

# Luca Pani, MD

## CURRICULUM VITAE

1. Date: June 20, 2026

### I. Personal

2. Name: Luca Pani

3. Home Phone:

4. Office Phone:

5. Home Address:

6. Current Academic Rank: Full Professor both in US and ITALY

6A. Current Track of US Appointment: Clinical Educator Track

6B. Current Track of IT Appointment: Tenured Clinical Educator Track

7. Primary Department: Department of Psychiatry and Behavioral Sciences, University of Miami, Miami, USA

8. Joint Appointment: Full Professor and Chair of Pharmacology and Clinical Pharmacology, University of Modena and Reggio Emilia, School of Medicine, Modena, Italy

9. Citizenship: American and Italian

10. Visa Type: N/A

### II. Higher Education

11. Institutional:

1990-1991 the University of Illinois at Chicago, USA – Post-Doctoral Fellowship in Molecular Biology

1985-1989 University of Naples, Italy – Specialty in Psychiatry

1979-1985 University of Cagliari, Italy – Medical Degree

12. Non-Institutional:

13. Certification and Licensure:

Specialty Certification Psychiatry, Naples - Italy, July 1989

Board Certification to practice Medicine, Cagliari - Italy, December 1985

### III. Experience

14. Academic

2023-present Medical Director CME Courses, Department of Psychiatry and Behavioral Sciences, University of Miami – M. Miller School of Medicine, Miami, USA

2018-present Full Professor of Pharmacology and Clinical Pharmacology, Department of Biomedical, Metabolic and Neural Sciences, the University of Modena and Reggio Emilia, Modena, Italy

2018-present Director I Level Master on “From Prevention to Clinical Skills in Alcohol Abuse related issues,” University of Modena and Reggio Emilia, Modena, Italy

2017-present Full Professor of Clinical Psychiatry, Educator Track, Department of Psychiatry and Behavioral Sciences, University of Miami – M. Miller School of Medicine, Miami, USA

2011-2017 Voluntary Professor, Department of Psychiatry and Behavioral Sciences, University of Miami – M. Miller School of Medicine

2007-2017 Appointed Teaching Professor, Courses on Psychopharmacology, Residency in Psychiatry, School of Medicine, University of Cagliari, Italy

2001-2018 Director of Research, Italian National Research Council (CNR) – Rome, Italy

1999-2001 First Researcher, Italian National Research Council (CNR) – Rome, Italy

1995-1999 Researcher, Italian National Research Council (CNR) – Rome, Italy

1992-1994 Assistant Professor in Molecular Biology and Pharmacology, Georgetown University, Washington DC, USA

15. Hospital Appointments:

1990-2010 Chief Psychiatrist, Centro San Michele, Cagliari Italy, Private Institution

1988-1989 Medical Assistant (tenured). Public Psychiatric Hospital “Villa Clara”. Cagliari, Italy

1985-1988 Resident in Psychiatry, Centro Lucio Bini, Rome, Italy, Private Institution

16. Non-Academic:

2026-2028: President International Scientists & Scholars in North America Foundation (ISSNAF)

2026-2028: Immediate Past-President, International Society for Clinical Trials Methodology (ISCTM)

2025-current Chief Scientific and Regulatory Advisor, RAIN Scientific, USA

2024-2026: President, International Society for Clinical Trials Methodology

2023-current Chief Advisor, Relmada Therapeutics, USA

2022-current Chief Innovation and Regulatory Officer, NetraMark, Canada

2022-current Member ISPOR Value-Based Healthcare Special Task Force

2021-2023 Chief Clinical Operations and Strategic Development, Relmada Therapeutics, USA

2020-current Member Program Committee ASCP American Society for Clinical Psychopharmacology

2020-current: Member Executive Committee International Society for Clinical Trials Methodology

2018-2022 VP for Regulatory Strategy and Market Access Innovation, VeraSci, Durham, NC, USA

2017-2018 Executive Director for Global Medical Innovation, NeuroCogTrial (now VeraSci), Durham, NC, USA

2017- 2021 Chief Scientific Officer – Inpeco Automation Healthcare Company, Lugano, Switzerland

2017-present Chief Scientific Officer – EDRA-LSWR Publishing Company, Milan, Italy

2011-2016 Director General, Italian Medicines Agency (AIFA), Rome, Italy

2013-2016 Chair of the European Union Management Board Telematic Committee (EUMBTC) of the European Medicines Agency (EMA), London UK

2016-2017 Chair of the EMA EU Network Pharmacovigilance Oversight Group, London UK

2011-2016 Member Management Board of the European Medicines Agency (EMA), London UK

2010- 2017 Italian Permanent Member, Committee for Human Medicine Products (CHMP), of the European Medicines Agency (EMA), London UK

2010-2017 Member of the Scientific Advice Working Party (SAWP), of the European Medicines Agency (EMA), London UK

2010- 2017 Member and then Participant of the Working Group on Central Nervous System (WG-CNS), of the European Medicines Agency (EMA), London UK

2015-2016 Member of the Management Group Heads of Medicines Agencies (HMA)

2013-2016 Chair of the European Risk Management Strategy Facilitation Group (ERMS-FG) of the European Medicines Agency (EMA), London UK

2009-2011 Member, Committee for Clinical Neurosciences, Italian Medicines Agency (AIFA)

2009-2011 Head of Research of the National Research Council's Institute of Translational pharmacology (CNR – ITP), Pula-Cagliari, Italy

2008-2010 3PS Media Ltd Consultant

2008-2011 Founder and Permanent Member of the Scientific Board of Fase 1, the first Government based (Regione Autonoma della Sardegna) Contract Research Organization dedicated to Phase 1 studies

2006-2010 Head Section of Neuropharmacology Pula-Cagliari, Institute of Biomedical Technologies, Milan Italian National Research Council (CNR)

2001-2018 Director of Research, CNR. Cagliari-Rome

2002-2010 President, Pharmaness Neuroscienze (Board of Directors member).

