

PERSONAL INFORMATION

Romaldas Mačiulaitis

WORK EXPERIENCE

December 1992–Present

Clinical and Regulatory Expert

Romaldas Maciulaitis (Lithuania)

As the clinical and regulatory expert of the Lithuanian State Medicines Control Agency serve for scientific evaluations of national and European marketing authorizations, variations, referrals, and other clinically related procedures since 1992.

Member of the national Council for Marketing Authorization since 2004 and chairing the Council since 2007.

May 2004–Present

Members of EMA committees (CHMP, later PDCO and CAT)

Romaldas Maciulaitis (United Kingdom)

In charge of National representation of regulatory and scientific competence in scientific committees at EMA since 2004 (member of the Committee for Medicinal Products for Human Use and since 2009 – Committee for Advanced therapies).

Contribution to number of public task forces: Ad hoc working groups for national legislation and implementation of EU law in medicines and bioethics (1994-2009), Efficacy Working Party (since 1998 (since 2011 - Rheumatology-Immunology WP)), nine (Co-) Rapporteurships for scientific evaluations of European centralized marketing authorisation applications serving as an (Co-) Rapporteur and assessor for pharmacokinetic, pharmacodynamic, and clinical parts; five Rapporteurships or contributions to European guidance documents on development of medicinal products (Solid Organ Transplantation, Progression of Renal Failure, Cell Based Medicinal Products, Tissue Engineered Products, Stem Cell Therapies, Cartilage regeneration); Scientific Advises in Scientific Advise Working Party of the EMA and SMCA (eight scientific advises in biomarkers qualification procedures and medicines developments - in the areas of translational, clinical and regulatory nephrology, solid organ transplantation, cell therapies, and infectious diseases); Cell Based Working Party (2007-2012).

September 1989–Present

Professor of Lithuanian Health Science University, LHSU (previously Assistant Professor, lecturer, and assistant)

Romaldas Maciulaitis (Lithuania)

Educational and scientific activities:

Leading one European interuniversity Module in postgraduate pharmaceutical medicines development course (Cooperative European Medicines Development Course) that is co-sponsored by IMI/EC and serve as professor of clinical pharmacology and clinical pharmacy in LHSU.

EDUCATION AND TRAINING

September 2003–June 2005

Nephrologist

Kaunas University of Medicine, Faculty of Medicine (Lithuania)

Nephrology

September 1984–June 1990

Doctor of Medicine (MD), Internist

Kaunas University of Medicine, Faculty of Medicine (Lithuania)

September 1979–June 1984

Doctor of Pharmacy (PharmD), Pharmaceutical Sciences

Kaunas University of Medicine, Faculty of Pharmacy (Lithuania)

ADDITIONAL INFORMATION

Expertise Infectious Diseases; Clinical Research; Clinical Pharmacology; Biomarkers; Pharmacokinetics; Stem Cells; Pharmacodynamics; Regulatory Affairs; Clinical Trials; Nephrology; Transplantation, Immunology, Clinical Development; Medical Education

