

Curriculum Vitae

Personal information Radu Botgros

Work experience

Senior Scientific Officer at the European Medicines Agency (EMA) (2009-present)

European Medicines Agency (EMA, www.ema.europa.eu), Amsterdam, the Netherlands

- 2020-present: Senior Scientific Officer in the Department of Health Threats at the EMA. I have been the topic leader for coordinating the therapeutic response to COVID-19 until February 2022. I now coordinate most relevant AMR-related activities for human medicines at the Agency.
- 2014-2020: Senior Scientific Officer, Office of Anti-infectives and Vaccines • EMA product lead, with focus on the scientific aspects of all medicines in my portfolio, which has been widened to also include antivirals and antimycotics.
- 2011-2014: Scientific Officer, Office of Anti-infectives and Vaccines • management of the assigned portfolio of antibacterial medicines (pre- and post-approval) • active regular participation in discussions of scientific committees • CHMP infectious diseases working party (IDWP) secretariat (regular involvement in the scientific discussions for the guidelines) • regular participation at internal (scientific advisory groups, workshops etc.) and external expert meetings, with primary focus on antibacterial and anti-TB medicines • special focus: paediatric TB medicines • topic leader for the EU regulatory guidelines on development of new antibacterial medicines • writing of scientific opinions, contribution to scientific reports of other EU bodies (e.g., ECDC).
- 2009-2011: Paediatric Coordinator, member of the EMA paediatric team • evaluation of paediatric investigation plan/waiver applications • data analysis on paediatric uses of medicinal products submitted by EU/EEA member states and writing a comprehensive report • PTM for assigned products, with constant involvement in paediatric related issues for procedures concerning medicinal products included in the portfolio

Fellow, Infectious Diseases Specialist, Infectious Diseases and Travel Medicine Department, at the Freiburg University Hospital, Germany (2008-09) University Hospital Freiburg (UKF, <https://www.uniklinik-freiburg.de/infektiologie.html>), Freiburg im Breisgau, Germany

- Infectious diseases specialist advice to patients admitted in the various departments of the university hospital; research activities.

Assistant Professor of Infectious Diseases, Carol Davila University of Medicine and Pharmacy, Infectious and Tropical Diseases Department (2008-16)

Carol Davila University of Medicine and Pharmacy (UMFCD), Bucharest, Romania

- Infectious and tropical diseases teaching activity with the 11 semester students from the Carol Davila University Bucharest,

Infectious Diseases Specialist, Dr. V. Babes Hospital for Infectious and Tropical Diseases (2004-08)

Dr. V Babes Hospital (HVB), Bucharest, Romania

- Infectious Diseases specialty care for inpatients

Medical Director, Medsana Bucharest Medical Center (2004-06)

Medsana Bucharest Medical Center (<https://www.medsana.ro/ro>), Bucharest, Romania

- Led a team of specialist physicians, nurses and auxiliary staff.
- Strategic planning of medical activities
- Constant delivery of quality, timely medical services within the allocated budget by overseeing workload, monitoring progress
- staff performance review, medical/technical guidance and oversight.
- presentations, publications and participation in national and international meetings and conferences

Infectious Diseases Specialist, Medsana Bucharest Medical Center (2004-08)

Medsana Bucharest Medical Center (<https://www.medsana.ro/ro>), Bucharest, Romania

Resident in Infectious Diseases, Dr. V. Babes Hospital for Infectious and Tropical Diseases (1999-2004)
Medsana Bucharest Medical Center (<https://www.medsana.ro/ro>), Bucharest, Romania

Medical Advisor, Diamedix Diagnostica (1998-2008)

Diamedix Diagnostica (www.diamedix.ro), Bucharest, Romania

- Infectious Diseases specialty advisor

Education and training

- Degree in Human Medicine (1989– 1996). Carol Davila University of Medicine and Pharmacy (Romania)
- Hospital Management Training (2006)– National School of Public Health, Management and Professional Development (<http://snsppms.ro/>), Bucharest, Romania