2004-2009 President, Proteios Srl

2005-2008 President ProKemia Consorzio

1999-2002 CEO, Pharmaness Neuroscienze Consortium

17. Military: 1986-1988, Lieutenant Medical Officer of the Italian Navy. Commander South Sardinia General Medicine Headquarters, Cagliari, Italy

#### **IV. Publications**

Luca Pani's Bibliography: <https://pubmed.ncbi.nlm.nih.gov/?term=pani+l.&sort=date>

1. Thase ME, Brennan B, MacIsaac R, Pani L, Valcheva V, Cubata WJ. GH001 Efficacy is Independent of Prior Antidepressant Treatment Failures in Treatment-Resistant Depression: A Post Hoc Analysis of a Phase 2b Randomized Controlled Trial. *Psychopharmacol Bull.* 2026 Jun 5;56(3):8-21. doi: 10.64719/pb.18507. PMID: 42267234. Clinical Trial.
2. Iannone LF, Romozzi M, Pani L, Tascedda F. Darigabat and subtype-selective GABA-A modulation: pharmacology, clinical development, and translational challenges. *Expert Opin Investig Drugs.* 2026 Jun 16:1-14. doi: 10.1080/13543784.2026.2687030. Online ahead of print. PMID: 42252536. Review.
3. Karlsen TH, Hutchinson SJ, Zelber-Sagi S, Carrieri P, Negro F, Lim AG, Cecchini M, Dirac MA, Murray F, Engebretsen E, Duffell E, Schomerus G, Voigt K, Brandtzaeg PB, Lerouge A, Kanavos P, Pani L, Razavi-Shearer D, Eshete MT, Vuik S, Leonhard A, McNaughton AL, Yumuk V, Ivancovsky-Wajcman D, Letourneau ID, Hickman M, Han H, Kautz A, Fabrellas N, Spann AL, Berg T, Ratzu V, Gheorghe LS, Mathurin P, Vickerman P, Shawcross DL, Paradis C, Razavi H, Naveira MCM, Buti M, Ginès P, Newsome PN, Berzigotti A, Guha N, Rutter H, Krag A, Burra P, Manns MP. Implementing sustainable liver health in Europe: a second EASL-Lancet Commission. *Lancet.* 2026 May 9;407(10541):1825-1890. doi: 10.1016/S0140-6736(26)00138-8. Epub 2026 Apr 29. PMID: 42068985. Review.
4. Lewis F, Renzetti S, Goulett N, Azmoun S, Sundar V, Ali M, Pitta L, Shoieb D, Caci M, Borghesi S, Covolo L, Oppini M, Gelatti U, Padovani A, Pilotto A, Pepe F, Turla M, Crippa P, Boffetta P, Pani L, Vermeulen R, Kromhout H, Lambertini L, Colicino E, Placidi D, Lucchini R. LIFETIME JEM-DERIVED OCCUPATIONAL EXPOSURE BURDEN AND ODDS OF PARKINSON'S DISEASE AND PARKINSONISM IN A MATCHED CASE-CONTROL STUDY. *medRxiv [Preprint].* 2026 Apr 14:2026.03.16.26348171. doi: 10.64898/2026.03.16.26348171. PMID: 42064924. Preprint.
5. Romozzi M, Palermo M, Scuteri D, Signorelli F, Romozzi P, Pani L, Tascedda F, Di Tella S, Vollono C, Calabresi P, Tosto F, Iannone LF. Awareness, attitudes, and clinical practices related to medication-overuse headache among Italian pharmacists: results from a cross-sectional survey. *J Headache Pain.* 2026 Apr 28;27(1):134. doi: 10.1186/s10194-026-02376-1. PMID: 42045999. Free PMC article.
6. Geraci J, Viirre E, Qorri B, Pani L. Psychedelics and the quantum brain: a falsifiable hypothesis on Posner molecules and spin-dependent pharmacology. *Front Pharmacol.* 2026 Mar 31;17:1777613. doi: 10.3389/fphar.2026.1777613. eCollection 2026. PMID: 41988526. Free PMC article.
7. Magaraggia I, Di Cesare F, Alonso J, Edgar CJ, Heckman P, Engler J, Domingo SZ, Pani L, Schreiber R. Application of the research domain criteria in early-phase clinical development of transdiagnostic neurotherapeutics: A multidisciplinary perspective. *Neurosci Appl.* 2026 Mar 7;5:106996. doi: 10.1016/j.nsa.2026.106996. eCollection 2026. PMID: 41958844. Free PMC article. Review.
8. Grueger J, Lainé E, Goncalves FN, Middelhoven H, Padula WV, Etges AP, Steuten L; ISPOR Value-Based Healthcare Implementation Special Task Force. Applying Health Economics and Outcomes Research Methods in Value-Based Healthcare Implementation: An ISPOR Special Task Force Report. *Value Health.* 2026 Mar 12:S1098-3015(26)00095-1. doi: 10.1016/j.jval.2026.02.014. Online ahead of print. PMID: 41831684. Review.