- Publications**
1. Key Learning Outcomes for Clinical Pharmacology and Therapeutics Education in Europe: A Modified Delphi Study. Brinkman DJ, Tichelaar J, Morkink LB, Christiaens T, Likic R, Maciulaitis R, Costa J, Sanz EJ, Maxwell SR, Richir MC, van Agtmael MA; Education Working Group of the European Association for Clinical Pharmacology and Therapeutics (EACPT) and its affiliated Network of Teachers in Pharmacotherapy (NOTIP). *Clin Pharmacol Ther.* 2018 Aug;104(2):317-325.
 2. Cell and Gene Therapies: European View on Challenges in Translation and How to Address Them. Rousseau CF, Mačiulaitis R, Śladowski D, Narayanan G. *Front Med (Lausanne).* 2018 May 28;5:158. doi: 10.3389/fmed.2018.00158. eCollection 2018.
 3. Pharmacology and Therapeutics Education in the European Union Needs Harmonization and Modernization: A Cross-sectional Survey Among 185 Medical Schools in 27 Countries. Brinkman DJ, Tichelaar J, Okorie M, Bissell L, Christiaens T, Likic R, Mačiulaitis R, Costa J, Sanz EJ, Tamba BI, Maxwell SR, Richir MC, van Agtmael MA; Education Working Group of the European Association for Clinical Pharmacology and Therapeutics (EACPT). *Clin Pharmacol Ther.* 2017 Nov;102(5):815-822.
 4. Challenges in conducting clinical trials in nephrology: conclusions from a Kidney Disease-Improving Global Outcomes (KDIGO) Controversies Conference. Baigent C, Herrington WG, Coresh J, Landray MJ, Levin A, Perkovic V, Pfeffer MA, Rossing P, Walsh M, Wanner C, Wheeler DC, Winkelmayr WC, McMurray JJV; KDIGO Controversies Conference on Challenges in the Conduct of Clinical Trials in Nephrology Conference Participants. *Kidney Int.* 2017 Aug;92(2):297-305.
 5. Pharmacology in Estonia, Latvia and Lithuania: From historical roots to nowadays achievements. Jansone B, Kuum M, Maciulaitis R. *Pharmacol Res.* 2016 Nov;113(Pt B):723-730.
 6. Regenerative pharmacology for the treatment of acute kidney injury: Skeletal muscle stem/progenitor cells for renal regeneration? Pavyde E, Usas A, Maciulaitis R. *Pharmacol Res.* 2016 Nov;113(Pt B):802-807.
 7. Characterization of tissue engineered cartilage products: Recent developments in advanced therapy. Mačiulaitis J, Rekštytė S, Ūsas A, Jankauskaitė V, Gudas R, Malinauskas M, Mačiulaitis R. *Pharmacol Res.* 2016 Nov;113(Pt B):823-832.
 8. Cell-based therapies for cardiac repair: a meeting report on scientific observations and European regulatory viewpoints. Schüssler-Lenz M, Beuneu C, Menezes-Ferreira M, Jekerle V, Bartunek J, Chamuleau S, Celis P, Doevendans P, O'Donovan M, Hill J, Hystad M, Jovinge S, Kyselovič J, Lipnik-Stangelj M, Maciulaitis R, Prasad K, Samuel A, Tenhunen O, Tonn T, Rosano G, Zeiher A, Salmikangas P. *Eur J Heart Fail.* 2016 Feb;18(2):133-41.
 9. Skeletal Muscle-Derived Stem/Progenitor Cells: A Potential Strategy for the Treatment of Acute Kidney Injury. Pavyde E, Maciulaitis R, Mauricas M, Sudzius G, Ivanauskaite Didziokiene E, Laurinavicius A, Sutkeviciene N, Stankevicius E, Maciulaitis J, Usas A. *Stem Cells Int.* 2016;2016:9618480. doi: 10.1155/2016/9618480.
- Preclinical study of SZ2080 material 3D microstructured scaffolds for cartilage tissue engineering made by femtosecond direct laser writing lithography. Mačiulaitis J, Deveikytė M, Rekštytė S, Bratchikov M, Darinskas A, Šimbelytė A, Daunoras G, Laurinavičienė A, Laurinavičius A, Gudas R, Malinauskas M, Mačiulaitis R. *Biofabrication.* 2015 Mar 23;7(1):015015.
10. GFR decline as an end point for clinical trials in CKD: a view from Europe. Mol PG, Maciulaitis R, Vetter T. *Am J Kidney Dis.* 2014 Dec;64(6):838-40.
 11. Topical photodynamic therapy of actinic keratoses with 5-aminolevulinic acid: Randomized controlled trial with six months follow-up. Buinauskaite E, Maciulaitis R, Buinauskiene J, Valiukeviciene S. *J Dermatolog Treat.* 2013 Nov 12.
 12. Development of a short questionnaire to identify the risk of nonadherence to antibiotic treatment. Kandrotaitė K, Smigelskas K, Janusauskiene D, Jievaltas M, Maciulaitis R, Briedis V. *Curr Med Res Opin.* 2013 Nov;29(11):1555-63.
 13. Augmented renal clearance - an evolving risk factor to consider during the treatment with vancomycin. Minkutė R, Briedis V, Steponavičiūtė R, Vitkauskienė A, Mačiulaitis R. *J Clin Pharm Ther.* 2013 Aug 8.
 14. Risk of tumorigenicity in mesenchymal stromal cell-based therapies—bridging scientific observations and regulatory viewpoints. Barkholt L, Flory E, Jekerle V, Lucas-Samuel S, Ahnert P, Bisset L, Büscher D, Fibbe W, Foussat A, Kwa M, Lantz O, Mačiulaitis R, Palomäki T, Schneider CK, Sensebé L, Tachdjian G, Tarte K, Tosca L, Salmikangas P. *Cytotherapy.* 2013 Jul;15(7):753-9.
 15. Clinical development of advanced therapy medicinal products in Europe: evidence that regulators

