert M. Ziff, Yasuhiro Tsume, Marival Bermejo, Paulo Paixao, James G. Brasseur, Alex Yu, Arjang Talattof, Gail Benninghoff, Peter Langguth, Hans Lennernas, William L. Hasler, Luca Marciani, Duxin Sun, Gregory E. Amidon, Joseph Dickens, Kerby Shedden, Raimar Lobenberg, and Gordon L. Amidon; "Summary of the In Vivo Predictive Dissolution (iPD) - Oral Drug Delivery (ODD) Conference 2018". Dissolution Technologies. 25(2), 50-53, 2018

16 Hens B, Sinko PD, Job N, Dean M, Al-Gousous J, Salehi N, Ziff RM, Tsume Y, Bermejo M, Paixao P, Brasseur JG, Yu A, Talattof A, Benninghoff G, Langguth P, Lennernas H, Hasler WL, Marciani L, Dickens J, Shedden K, Sun D, Amidon GE, Amidon GL; "Formulation predictive dissolution (fPD) testing to advance oral drug product development: An introduction to the US FDA funded '21st Century BA/BE' project". Int J Pharm. 548(1):120-127, 2018

17 Paixao P, Bermejo M, Hens B, Tsume Y, Dickens J, Shedden K, Salehi N, Koenigsknecht MJ, Baker JR, Hasler WL, Lionberger R, Fan J, Wysocki J, Wen B, Lee A, Frances A, Amidon GE, Yu A, Benninghoff G, Lobenberg R, Talattof A, Sun D, Amidon GL; "Gastric emptying and intestinal appearance of nonabsorbable drugs phenol red and paromomycin in human subjects: A multi-compartment stomach approach". Eur J Pharm Biopharm. 129:162-174, 2018

18 Tukulula M, Gouveia L, Paixao P, Hayeshi R, Naicker B, Dube A; "Functionalization of PLGA Nanoparticles with 1,3--glucan Enhances the Intracellular Pharmacokinetics of Rifampicin in Macrophages". Pharm Res. 35(6):111, 2018

19 Hens B, Talattof A, Paixao P, Bermejo M, Tsume Y, Lobenberg R, Amidon GL; "Measuring the Impact of Gastrointestinal Variables on the Systemic Outcome of Two Suspensions of Posaconazole by a PBPK Model". AAPS J. 20(3):57, 2018

20 Cardot JM, Garcia-Arieta A, Paixao P, Tasevska I, Davit B; "Implementing the additional strength biowaiver for generics: EMA recommended approaches and challenges for a US-FDA submission". Eur J Pharm Sci. 111:399-408, 2017

21 Bart Hens, Yasuhiro Tsume, Marival Bermejo, Paulo Paixao, Mark J. Koenigsknecht, Jason R. Baker, William L. Hasler, Robert Lionberger, Jianghong Fan, Joseph Dickens, Kerby Shedden, Bo Wen, Jeffrey Wysocki, Raimar Loebenberg, Allen Lee, Ann Frances, Greg Amidon, Alex Yu, Gail Benninghoff, Niloufar Salehi, Arjang Talattof, Duxin Sun, Gordon L. Amidon; "Low Buffer Capacity and Alternating Motility along the Human Gastrointestinal Tract: Implications for in Vivo Dissolution and Absorption of Ionizable Drugs". Mol. Pharmaceutics, 14(12):4281-4294, 2017

22 Paixao P, Gouveia LF, Silva N, Morais JA.; Evaluation of dissolution profile similarity - Comparison between the f2, the multivariate statistical distance and the f2 bootstrapping methods. Eur J Pharm Biopharm. 112:67-74, 2017

23 Duarte H, Cruz JP, Aniceto N, Ribeiro AC, Fernandes A, Paixao P, Antunes F, Morais J.; "Population Approach to Efavirenz Therapy". J Pharm Sci. Epub ahead of print, 2017

24 Cardot JM, Garcia Arieta A, Paixao P, Tasevska I, Davit B; Implementing the Biopharmaceutics Classification System in Drug Development: Reconciling Similarities, Differences, and Shared Challenges in the EMA and US-FDA-Recommended Approaches. AAPS J, 18(4):1039-46, 2016

25 Paixao, Paulo (corresponding author); Aniceto, Natalia; Gouveia, Luis F.; Morais, Jose A.G.; Prediction of Drug Distribution in Rat and Humans Using an Artificial Neural Networks Ensemble and a PBPK Model. Pharmaceutical research, May 2014

26 Paixao, Paulo (corresponding author); Aniceto, Natalia; Gouveia, Luis F.; Morais, Jose A.G.; Tissue-to-blood distribution coefficients in the rat: Utility for estimation of the volume of distribution in man. European Journal of Pharmaceutical Sciences, v. 50, n. 3-4, p. 526-543, 2013