9. Guidetti C, Papakostas GI, Stahl S, Pani L, De Martin S, Mattarei A, Comai S, Kröger C, Champasa P, Gorodetzky CW, Vocci FJ, Kosten TR, Bushnell D, Kappler M, Folli F, Inturrisi CE, Pappagallo M, Manfredi PL, Fava M. Depression severity and efficacy outcomes: post hoc analyses from a phase 3 trial of esmethadone for the adjunctive treatment of major depressive disorder with inadequate response to standard antidepressants. *Int Clin Psychopharmacol.* 2026 Jul 1;41(4):213-224. doi: 10.1097/YIC.0000000000000618. Epub 2026 Feb 17. PMID: 41749468. Clinical Trial.
10. Blom JMC, Staunton C, Tascadda S, Slabbert N, Pani L, Labuschaigne M. Embedding equity in clinical research governance. *Nat Med.* 2026 Apr;32(4):1185-1187. doi: 10.1038/s41591-026-04232-w. PMID: 41688567.
11. Geraci J, Qorri B, Tsay M, Cumbaa C, Leonczyk P, Alphas L, Ballard ED, Zarate CA Jr, Pani L. Explainable AI-driven precision clinical trial enrichment: demonstration of the NetraAI platform with a phase II depression trial. *NPJ Digit Med.* 2025 Dec 8;8(1):749. (IF) 15.1
12. Guidetti C, Papakostas GI, Pani L, De Martin S, Serra G, Apicella M, Kröger C, Champasa P, Comai S, Mattarei A, Folli F, Pappagallo M, Manfredi PL, Fava M. Esmethadone (REL-1017) in Patients With Major Depressive Disorder and Antidepressant Tachyphylaxis: An Exploratory Post Hoc Analysis From a Phase 3 Randomized Controlled Trial. *J Clin Psychiatry.* 2025 Oct 6;86(4):24m15748. (IF) 5.3
13. Lo Castro F, Bonini N, Iannone LF, Boccalini A, Brovia D, Pani L, Boriani G, Guerzoni S. No Increase in Blood Pressure Assessed With the 24-h Holter Monitoring in Patients With Episodic Migraine During Early Treatment With Anti-CGRP Monoclonal Antibodies: A Prospective Observational Study (SAFHYPHER). *Eur J Neurol.* 2025 Sep;32(9):e70351. (IF) 3.9
14. Blom JMC, Rivi V, Tascadda F, Pani L. Building trust in clinical research: a systems approach to ethical engagement and sustainable outcomes. *Front Pharmacol.* 2025 Jul 16;16:1570899. (IF) 4.9
15. Rivi V, Sarti P, Fodor I, Pirger Z, Koene JM, Pani L, Batabyal A, Lukowiak K, Blom JMC, Tascadda F, Benatti C. First evidence of an anxiety-like behavior and its pharmacological modulation in a molluscan model organism, *Lymnaea stagnalis*. *Transl Psychiatry.* 2025 May 22;15(1):177. (IF) 5.8
16. Xiong Z, Guo Z, Zhao L, Qiu D, Mei Y, Li X, Zhang P, Zhang M, Liu G, Gao T; International Consortium for Cluster Headache Genetics; Wang Y, Yu X. Correction: Uncovering drug targets for cluster headache through proteome-wide Mendelian randomization analysis. *J Headache Pain.* 2025 Apr 29;26(1):94. (IF) 7.3
17. Xiong Z, Guo Z, Zhao L, Qiu D, Mei Y, Li X, Zhang P, Zhang M, Liu G, Gao T; International Consortium for Cluster Headache Genetics; Wang Y, Yu X. Uncovering drug targets for cluster headache through proteome-wide Mendelian randomization analysis. *J Headache Pain.* 2025 Mar 20;26(1):57. (IF) 7.3
18. Rivi V, Rigillo G, Alboni S, Koene JM, Pani L, Lukowiak K, Tascadda F, Blom JMC, Benatti C. Unraveling lipopolysaccharide-induced behavioral and molecular effects in *Lymnaea stagnalis*, an emerging model organism for translational neuroscience. *Int Immunopharmacol.* 2025 Apr 16;152:114418. (IF): 4.8
19. Fava M, Pani L, De Martin S, Cutler AJ, Gorodetzky CW, Vocci FJ, Sapienza FL, Kosten TR, Kröger C, Champasa P, Guidetti C, Comai S, Mattarei A, Folli F, Bushnell D, Traversa S, Inturrisi CE, Manfredi PL, Pappagallo M., Long-Term Safety and Efficacy of Esmethadone