Additional information

Publications

- 1: Jjingo CJ, Bala S, Waack U, Needles M, Bensman TJ, McMaster O, Smith T, Blakely B, Chan IZ, Puthawala K, Dixon C, Kim Y, Lim R, Colangelo P, St Clair C, Nambiar S, Moss RB, Botgros R, Bazaz R, Denning DW, Marr KA, Husain S, Berman L, Christensen DJ, Keywood C, Clayton RG, Walsh TJ, Song HSE, Shukla SJ, Farley J. Food and Drug Administration Public Workshop Summary-Addressing Challenges in Inhaled Antifungal Drug Development. Clin Infect Dis. 2024 Jun 14;78(6):1564-1570. doi: 10.1093/cid/ciad607. PMID: 37802928.
- 2: Nachman S, Ahmed A, Amanullah F, Becerra MC, Botgros R, Brigden G, Browning R, Gardiner E, Hafner R, Hesselting A, How C, Jean-Philippe P, Lessem E, Makhene M, Mbele N, Marais B, McIlleron H, McNeeley DF, Mendel C, Murray S, Navarro E, Anyalechi EG, Porcalla AR, Powell C, Powell M, Rigaud M, Rouzier V, Samson P, Schaaf HS, Shah S, Starke J, Swaminathan S, Wobudeya E, Worrell C. Towards early inclusion of children in tuberculosis drugs trials: a consensus statement. Lancet Infect Dis. 2015 Jun;15(6):711-20. doi: 10.1016/S1473-3099(15)00007-9. Epub 2015 May 6. PMID: 25957923; PMCID: PMC4471052.
- 3: Gupta A, Mathad JS, Abdel-Rahman SM, Albano JD, Botgros R, Brown V, Browning RS, Dawson L, Dooley KE, Gnanashanmugam D, Grinsztejn B, Hernandez-Diaz S, Jean-Philippe P, Kim P, Lyerly AD, Mirochnick M, Mofenson LM, Montepiedra G, Piper J, Sahin L, Savic R, Smith B, Spiegel H, Swaminathan S, Watts DH, White A. Toward Earlier Inclusion of Pregnant and Postpartum Women in Tuberculosis Drug Trials: Consensus Statements From an International Expert Panel. Clin Infect Dis. 2016 Mar 15;62(6):761-769. doi: 10.1093/cid/civ991. Epub 2015 Dec 9. PMID: 26658057; PMCID: PMC4772846.
- 4: Hiruy H, Bala S, Byrne JM, Roche KG, Jang SH, Kim P, Nambiar S, Rubin D, Yasinskaya Y, Bachmann LH, Bernstein K, Botgros R, Cammarata S, Chaves RL, Deal CD, Drusano GL, Duffy EM, Eakin AE, Gelone S, Hiltke T, Hook III EW, Jerse AE, McNeil CJ, Newman L, O'Brien S, Perry C, Reno HEL, Romaguera RA, Sato J, Unemo M, Wi TEC, Workowski K, O'May GA, Shukla SJ, Farley JJ. FDA, CDC, and NIH Co-sponsored Public Workshop Summary-Development Considerations of Antimicrobial Drugs for the Treatment of Gonorrhea. Clin Infect Dis. 2024 Jul 24;ciae386. doi: 10.1093/cid/ciae386. Epub ahead of print. PMID: 39045871.
- 5: Yasinskaya Y, Bala S, Waack U, Dixon C, Higgins K, Moore JN, Jjingo CJ, O'Shaughnessy E, Colangelo P, Botgros R, Nambiar S, Angulo D, Dane A, Chiller T, Hodges MR, Sandison T, Hope W, Walsh TJ, Pappas P, Katragkou A, Kovanda L, Rex JH, Marr KA, Ostrosky-Zeichner L, Sekine S, Deshpande M, Shukla SJ, Farley J. Food and Drug Administration Public Workshop Summary-Development Considerations of Antifungal Drugs to Address Unmet Medical Need. Clin Infect Dis. 2023 Aug 14;77(3):380-387. doi: 10.1093/cid/ciad195. PMID: 37021650.
- 6: Pelfrene E, Botgros R, Cavaleri M. Antimicrobial multidrug resistance in the era of COVID-19: a forgotten plight? Antimicrob Resist Infect Control. 2021 Jan 29;10(1):21. doi: 10.1186/s13756-021-00893-z. PMID: 33514424; PMCID: PMC7844805.
- 7: Both L, Botgros R, Cavaleri M. Analysis of licensed over-the-counter (OTC) antibiotics in the European Union and Norway, 2012. Euro Surveill. 2015;20(34):30002. doi: 10.2807/1560-7917.ES.2015.20.34.30002. PMID: 26530125.
- 8: Donnelly H, Alemayehu D, Botgros R, Comic-Savic S, Eisenstein B, Lorenz B, Merchant K, Pelfrene E, Reith C, Santiago J, Tiernan R, Wunderink R, Tenaerts P, Knirsch C. Streamlining Safety Data Collection in Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia Trials: Recommendations of the Clinical Trials Transformation Initiative Antibacterial Drug Development Project Team. Clin Infect Dis. 2016 Aug 15;63 Suppl 2:S39-45. doi: 10.1093/cid/ciw316. PMID: 27481952.
- 9: Knirsch C, Alemayehu D, Botgros R, Comic-Savic S, Friedland D, Holland TL, Merchant K, Noel GJ, Pelfrene E, Reith C, Santiago J, Tiernan R, Tenearts P, Goldsack JC, Fowler VG Jr. Improving Conduct and Feasibility of Clinical Trials to Evaluate Antibacterial Drugs to Treat Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Recommendations of the Clinical Trials Transformation Initiative Antibacterial Drug Development Project Team. Clin Infect Dis. 2016 Aug 15;63 Suppl 2:S29-36. doi: 10.1093/cid/ciw258. PMID: 27481950.
- 10: Murray S, McKenna L, Pelfrene E, Botgros R. Accelerating clinical drug development for children with tuberculosis. Int J Tuberc Lung Dis. 2015 Dec;19 Suppl 1:69-74. doi: 10.5588/ijtld.15.0616. PMID: 26564546.

Projects

Memberships

Member of the European Society of Clinical Microbiology and Infectious Diseases

Member of the American Society of Microbiology

Member of the German Society of Infectious Diseases

Member of the Romanian Society of Infectious Diseases

Member of the International Society for Human and Animal Mycology

Observer at EUCAST

Other Relevant Information