- must be proactive. Maciulaitis R, D'Apote L, Buchanan A, Pioppo L, Schneider CK. *Mol Ther.* 2012 Mar;20(3):479-82. No abstract available.
16. Skeletal muscle-derived stem cells: implications for cell-mediated therapies. Usas A, Mačiulaitis J, Mačiulaitis R, Jakubonienė N, Milašius A, Huard J. *Medicina (Kaunas).* 2011;47(9):469-79. Review.
17. Rationality of administered gentamicin dose in cerebral coma patients treated in an intensive care unit. Janušonis T, Mačiulaitis R, Sveikata A, Milašius A, Kregždūtė R. *Medicina (Kaunas).* 2011;47(2):79-84. English, Lithuanian.
18. Renal biomarker qualification submission: a dialog between the FDA-EMEA and Predictive Safety Testing Consortium. Dieterle F, Sistare F, Goodsaid F, Papaluca M, Ozer JS, Webb CP, Baer W, Senagore A, Schipper MJ, Vonderscher J, Sultana S, Gerhold DL, Phillips JA, Maurer G, Carl K, Laurie D, Harpur E, Sonee M, Ennulat D, Holder D, Andrews-Cleavenger D, Gu YZ, Thompson KL, Goering PL, Vidal JM, Abadie E, Maciulaitis R, Jacobson-Kram D, Defelice AF, Hausner EA, Blank M, Thompson A, Harlow P, Throckmorton D, Xiao S, Xu N, Taylor W, Vamvakas S, Flamion B, Lima BS, Kasper P, Pasanen M, Prasad K, Troth S, Bounous D, Robinson-Gravatt D, Betton G, Davis MA, Akunda J, McDuffie JE, Suter L, Obert L, Guffroy M, Pinches M, Jayadev S, Blomme EA, Beushausen SA, Barlow VG, Collins N, Waring J, Honor D, Snook S, Lee J, Rossi P, Walker E, Mattes W. *Nat Biotechnol.* 2010 May;28(5):455-62.
19. Towards consensus practices to qualify safety biomarkers for use in early drug development. Sistare FD, Dieterle F, Troth S, Holder DJ, Gerhold D, Andrews-Cleavenger D, Baer W, Betton G, Bounous D, Carl K, Collins N, Goering P, Goodsaid F, Gu YZ, Guilpin V, Harpur E, Hassan A, Jacobson-Kram D, Kasper P, Laurie D, Lima BS, Maciulaitis R, Mattes W, Maurer G, Obert LA, Ozer J, Papaluca-Amati M, Phillips JA, Pinches M, Schipper MJ, Thompson KL, Vamvakas S, Vidal JM, Vonderscher J, Walker E, Webb C, Yu Y. *Nat Biotechnol.* 2010 May;28(5):446-54.
20. Challenges with advanced therapy medicinal products and how to meet them. Committee for Advanced Therapies (CAT); CAT Scientific Secretariat, Schneider CK, Salmikangas P, Jilma B, Flamion B, Todorova LR, Paphitou A, Haunerova I, Maimets T, Trouvin JH, Flory E, Tsiftoglou A, Sarkadi B, Gudmundsson K, O'Donovan M, Migliaccio G, Ancāns J, Maciulaitis R, Robert JL, Samuel A, Ovelgönne JH, Hystad M, Fal AM, Lima BS, Moraru AS, Turcáni P, Zorec R, Ruiz S, Akerblom L, Narayanan G, Kent A, Bignami F, Dickson JG, Niederwieser D, Figuerola-Santos MA, Reischl IG, Beuneu C, Georgiev R, Vassiliou M, Pychova A, Clausen M, Methuen T, Lucas S, Schüssler-Lenz M, Kokkas V, Buzás Z, MacAleenan N, Galli MC, Linē A, Gulbinovic J, Berchem G, Fraczek M, Menezes-Ferreira M, Vilceanu N, Hrubisko M, Marinko P, Timón M, Cheng W, Crosbie GA, Meade N, di Paola ML, VandenDriessche T, Ljungman P, D'Apote L, Oliver-Diaz O, Büttel I, Celis P. *Nat Rev Drug Discov.* 2010 Mar;9(3):195-201.
21. Regulatory requirements for clinical trial and marketing authorisation application for cell-based medicinal products. Salmikangas P, Flory E, Reinhardt J, Hinz T, Maciulaitis R. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz.* 2010 Jan;53(1):24-9. doi: 10.1007/s00103-009-0991-5.
22. Evaluation of needs for therapeutic monitoring of digoxin in a tertiary hospital. Penkauskaitė J, Maciulaitis R, Varanaviciene B, Milvidaite I, Tarutiene B. *Medicina (Kaunas).* 2009;45(1):46-50.
23. [Analysis of antibiotic consumption and microorganism resistance changes]. Galinyte D, Maciulaitis R, Budnikas V, Kubilius D, Varanaviciene B, Vitkauskiene A, Jokimas J, Jodkonis L. *Medicina (Kaunas).* 2008;44(10):751-67. Lithuanian.
24. Ibogaine, an anti-addictive drug: pharmacology and time to go further in development. A narrative review. Maciulaitis R, Kontrimaviciute V, Bressolle FM, Briedis V. *Hum Exp Toxicol.* 2008 Mar;27(3):181-94. doi: 10.1177/0960327107087802. Review.
25. [Administration and dosing of gentamicin (data from Kaunas University of Medicine Hospital)]. Leksiene R, Janusonis T, Maciulaitis R, Balciuviene V, Petrauskaite D, Seputyte A. *Medicina (Kaunas).* 2007;43 Suppl 1:1-5. Lithuanian.
26. [Secondary prevention of ischemic heart disease: pharmacological treatment after myocardial infarction according to follow-up protocol]. Milvidaite I, Luksiene D, Slapikiene B, Babarskiene MR, Liukaitis V, Maciulaitis R, Kadusevicius E, Pilviniene R. *Medicina (Kaunas).* 2007;43(2):131-6. Lithuanian.
27. [Breastfeeding and medications]. Pilviniene R, Maciulaitis R, Jankūnas R, Milvidaite I, Markūniene E. *Medicina (Kaunas).* 2006;42(12):1035-45. Review. Lithuanian.
28. Trends in the consumption of antidepressant drugs in Lithuania in 2002-2004.