- in Patients With Major Depressive Disorder: Findings From a 12-Month Open-Label Study. *J Clin Psychiatry*. 2025 Feb 17;86(1):24m15438. (IF): 5.2
20. Rigillo G, Bains G, Bruni R, Puja G, Miraldi E, Pani L, Tascetta F, Biagi M. Red Yeast Rice or Lovastatin? A Comparative Evaluation of Safety and Efficacy Through a Multifaceted Approach. *Phytother Res*. 2024 Nov 7. (IF) 7.20
  21. Rigillo G, Cappellucci G, Bains G, Vaccaro F, Miraldi E, Pani L, Tascetta F, Bruni R, Biagi M. "Comprehensive Analysis of *Berberis aristata* DC. Bark Extracts: In Vitro and In Silico Evaluation of Bioaccessibility and Safety." *Nutrients*. 2024 Sep 2;16(17):2953. PMID: 39275269 (IF): 6.706
  22. Rivi V, Caruso G, Caraci F, Alboni S, Pani L, Tascetta F, Lukowiak K, Blom JMC, Benatti C. "Behavioral and transcriptional effects of carnosine in the central ring ganglia of the pond snail *Lymnaea stagnalis*." *J Neurosci Res*. 2024 Aug;102(8) PMID: 39078068 (IF): 3.828
  23. Ciani M, Rigillo G, Benatti C, Pani L, Blom JMC, Brunello N, Tascetta F, Alboni S. "Time- and Region-specific Effect of Vortioxetine on Central LPS-induced Transcriptional Regulation of NLRP3 Inflammasome." *Curr Neuroparmacol*. 2024 Jul 12. (IF): 4.568
  24. Jack CR Jr, Andrews SJ, Beach TG, Buracchio T, Dunn B, Graf A, Hansson O, Ho C, Jagust W, McDade E, Molinuevo JL, Okonkwo OC, Pani L, Rafii MS, Scheltens P, Siemers E, Snyder HM, Sperling R, Teunissen CE, Carrillo MC. "Revised criteria for the diagnosis and staging of Alzheimer's disease." *Nat Med*. 2024 Jun 28. doi: 10.1038/s41591-024-02988-7. Online ahead of print. PMID: 38942991. (IF): 53.44.
  25. Jack CR Jr, Andrews JS, Beach TG, Buracchio T, Dunn B, Graf A, Hansson O, Ho C, Jagust W, McDade E, Molinuevo JL, Okonkwo OC, Pani L, Rafii MS, Scheltens P, Siemers E, Snyder HM, Sperling R, Teunissen CE, Carrillo MC. "Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup." *Alzheimers Dement*. 2024 Jun 27. doi: 10.1002/alz.13859. Online ahead of print. PMID: 38934362. (IF): 17.12.
  26. Rivi V, Rigillo G, Batabyal A, Lukowiak K, Pani L, Tascetta F, Benatti C, Blom JMC. "Different stressors uniquely affect the expression of endocannabinoid-metabolizing enzymes in the central ring ganglia of *Lymnaea stagnalis*." *J Neurochem*. 2024 Jun 22. doi: 10.1111/jnc.16147. Online ahead of print. PMID: 38922726. (IF): 5.02.
  27. Fava M, Stahl SM, Pani L, De Martin S, Cutler AJ, Maletic V, Gorodetzky CW, Vocci FJ, Sapienza FL, Kosten TR, Kröger C, Champasa P, O'Gorman C, Guidetti C, Alimonti A, Comai S, Mattarei A, Folli F, Bushnell D, Traversa S, Inturrisi CE, Manfredi PL, Pappagallo M. "Efficacy and Safety of Esmethadone (REL-1017) in Patients With Major Depressive Disorder and Inadequate Response to Standard Antidepressants: A Phase 3 Randomized Controlled Trial." *J Clin Psychiatry*. 2024 Jun 17;85(3):24 (IF): 4.06.
  28. Guidetti C, De Martin S, Serra G, Apicella M, Pani L, Pappagallo M, Mattarei A, Folli F, Manfredi P, Fava M. "Effect of Time From Onset of Major Depressive Disorder on the Therapeutic Response to Esmethadone (REL-1017)." *J Clin Psychiatry*. 2024 May 13;85(2):22m14735. (IF): 4.06.
  29. Lee M, Larose H, Gräbeldinger M, Williams J, Baird AM, Brown S, Bruns J, Clark R, Cortes J, Curigliano G, Ferris A, Garrison LP, Gupta YK, Kanavarar R, Lyman G, Pani L, Pemberton-Whiteley Z, Salmonson T, Sawicki P, Stein B, Suh DC, Velikova G, Grueger J. The evolving value assessment of cancer therapies: Results from a modified Delphi study. *Health Policy Open*. 2024 Mar 1;6:100116. IF 3.3

30. Geraci J, Bhargava R, Qorri B, Leonchik P, Cook D, Cook M, Sie F, Pani L. Machine learning hypothesis-generation for patient stratification and target discovery in rare disease: our experience with Open Science in ALS. *Front Comput Neurosci*. 2024 Jan 4;17:1199736. doi:10.3389/fncom.2023.1199736. IF 3.2
31. Guerzoni S, Castro FL, Brovia D, Baraldi C, Pani L. Evaluation of the Risk of Hypertension in Patients Treated with Anti-CGRP Monoclonal Antibodies in a Real-Life Study. *Neurol Sci*. 2023 Nov 6. doi: 10.1007/s10072-023-07167-z. PMID: 37926748. IF 3.3
32. Sarti P, Colliva C, Varrasi S, Guerrera CS, Platania GA, Boccaccio FM, Castellano S, Pirrone C, Pani L, Tascedda F, di Nuovo S, Caraci F, Blom JMC. A Network Study to Differentiate Suicide Attempt Risk Profiles in Male and Female Patients with Major Depressive Disorder. *Clin Psychol Psychother*. 2023 Nov 3. doi: 10.1002/cpp.2924. Online ahead of print. PMID: 37922512. IF 3.6
33. Blom JMC, Rivi V, Tascedda F, Pani L. The Nexus of Social Alliances and Diverse Moral Domains: A Bedrock for Participatory Clinical Research. *Front Med (Lausanne)*. 2023 Oct 2;10:1250247. doi: 10.3389/fmed.2023.1250247. eCollection 2023. PMID: 37849486. Free PMC article. IF 3.9
34. Winsvold BS, Harder AVE, Ran C, et al. Cluster Headache Genomewide Association Study and Meta-Analysis Identifies Eight Loci and Implicates Smoking as Causal Risk Factor. *Ann Neurol*. 2023 Oct;94(4):713-726. doi: 10.1002/ana.26743. Epub 2023 Aug 7. PMID: 37486023. [See abstract for full author list]IF 11.2
35. Guerzoni S, Baraldi C, Brovia D, Cainazzo MM, Castro FL, Pani L. Correction to: Monoclonal Anti-CGRP Antibodies in Post-Menopausal Women: A Real-Life Study. *Acta Neurol Belg*. 2023 Oct;123(5):2075. doi: 10.1007/s13760-023-02340-9. IF 2.6
36. Rivi V, Benatti C, Blom JMC, Pani L, Brunello N, Drago F, Papaleo F, Caraci F, Geraci F, Torrisi SA, Leggio GM, Tascedda F. The Role of Dopamine D3 Receptors, Dysbindin, and Their Functional Interaction in the Expression of Key Genes for Neuroplasticity and Neuroinflammation in the Mouse Brain. *Int J Mol Sci*. 2023 May 12;24(10):8699. IF 5.6
37. Guerzoni S, Baraldi C, Castro FL, Cainazzo MM, Pani L. Galcanezumab for the treatment of chronic migraine and medication overuse headache: Real-world clinical evidence in a severely impaired patient population. *Brain Behav*. 2023 Jun;13(6):e2799. doi: 10.1002/brb3.2799. Epub 2023 May 19. IF 3.1
38. Pandina G, Busner J, Horrigan JP, McSherry C, Bateman-House A, Pani L, Kando J. Implications of Pediatric Initiatives on CNS Drug Development for All Ages-2020 and Beyond: Second of Three Sets of Expanded Proceedings from the 2020 ISCTM Autumn Conference on Pediatric Drug Development. *Innov Clin Neurosci*. 2023 Jan-Mar;20(1-3):18-24.
39. Fava M, Stahl SM, De Martin S, Mattarei A, Bettini E, Comai S, Alimonti A, Bifari F, Pani L, Folli F, Guidetti C, Furlan A, Sgrignani J, Locatelli P, Cavalli A, O'Gorman C, Traversa S, Inturrisi CE, Pappagallo M, Manfredi PL.; Esmethadone-HCl (REL-1017): a promising rapid antidepressant. *Eur Arch Psychiatry Clin Neurosci*. 2023 Mar 8. doi: 10.1007/s00406-023-01571-4. Online ahead of print.
40. Guidetti C, Serra G, Pani L, Pappagallo M, Maglio G, Martin S, Mattarei A, Folli F, Manfredi PL, Fava M. Subanalysis of Subjective Cognitive Measures From a Phase 2, Double-Blind,