27 Paixao, Paulo (corresponding author); Gouveia, Luis F.; Morais, Jose A.G.; Prediction of the human oral bioavailability by using in vitro and in silico drug related parameters in a physiologically based absorption model. International Journal of Pharmaceutics, v.429, n. 1-2, p. 84-98, 2012

28 Paixao, Paulo (corresponding author); Gouveia, Luis F.; Morais, Jose A.G.; An alternative single dose parameter to avoid the need for steady-state studies on oral extended-release drug products. European Journal of Pharmaceutics and Biopharmaceutics, v. 80, n. 2, p. 410-417, 2012

29 Paixao, Paulo; Gouveia, Luis F.; Morais, Jose A.G.; Prediction of the in vitro permeability determined in Caco-2 cells by using artificial neural networks. European Journal of Pharmaceutical Sciences, v. 41, n. 1, p. 107-117, 2010

30 Paixao, Paulo; Gouveia, Luis F.; Morais, Jose A.G.; Prediction of the in vitro intrinsic clearance determined in suspensions of human hepatocytes by using artificial neural networks. European Journal of Pharmaceutical Sciences, v. 39, n. 5, p. 310-321, 2010

31 Paixao, Paulo; Gouveia, Luis F.; Morais, Jose A.G. Prediction of drug distribution within blood. European Journal of Pharmaceutical Sciences, v. 36, n. 4-5, p. 544-554, 2009

32 Paixao, Paulo; Use of artificial neural networks for outcome prediction in paraquat intoxications. Revista Lusofona de Ciencias e Tecnologias de Saude, v. 1, n. 2, p. 85-92, 2006. (http://revistas.ulusofona.pt/index.php/revistasaude/article/view/16)

33 Paixao, Paulo; Costa, P; Bugalho, T; Fidalgo, C; Pereira, L.; Simple method for determination of paraquat in plasma and serum of human patients by high-performance liquid chromatography. Journal of Chromatography B, v. 775, n. 1, p. 109-113, 2002

34 Constantino, L.; Paixao, Paulo; Moreira, R.; Portela, M.J.; Do Rosario, V.E.; Iley, J. Metabolism of primaquine by liver homogenate fractions. Experimental and Toxicologic Pathology, v. 51, n. 4-5, p. 299-303, 1999

Projects

As Coordinator;

1. "PopPK-PD of vancomicin on UCI patients" a joint project between FFUL and Hospital de S. Teotonio - Viseu. Period: 2012-15.

As Researcher;

1. MCMember, COST Action CA21147, "ENOTTA - European Network on Optimising Treatment with Therapeutic Antibodies in chronic inflammatory diseases". Period: 2022-2025

2. Researcher, "NPSTEENBRAIN - Novas Substancias Psicoactivas, Cerebro e Adolescencia - Uma plataforma de Avaliacao de Risco"; FCT aviso 02/SAICT/2017, projecto: 32515. Period: 2018-2020. (223.673,00)

3. MCMember, COST Action CA16205, "UNGAP - European Network on Understanding Gastrointestinal Absorption-related processes". Period: 2017-2021

4. Invited Researcher, (FDA contract Number HHSF223201310144C) in the project "Innovations in Regulatory Science: in vivo Predictive Dissolution to Advance Oral Product Bioequivalence (BE) Regulation." (2016 - 2019) ($7.716.465,00)

5. Researcher, (European Commission reference HOME/2014/JDRU/AG/DRUG/7086) in the project "Identification and assessment of new psychoactive substances: a European network." (2016 - 2019) (601.087,06)

6. Researcher, (Instituto Portugues de Oncologia de Lisboa Francisco Gentil E.P.E. reference UIC/963) in the project "Monitorizacao terapeutica individualizada de Bussulfano em doentes submetidos a regimes de condicionamento pre-transplante de celulas progenitoras hematopoieticas no IPO de Lisboa" (2014 -)

7. Researcher, (FCT reference PTDC/DTP-FTO/1747/2012) in the project "Pharmacokinetic/Pharmacogenetic modulation of HIV infection therapy by bayesian and artificial intelligence methods" (140.000,00) (2012 - 2015)

8. Pos-Doc Scholarship (FCT reference SFRH/BPD/69748/2010 (2011 - 2012)) with the project "PBPK models for development of new drugs"

9. PhD scholarship (FCT reference SFRH/BD/28545/2006 (2006-2010)) with the project "PBPK models of absorption"

10. Research scholarship within UFEB (Unidade de farmacocinetica e estudo biofarmaceuticos) financed by FCT (2000-2002) with the project "Toxicokinetics of Parauqat in Human Patients".

11. Research scholarship within the project "Development of cationic lipossomes for DNA therapy", Praxis XXI nº 3/3.1/CTAE/1921/95, (1997 -2000)

12. Research Scholarship within the project "Metabolism of Primaquine in the rat" PCIB/BIA/2047/95 from FCT (1996-1997)

Memberships

Other Relevant Information