

2014 - Medicines and Medical Devices: Safety & Risk Management in the Real-World Clinical Practice

Ana Paula Martins Silvestre Correia

Ana Paula Martins Silvestre Correia born in 1965, is married and has two children. She gets her graduation in Pharmaceutical Sciences from the Faculty of Pharmacy University of Lisbon in 1990, her Master Degree in Epidemiology in 1995 from the Faculty of Biomedical Sciences and the PhD in Clinical Pharmacy in 2015 from the University of Lisbon.

Ana Paula is Assistant Professor in the Faculty of Pharmacy, University of Lisbon in the Department of Social Pharmacy. She leads the units of Pharmacoepidemiology and Pharmacovigilance either in the Pharmaceutical Sciences undergraduate Programme Post-Graduation and PhD programs. Her main research interests are comparative effectiveness and safety monitoring.

She published around 30 articles in peer reviewed journals in the field and currently has 8 PhD students under her supervision. She is also the Head of two of the Pharmacovigilance Units of the Portuguese Pharmacovigilance System in Portugal.

Between 2006-2014, Ana Paula was the External Affairs Director of MSD Portugal, and for 13 years (1994-2006) the Director of CEFAR (Center for Pharmacoepidemiology Studies of National Association of Pharmacies).

For about 7 years she was the representative of the Portuguese Pharmaceutical Industry (APIFARMA) in the EFPIA- HTA Task Force. She is member both of the Portuguese Epidemiology Association and the Pharmacology Portuguese Society.

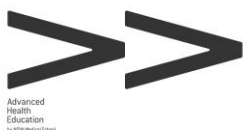
Since 16 February 2016, Ana Paula Martins is the President of the Portuguese Pharmaceutical Society.

Andreia Leite

Andreia Leite is a Public Health Registrar at Amadora's Public Health Unit and an Invited Assistant Professor at the National School of Public Health, Nova University Lisbon. She teaches Epidemiology on several MSc and PhD degrees. Andreia studied Medicine at the Faculty of Medicine in Lisbon, Portugal. She has also completed an MSc in Biostatistics at the Faculty of Sciences in Lisbon, Portugal and a Master in Public Health at Umeå University, Sweden. In 2018, she completed her PhD at the London School of Hygiene and Tropical Medicine, where she worked within the Electronic Health Records group, in the faculty of Epidemiology and Population Health, in partnership with Public Health England. Her PhD project focused on vaccine safety and electronic health records, in particular on the methods used to identify adverse events to vaccines using these data. She has authored several papers and presentations on this topic.

Bruno Sepodes

Assistant Professor (with Habilitation) of Pharmacology and Pharmacotherapy at the Faculty of Pharmacy of the University of Lisbon (Portugal). He is a Pharmacist (PharmD) by training, holding a MSc in Regulatory Science, a PhD in Pharmacology and Habilitation in Pharmacology and Pharmacotherapy, all by the University of Lisbon. Currently Bruno is a graduate student at Johns Hopkins University (USA), completing his MPH degree from the Bloomberg School of



Public Health. Besides being Senior Expert for INFARMED (the Portuguese National Authority for Medicines and Health Products), he became a member of the European Medicines Agency's Committee for Orphan Medicinal Products (COMP) in 2008 and served for two mandates as Chairperson of this Committee (2012-2018). Additionally, Bruno is a member of the European Medicines Agency's Committee for Human Medicinal Products (CHMP) and of the Committee of Advanced Therapies (CAT). Since November 2018, Bruno Sepodes is the Vice-Chair of the Committee of Human Medicinal Products (CHMP). Also, in 2018 he was awarded with the "EURORDIS Leadership Black Pearl Award" on Rare Diseases, attributed to an individual who has demonstrated remarkable leadership in the field of rare diseases at a European level. Bruno received 15 national and international scientific awards and was on the top 100 inspirational industry professionals of "The Medicine Maker Power List 2018", under the category 'Masters of Change' for year 2018.

Carla Torre

Graduated in Pharmaceutical Sciences by the Faculty of Pharmacy of the University of Lisbon, in 2004. She is post-graduated in Pharmacy and Medicinal Products Law by the Faculty of Law of the University of Coimbra (2006) and she holds a master's degree in Epidemiology by the Faculty of Medicine of the University of Porto (2009). In 2018, she completed her PhD in Pharmacoepidemiology at the Faculty of Pharmacy of the University of Lisbon, where she is currently Invited Assistant Professor, and teaches pharmacoepidemiology, pharmacovigilance and public health. Her doctoral thesis focused on intensive monitoring methods as a tool to assess the benefit-risk of medicines in real-life conditions. Currently, she is one of the experts of the Pharmacovigilance Unit of Setúbal and Santarém.

Other post-graduation competencies included the Program in Basic, Intermediate and Advanced Pharmacoepidemiology at the University McGill (Montreal, 2014/15), International Meyler Course in Pharmacovigilance (University of Groningen, 2013), Pharmacoepidemiology and Drug Safety and Pharmaceutical Policy (Utrecht University, 2011/12).

At the moment, in her field of expertise, Carla Torre tutors master's projects in the areas of pharmacoepidemiology and pharmacovigilance and she has authored and co-authored several papers and presentations on these topics.

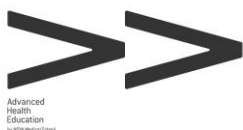
Since 2016, Carla Torre is the Secretary General of the Portuguese Pharmaceutical Society where she assists the President and the Board in political and professional affairs. Previously, she was the pharmacoepidemiology project manager at CEFAR (Center for Health Evaluation & Research) of the National Association of Pharmacies (ANF) in Portugal (2009-2016) where she held responsibilities on conducting pharmacoepidemiology and outcomes research studies. Between 2006 and 2009 she was technical advisor to the National Coordinator for HIV/AIDS Infection of the Ministry of Health.