- Randomized Trial of REL-1017 in Patients With Major Depressive Disorder. *Prim Care Companion CNS Disord.* 2023 Feb 14; 25(1):2
41. Blom JMC, Benatti C, Mascalzoni D, Tascetta F, Pani L. Editorial: Digital biomarkers in testing the safety and efficacy of new drugs in mental health: A collaborative effort of patients, clinicians, researchers, and regulators. *Front Psychiatry.* 2023 Jan 11;13:1107037.
  42. Baraldi C, Lo Castro F, Ornello R, Sacco S, Pani L, Guerzoni S. OnabotulinumtoxinA: Still the Present for Chronic Migraine. *Toxins (Basel).* 2023 Jan 10;15(1):59.
  43. Blom JMC, Barisone E, Bertolotti M, Caprino D, Cellini M, Clerici CA, Colliva C, Favara-Scacco C, Di Giuseppe S, Jankovic M, Pancaldi A, Pani L, Poggi G, Rivi V, Tascetta F, Torta R, Scarponi D. The Use of Psychotropic Medication in Pediatric Oncology for Acute Psychological and Psychiatric Problems: Balancing Risks and Benefits. *Children (Basel).* 2022 Nov 30;9(12):1878.
  44. Stahl SM, De Martin S, Mattarei A, Bettini E, Pani L, Guidetti C, Folli F, de Somer M, Traversa S, Inturrisi CE, Pappagallo M, Gentilucci M, Alimonti A, Fava M, Manfredi PL. Esmethadone (REL-1017) and Other Uncompetitive NMDAR Channel Blockers May Improve Mood Disorders via Modulation of Synaptic Kinase-Mediated Signaling. *Int J Mol Sci.* 2022 Oct 13;23(20):12196.
  45. Gallucci D, Ho ECY, Geraci J, Loren J, Pani L. Respondents of health survey powered by the innovative NURO app exhibit correlations between exercise frequencies and diet habits, and between stress levels and sleep wellness. *Front Psychiatry.* 2022 Sep 6;13:945780.
  46. Ornello R, Baraldi C, Ahmed F, Negro A, Miscio AM, Santoro A, Alpuente A, Russo A, Silvestro M, Cevoli S, Brunelli N, Vernieri F, Grazi L, Pani L, Andreou A, Lambru G, Frattale I, Kamm K, Ruscheweyh R, Russo M, Torelli P, Filatova E, Latysheva N, Gryglas-Dworak A, Straburzyński M, Butera C, Colombo B, Filippi M, Pozo-Rosich P, Martelletti P, Guerzoni S, Sacco S. Excellent Response to OnabotulinumtoxinA: Different Definitions, Different Predictors. *Int J Environ Res Public Health.* 2022 Sep 2;19(17):10975.
  47. Bettini E, Stahl SM, De Martin S, Mattarei A, Sgrignani J, Carignani C, Nola S, Locatelli P, Pappagallo M, Inturrisi CE, Bifari F, Cavalli A, Alimonti A, Pani L, Fava M, Traversa S, Folli F, Manfredi PL. Pharmacological Comparative Characterization of REL-1017 (Esmethadone-HCl) and Other NMDAR Channel Blockers in Human Heterodimeric N-Methyl-D-Aspartate Receptors. *Pharmaceuticals (Basel).* 2022 Aug 13;15(8):997.
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  49. Guerzoni S, Baraldi C, Pani L. The association between onabotulinumtoxinA and anti-CGRP monoclonal antibodies: a reliable option for the optimal treatment of chronic migraine. *Neurol Sci.* 2022 Sep;43(9):5687-5695. doi: 10.1007/s10072-022-06195-5.
  50. Persico AM, Ricciardello A, Alessandrini S, Viola L, Bergonzini P, Iughetti L, Pani L.

- Depression and Catatonia Associated With Lansoprazole in an Adolescent With Phelan-McDermid Syndrome: A Case Report. *J Clin Psychopharmacol*. 2022 May 13. doi: 10.1097/JCP.0000000000001555. Online ahead of print. PMID: 35551397
51. Guerzoni S, Baraldi C, Pensato U, Favoni V, Lo Castro F, Cainazzo MM, Cevoli S, Pani L. Chronic migraine evolution after 3 months from erenumab suspension: real-world-evidence-life data. *Neurol Sci*. 2022 Jan 11; doi: 10.1007/s10072-022-05870-x. [Epub ahead of print] PubMed PMID: 35015202.
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#### 18. Books and Monographs Published:

##### **Chapters in Books:**

1) Rossetti Z.L.; Pani L.; Portas C.; Carboni S.; Gessa G.L.