Kadusevicius E, Mikucionyte L, Maciulaitis R, Milvidaite I, Sveikata A. Medicina (Kaunas). 2006;42(12):1020-9.

29. [Rational treatment of diabetes mellitus in Siauliai and Telsiai regions, Lithuania].

Maciulaitis R, Ozoliene D, Pilviniene R, Preiksa RT. Medicina (Kaunas). 2006;42(12):1013-9. Lithuanian.

30. [Compliance in psychiatry: results of a survey of depressed patients using orally disintegrating tablet]. Danileviciute V, Adomaitiene V, Sveikata A, Maciulaitis R, Kadusevicius E, Volbekas V. Medicina (Kaunas). 2006;42(12):1006-12. Lithuanian.

31. [Assessment of antibiotic use and comparison with recommendations for their rational use]. Maciulaitis R, Janusonis T, Petrikaite V, Aukstakalniene A. Medicina (Kaunas). 2006;42(12):999-1005. Lithuanian.

32. Comment: analysis of severe adverse events related to the use of mifepristone as an abortifacient. Svedas E, Maciulaitis R, Stakisaitis D. Ann Pharmacother. 2006 Apr; 40(4): 784; author reply 784-5.

33. Possible association between cell membrane band 3 impairment function and renal tubular acidosis (liver diseases, malignancies and adverse drug reactions).

Stakisaitis D, Didziapetriene J, Maciulaitis R, Tschaika M. Medicina (Kaunas). 2004;40(1):9-15. Review.

34. [Irrational drug use in Siauliai, Panevezys and Utena counties of Lithuania].

Maciulaitis R, Janusonis T. Medicina (Kaunas). 2003;39 Suppl 2:9-18. Review. Lithuanian.

Projects

Memberships

ESCPT

UEMS Pharmacology

Other Relevant Information

I married Dr Sondra Kybartienė on 2014-07-11