Carlos Miguel Costa Alves

Education and Degrees:

PhD in Pharmaceutical Sciences – Clinical Pharmacy – University of Coimbra (2015)

Integrated Master's Degree in Pharmaceutical Sciences – School of Pharmacy, University of Coimbra (2009)



Francisco Jorge Batel Marques

Education and Degrees:

PhD in Pharmaceutical Sciences – Clinical Pharmacy – University of Wales, UK

Degree in Pharmaceutical Sciences – School of Pharmacy, University of Coimbra, Portugal

Rui Loureiro

Graduated in Pharmacy (Industrial Pharmacy) from the Faculty of Pharmacy of the University of Lisbon (FFUL) and post-graduated in Industrial Engineering from INETI-Lisbon, and in quality management from Universidade Aberta-Lisboa is also a specialist in pharmaceutical industry by the Order of Pharmacists. He is a member of the European Health Futures Forum (EHFF) and a university lecturer (and supervisor and co-supervisor of master's theses) at FFUL in the area of Quality Management Systems in Health and Risk. From his professional career, are positions and functions as a consultant in Industrial Pharmacy, interlocutor for the industry in Infarmed, auditor in national and international health units or Industrial Pharmaceutical in pharmaceutical laboratories and evaluator of community projects in the area of health. He has set up quality systems in pharmacovigilance units, hospital services, medical and medical devices wholesaler, and control laboratories.

Since 1998, he has been the author or co-author of a series of scientific articles and book chapters - in national and international publications, as well as frequent speaker in lectures and conferences - on Health Quality Management and Health Risk Management.

Helder Mota-Filipe

Degree in Pharmaceutical Sciences and PhD in Pharmacology.

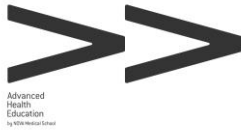
Present:

Associate Professor (Faculty of Pharmacy, University of Lisbon), Member of the National Ethics Committee for Clinical Research (Ministry of Health, 2005; 2017- ...), Member of the National Coordination for the Medicines and Health Products Strategy (Ministry of Health, 2017-...), President of National Council for Cooperation of the Portuguese Pharmaceutical Society (2016 -...). Member of the Medicines Evaluation Committee (INFARMED, I.P.) (1996-2013; 2017-É). Member of the HTA Committee (INFARMED, I.P.) (2017-É). Regulatory Affairs Specialist (Portuguese Pharmaceutical Society). Expert of the European Medicines Agency (EMA).

Positions held in the last 5 years:

Vice-President (2005-2015) and President of Infarmed, IP. (2015-2017). President of the Social Pharmacy Department, Faculty of Pharmacy, University of Lisbon (2015-2017). Member of the Management Board, European Medicines Agency (EMA) (2012-2015). Member of the HTA Network (European Commission) (2012-2015). Member of the Pharmaceutical Committee (European Commission) (2005-2015). Member of the Committee for Medicinal Products for Human Use (CHMP, EMA, London) (2011-2012).

Supervisor of eight PhD thesis and more than a dozen of master thesis in pharmacology, experimental medicine and regulatory sciences. Author of more than one hundred of scientific papers in international scientific journals with peer review in pharmacology, experimental medicine, medicines use, and regulatory sciences and more than 300 communications to scientific meetings.



Maria Isabel Boaventura - Current Position - Senior Director Corporate and Market Access Affairs, since April 2018.

Summary

A specialist in Internal Medicine, had 12 years of medical practice in the University Hospital of Lisboa and above 25 years of experience in the pharmaceutical industry.

She started her career in the pharmaceutical industry as scientific advisor in Bayer Portugal, moving one year later to Merck, Sharp & Dohme. In addition to the activity of scientific advisor, she developed the units of pharmacovigilance, medical information and clinical operations. Later, promoted to medical director in Merck, Sharp & Dohme, she supervised the areas of medical affairs, regulatory affairs, reimbursement & access and clinical operations.

Medical Director at Celgene since 2007, with responsibility for the areas of scientific support, clinical research, regulatory, pharmacovigilance and risk management of new drugs. She implemented at national level the risk management programs (RMP) and pregnancy prevention programs (PPG) for the medicines thalidomide, lenalidomide and pomalidomide in accordance with European regulations and duly adapted to the product's legal framework and clinical practices at national level. She developed in parallel, process indicators and results indicators for monitoring the efficiency of RMP and PPG. She implemented at national level an education program for health professionals about RMP, in partnership with the regulatory authorities. She made several public presentations on the results of the monitoring of RMP and PPG in Portugal. She implemented the Post-Approval Safety Study of Lenalidomide at the national level, and made two public presentations of the results of this study at the scientific meetings of the Portuguese Society of Hematology.

Teacher in Clinical Pharmacology and Therapeutics, Faculdade de Medicina de Lisboa, University of Lisboa (2007-Present).

Regular participation in Master and PhD training programs about medicines research & development and risk-management, Faculdade de Medicina de Lisboa (2007-Present).

Guest Lecturer of Faculdade de Farmácia de Lisboa (2008-Present) and Universidade de Aveiro, Training Programme in Pharmaceutical Medicine (2010-2014).

Mario Miguel Coelho da Silva Rosa

Neurology Professor; Clinical Pharmacology Professor

Faculdade de Medicina da Universidade de Lisboa (Portugal) Clinical Pharmacology and

Neurology Professor

Medical Ethics Lecturer

Clinical Pharmacology Investigator (Pharmacoepidemiology)

Coordinator of Medical Ethics - Master and PhD Programs at Universidade de Lisboa

Alternate Member of the Academic Council- Faculdade de Medicina da Universidade de Lisboa
2017, ongoing