Evidence for D2-dopamine receptors modulating noradrenaline release in the rat frontal cortex in *The Basal Ganglia III*,  
Bernardi et al. Eds., 1990

2) Tondo L; Pani PP; Pani L; Carcassi L; Manconi PE; Rudas N.

T-Lymphocyte in depression in: *The modes of depression: from psychobiology to psychodynamics.* Ravizza, Genazzani,  
Torta and Eva eds. Cortina. Torino, 1990

3) Costa E., Cheney D.L., Grayson D.R., Korneyev A., Longone P., Pani L., Romeo E., Zivkovich E., Guidotti A.

Pharmacology of Neurosteroids Biosynthesis: Role of the Mitochondrial DBI receptor (MDR) complex. In *Brain Corticosteroid Receptors: Studies on the Mechanism, Function, and Neurotoxicity of Corticosteroid Action.*

Vol. 746 of *The Annals of the New York Academy of Sciences*, 1994, 223-242

4) Serra G., Pani L., Collu M, Gessa G.L.

Ruolo delle Monoamine nella patogenesi dei disturbi dell'umore. In La depressione nel bambino e nell'adolescente.

G. Lanzi et al. (eds) 1994, 179-192

5) Koukopoulos A., Reginaldi D., Minnai G., Serra G., Pani L., Johnson FN

The Long Term Prophylaxis of Affective Disorders in Depression and Mania: from Neurobiology to Treatment,

Gessa GL, Fratta W., Pani L and Serra G. (eds), Raven Press, May 1995, 127-147

6) Gessa G.L., Pani L., Serra W., Fratta W

Animal Models of Mania in Depression and Mania: from Neurobiology to Treatment,

Gessa G.L., Fratta W., Pani L and Serra G. (eds), Raven Press, May 1995, 43-67

7) Gessa G.L., Serra G., Pani L.

Biochimica della Distimia: il ruolo della dopamina

Nuova Rivista di Neurologia, Suppl Vol. 5, 10-18 (1995)

8) Pani L., Gessa G.L.

The role of dopamine in the biological basis of dysthymia in Dysthymia in neurological disorders,

Proceedings of the WHO Meeting, J. Licinio; L. Prilipko and C.L. Bolis (eds), WHO Geneva, Switzerland, 1997.

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Stress and the dopaminergic System in Stress and the nervous system, Proceedings of the WHO Meeting,

J. Licinio and C.L. Bolis (eds), WHO Athens, Greece, 1998.

10) Serra G., Pani L., Gessa G.L.

Clozapina Enciclopedia Medica Italiana, Agg. II, Tomo I, 1284-1288, 1998

11) Pani L., Porcella A. and Gessa G.L.

Dysthymia: Psychosocial Aspects. in Dysthymia in Public Health, Proceedings of the Joint WHO/AIREN Meeting,

J. Licinio and C.L. Bolis (eds), WHO Geneva, Switzerland, 1999.

12) Pani L., Porcella A, Gessa G.L.

Hypothesis testing: dopaminergic system, environmental pressure and evolutionary mismatch, in Dopaminergic System: Evolution from Biology to Clinical Aspects,

Bolis CL, Pani L and Licinio J. (eds) Lippincott Williams & Wilkins Healthcare, Philadelphia, 2001

13) Gessa G.L., Pani L, Devoto P

Is dopamine in the prefrontal cortex released from noradrenergic neurons? in

Dopaminergic System: Evolution from Biology to Clinical Aspects, Bolis CL, Pani L and Licinio J. (eds)

Lippincott Williams & Wilkins Healthcare, Philadelphia, 2001

14) Pani L, Biggio G

Effetti collaterali delle benzodiazepine in Benzodiazepine dalle molecole alla pratica clinica,

Biggio G, (ed), Springer-Verlaag Italia, Milano 2001

15) Canali S, De Anna G, Pani L

Evolutionary Psychopharmacology mental disorders and ethical behaviour in:

Evolutionary ethics and contemporary Biology, Boniolo G, (ed) Cambridge University Press Cambridge, 2006

16) Pani L, Saba L

Farmacogenetica degli Antipsicotici in:

Trattato Italiano di Psichiatria, Cassano GB (ed), Masson-Elsevier, Milano 2008

17) Salloum IM, Pani L, Cooke T

Management of Comorbidity in Bipolar Disorder in:

Bipolar Disorder: Clinical and Neurobiological Foundations, Edited by Lakshmi N. Yatham and Mario Maj, John Wiley & Sons, 2010

18) Pani L,

La fine Anatomia di un Asperger o, anzi, due: Santiago Felipe Ramón y Cayal in:

Sei personaggi in cerca di Autismi (a cura di Paolo Cornaglia Ferraris)

Edizioni LSWR, 2018

## **b) Books:**

1) Gian Luigi Gessa e Luca Pani

Il ruolo della dopamina nei disturbi depressivi Parte Prima: Neurobiologia della Distimia: il ruolo della dopamina.

Mediserve Milano, 1998 (I edizione)

2) Luca Pani e Gian Luigi Gessa

Il ruolo della dopamina nei disturbi depressivi Parte Seconda Distimia: diagnosi e trattamento.

Mediserve Milano, 1998 (I edizione)

3) Gian Luigi Gessa e Luca Pani

Il ruolo della dopamina nei disturbi depressivi. Volume Unico

Mediserve Milano, 1999 (II edizione)

4) Gerardo Medea e Luca Pani

I Disturbi depressivi in Medicina Generale. Diagnosi e Gestione

UTET Periodici Milano, 2000

5) Luca Pani

La Biochimica del Cervello

Masson, Milano 2001

6) Stefano Canali e Luca Pani

Emozioni e malattia. Dall'evoluzione biologica al tramonto del pensiero psicosomatico

Paravia Bruno Mondadori Editori, Milano 2003

7) Luca Pani

Distimia: dal temperamento alla malattia

Masson, Milano 2004

8) Luca Pani

La Rivoluzione di Paul Janssen

Cinquant'anni di Terapia della Schizofrenia: dall'aloiperidolo al paliperidone

Elsevier, Milano 2009

9) Luca Pani

Le Carte di Ephedra.

Kalb Editore, Cagliari, Italy 2006 (168 pp.)

10) Pani L., Martinez F.

Prove di Volo: Manuale di Psiconautica Elementare.

Edra, Milano, MILANO, October 2015

11) Pani L., Corbellini

Imperfezioni Umane

Rubbettino, Cosenza, October 2015

12) Pani L.

L'innovazione sostenibile

Edra, Milano, MILANO, January 2016

13) Pani L.

Sustainable Innovation

Edra, Milano, MILANO, June 2016

15) Pani L., (dipinti di Martinez F.)

Prove di Volo II: Manuale di Psiconautica Normale.

Edra, Milano, MILANO, October 2016

16) Pani L.,

Lo strano caso Avastin-Lucentis. Perché tutti vogliono delle Agenzie Regolatorie indipendenti che però quasi nessuno può permettersi?

Edra, Milano, MILANO, July 2017

17) Pani L.,

The strange case of Avastin-Lucentis. Why everybody wants independent Regulatory Agencies that almost nobody can handle?

Edra, Milano, MILANO, September 2017

18) Pani L., Corbellini G.

Prescrivere Valore. Storia e Scienza dei Farmaci che ci fanno vivere piu' a lungo e meglio.

Edra, Milano, MILANO, September 2017

19) Pani L., (dipinti di Mulas PG.)

Buddha non è un bar: Psiconautica Nuda

Edra, Milano, MILANO, October 2017

20) Pani L.

Resilienza Farmaceutica

Edra, Milano, MILANO, December 2017

21) Pani L.

Pharmaceutical Resilience

Edra, Milano, MILANO, March 2018

22) Pani L. (dipinti di Mulas PG.)

E Adesso Spogliati. Tecniche di spogliarello mentale. I pensieri da buttare e quelli da tenere

Edra, Milano, MILANO, November 2019

23) Mantua V., Pani L.

Guida all'Uso dei Farmaci in Psichiatria

Edra Milano, MILANO, December 2019

24) Pani L., Capitanio ME

Effetto Quarentena: Chi siamo e Cosa saremo Nella Stagione del Covid-19

Edra Milano, MILANO, May 2020

25) Cammarata S., Pani L.

Elementi di Scienze Regolatorie del Farmaco,

Edra Milano, April 2022

26) Pani L. (dipinti di Mulas PG.)

Pandenostrum. Psiconautica Virale

Edra, Milano, MILANO, January 2023

19. Juried or Refereed Journal Articles or Exhibitions: -

20. Other Works, Publications and Abstracts:

Over 150 articles on the most prominent Italian Newspaper and Specialty Magazines requested by the Newspaper director on issues related to Mental Disorders, Evolutionary Mismatch, Digital Medicine and Health or Academic Policies

Starting with 1994, invited to give CME presentation in more than 1200 Conferences, Seminars, Expert Opinion, Round Tables etc. I have been a Member of Educational /

Editorial Strategic Boards: not product specific until 2016 and sometime product specific afterwards and open to delegates primarily health care professionals and organized through a provider of medical education to pharmaceutical companies

I have been a Speaker in Medical Education Events: such events were not all product specific, open to all delegates (healthcare professionals), without restriction, and focused on psychopharmacology (animal models, relationship between PK profiles and clinical impact). I was involved as a paid speaker in some of these events, and in most cases the participation was together with other experts in the field. A list of the most recent can be provided upon request

21. Other Works Accepted for Publication: -

## V. Professional

22. Funded Research Awarded: IMI2 - Call 23 Call ID: H2020-JTI-IMI2-2020-23-two-stage Action Type: RIA – Research and Innovation Actions [Topic 1: Returning clinical trial data to study participants within a GDPR compliant and approved ethical framework](#). Luca Pani European Coordinator (6.6 M Euro total budget) 2022-2025

23. Editorial Responsibilities:

2017-present Chief Editor of [PharmAdvances](#) the Journal of Italian Society for Pharmacology

2017-present Chief Scientific Officer of Edra Publishing Company (<http://www.edraspa.com/>) which publishes more than 50% of all the medical texts in Italy and has a catalog of hundreds of scientific titles which I supervise and/or counsel about.

1993-2003 I have founded, launched and co-directed with PP Pani and GL Gessa, The Italian Journal of the Addictions ([www.medicinatossicodipendenze.it](http://www.medicinatossicodipendenze.it)) and I have selected, judged and edited the articles of the Journal over a decade.

24. Professional and Honorary Organizations:

2024- 2026 President, International Society for Clinical Trials Managements, USA

2022- 2024 President Elect, International Society for Clinical Trials Managements, USA

2021- Fellow Royal Society of Medicine (London)

2018-Present Member Italian Society of Pharmacology

2015-Present Member and Executive Committee Member (since 2018) of ISCTM | The International Society for CNS Clinical Trials and Methodology

2016-Present Conference Steering Committee Member | American Society of Clinical Psychopharmacology (ASCP)

2017-Present ECNP New Frontiers Meeting programme Committee Member

2009-2012 Scientific Advisor of the Psychotic Disorders and Antipsychotic Panel of the European College of Neuropsychopharmacology (ECNP).

1990-present Italian Society of Pharmacology;

1990-2010 Italian Society of Psychopathology;

1995-2010 Italian Society of Psychiatry.

25. Honors and Awards:

2021- Gelfand Lecture US National Invitation Phi Delta Epsilon Medical Fraternity

2019- IBDO Award – Galileo Galilei Medal, IBDO Foundation, Rome, Italy

2014- Eurordis Prize for Innovation, Brussel, Belgium

1994-1996-1998 Platano d'Oro: Italian National Medical Writing Prize, Finalist in all the first three editions of the prize, Cagliari, Italy

1990-1991 Fidia Research Foundation International Fellowship in Neuroscience, Washington DC, USA

26. Post-Doctoral Fellowships:

1990-1992 Post-Doctoral Fellow in Molecular Biology University of Illinois at Chicago, USA

27. Other Professional Activities:

I am one of the inventors (I do not have ownership) of two new U.S. and one E.C. Patents namely:

US2010029622A1 on Microemulsion

US2010028257A1 on Novel Omepiperazines Opioids

EP2223681A1 on Composition of spores of non pathogenic bacteria

## VI. Teaching

2018- present Pharmacology and Clinical Pharmacology – Full Course for Medical School Students and Residents – University of Modena and Reggio Emilia – Italy

2017- present Clinical Psychiatry and Psychopharmacology – I and III year Medical Students and MD, MPH Curriculum – PGY 1-4 Residents in Psychiatry – University of Miami – School of Medicine

1994-2017 I have taught for over two decades both specialty psychopharmacology and clinical psychiatry to the medical resident program and medical school students both in Italy and USA. Since 1994, I have held as supervisor, organizer, chairperson and speaker for hundreds of CME courses and conferences worldwide.

28. Teaching Awards Received:

2021- Gelfand Prize US National Phi Delta Epsilon Medical Fraternity

29. Teaching Specialization:

Clinical Psychiatry - Psychopharmacology – Regulatory and Market Access - Digital Medicine

30. Thesis and Dissertation Advising/Post-doctoral Student Supervision:

I have been mentor and/or advisor for several dissertation and post-doctoral thesis in the Medicine or Pharmacy Faculty in Italy.

## VII. Service

31. University Committee and Administrative Responsibilities:

From 2010 I joined the top worldwide regulatory community in the field of Medicines at the European Medicines Agency (EMA) in London. I served from 2011 to 2016 as Director General of

the Italian Medicine Agency (AIFA) – a ranking somewhat equivalent to a Deputy Minister of Health - responsible for the country's approval and reimbursement of human therapeutically active products for an equivalent of almost 30 billion Euro per year. Under my guidance AIFA implemented the first Conflict of Interest regulation and won (for four years in a row) the Italian Government prize for the most transparent public administration in Italy. I have supervised and managed a work force of over 400 specialists and succeeded in obtaining Italian Parliament's approval to increase AIFA's staff to 630 personnel. As Chair of important EMA's Committees and Working Parties I have coordinated the execution of the European pharmacovigilance directive and the multiannual working plan in the telematics strategy of the European Medicines Agency for the benefit of the entire national competent authorities' network.

In the previous 15 years I have supervised and followed to successful completion several project and research grants both at regional, national and international level. I have worked on all major molecular biology techniques with respect to gene expression; General and Molecular Pharmacology; Brain Microdialysis and Animal models; and I possess advanced Clinical Skills in Psychiatry.

I have also managed large organization with groups up to 400 individuals with multiple competences and have been personally interacting both at the national and international level with Government, Patients Organization, Health Care Providers Professionals, Charities, Payers and Industry.

## 32. Active Grants:

A) European Commission IMI-2 TOPIC ID: IMI2-2020-23-01 Returning Clinical Trial Data to study participants within a GDPR compliant and approved ethical framework

**COORDINATOR:** Luca Pani University of Modena and Reggio Emilia, Modena, ITALY. Chief Operation Coordinator: Johanna Blom University of Modena and Reggio Emilia, Modena, ITALY

**TITLE:** FACILITATE (FrAmework for Clinlcal trial participants' daTa reutilizAtion for a fully Transparent and Ethical ecosystem)

**DURATION:** 4 years, Awarded May 31<sup>st</sup>, 2021 – Start Date from Jan 1<sup>st</sup>, 2022 to end date Dec., 31<sup>st</sup> 2025

**PARTNERS:** 27, of which 20 UE (Italia, Austria, Belgium, Finland, France, Germany, Netherlands, Cech Republic, Poland, Romania, Spain, Sweden) e 7 extra-UE (Serbia, Switzerland, USA, UK)

Public/private: 18 partners, of which 4 Universities/Research Centers, 6 Hospital Centers, 3 citizens/patients representatives, 5 for profit companies

Industry: 9 EFPIA members, of which 8 Pharma, 1 Service/Technology provider

**BUDGET:** € 3.260.000 EU contribution + € 3.363.904 In-kind = € 6.623.904

**BOARDS:** 3 Decision Experts Committees: Patient Associations, Ethical committees, Data protection authorities, National Medicine/Drug Regulators, Healthcare professionals, Researchers, Geneticists

B) Italian Ministry of Research and Education

**COORDINATOR:** Luca Pani University of Modena and Reggio Emilia, Modena, ITALY.

Dipartimento di Scienze Biomediche, Metaboliche e Neuroscienze

**Type of project** PRIN – Bando 2022 Scienze della vita (LS5) Codice identificativo del bando e del progetto DD n. 104 del 02-02-2022

**TITLE** The adolescent window of vulnerability for migraine: investigating the role of serotonin to #stopthepain in young rodents and (wo)men

**DURATION:** 24 months (2024-2026)

**TOTAL BUDGET:** € 194.980; UNIMORE = € 109.980

Date: June 20, 2026

Signature: \_\_\_\_\_