

Curriculum Vitae

Personal information Anna Chioti

Work experience

Aug 2019 - Present

Head of Division Pharmacy and Medicines

Luxembourg Health Directorate - Direction de la santé (https://sante.public.lu/)

• Leading the scientific, technical and regulatory activities aiming to advise the Ministry of Health to fulfil its NCA obligations for human and veterinary medicines as well as other health products, including medical devices, IVD, cosmetics and medicinal cannabis.

Business or sector Government administration / Healthcare

Mar 2018 - Present

MD in charge of the development of the Luxembourg Agency for Medicines and Health **Products**

Luxembourg Health Directorate - Direction de la santé (https://sante.public.lu/)

• Piloting the set-up of a new public administration that will act as the NCA for medicines and health products in Luxembourg.

Mar 2022 - Present

Business or sector Government administration / Healthcare

Science & Innovation Panel Member & Chairperson Innovative Health Initiative (IHI) (www.ihi.europa.eu/)

• The Science and Innovation Panel (SIP) provides the Governing Board with advice on matters relevant to IHI's research and innovation activities.

Jan 2022 - Present

Business or sector Public-private partnership (PPP) / Research

Founding Board Member

EUPATI

- EUPATI Luxembourg is a platform that brings together patients, the academic world, the pharmaceutical industry and all other persons interested in the objectives of EUPATI.
- This platform aims to enable patients to better understand the world of biomedical research, the world of drug research and development and the functioning of the Luxembourg health system. The objective of EUPATI Luxembourg is to raise awareness and train patients so that they become active players in biomedical research and in the Luxembourg health system.
- Another role of EUPATI Luxembourg is to facilitate communication between patients, researchers, healthcare professionals and the Luxembourg health-

www.ema.europa.eu

related authorities.

Business or sector NGO / non-profit

Oct 2016 – Dec 2021 Scientific Committee Member

Innovative Medicines Initiative (IMI) (www.imi.europa.eu)

 The Scientific Committee gives strategic science-based recommendations to IMI and advises on the continued relevance of the Strategic Research Agenda and the scientific priorities, which are the basis for the Call Topics.

Business or sector Public-private partnership (PPP) / Research

Nov 2017 - Present President, Founding Board Member

Luxembourg Public Health Association (LUXPHA)

 Guiding the set-up of the scientific association, which aims at bringing together researchers, health professionals and officials in the field of public health.

Business or sector Non-profit organization / Public Health / Research

Dec 2014 – Present Associate Editor

EPMA Journal (https://www.springer.com/journal/13167)

Feb 2019 – Aug 2019 Associate Head of Division of Pharmacy and

Medicines

Luxembourg Health Directorate - Direction de la santé ($\underline{\text{https://sante.public.lu/}})$

Business or sector Government administration / Healthcare

Jan 2012 – Oct 2018 Board Member

EFGCP -- European Forum for Good Clinical Practice ($\underline{https://efgcp.eu/})$

 EFGCP enables partnership between patients, researchers and other healthcare stakeholders to ensure ethical awareness as well as research integrity in health research and facilitates transparent implementation of preventive health measures & treatments.

Business or sector Not-for-profit organisation / Health / Research Ethics

Aug 2017 – Feb 2018 Associate Director, Department of Population Health

Luxembourg Institute of Health (https://www.lih.lu/)

Business or sector Public Research Institute

Nov 2016 – Feb 2018 Executive Board Member

EuroHealthNet (https://eurohealthnet.eu/)

 Addressing the social determinants of health to help build fairer, healthier, and more sustainable communities for all.

Business or sector Not-for-profit organisation / Public Health

Dec 2016 – Jan 2018 Board Member

Luxembourg Agency for Research Integrity (LARI) ($\underline{\text{https://lari.lu/}})$

 Contributed to set up the national agency promoting and investigating research integrity in Luxembourg.

Business or sector Not-for-profit organisation / Research

Jan 2016 – Jan 2018 Editorial board member

International Journal of Clinical Research & Trials

Sep 2016 – Aug 2017 Director of Population Health Department (ad int.)

Luxembourg Institute of Health (https://www.lih.lu/)

Business or sector Public Research Institute

Mar 2015 – Sep 2016 Director of Operations, Department of Population

Health

Luxembourg Institute of Health (https://www.lih.lu/)

Business or sector Public Research Institute

Sep 2010 – Sep 2016 Member of Scientific Council

Centre François Baclesse - CHEM (https://www.baclesse.lu/)

 Providing scientific guidance on questions relating to the medical orientation of the Center, the engagement of doctors, relations between doctors, medical ethics and the monitoring and evaluation of medical practices, care and other forms of care.

Business or sector Hospital / Radiotherapy

Apr 2010 – Sep 2016 Head of the Clinical Investigation and Epidemiological Center (CIEC)

Luxembourg Institute of Health (https://www.lih.lu/)

- Assist and support clinical research projects by setting up a network of partnerships and bringing together key players in the scientific community: medical doctors, researchers, healthcare professionals, hospitals, pharmaceutical industry and universities.
- Ensure the clinical expertise for the development of innovative therapeutic and diagnostic procedures at a national level, in the Greater Region and at a European and international level.

Business or sector Public Research Institute

Dec 2014 – Mar 2016 Co-Chair Medical technology Working Party

EFGCP -- European Forum for Good Clinical Practice (https://efgcp.eu/)

Business or sector Not-for-profit organisation / Health / Research Ethics

May 2012 – Dec 2015 Chair of Network Committee

ECRIN (European Clinical Research Infrastructure Network)

 Contributed to build a consistent organisation for clinical research in Europe, providing generic tools and services to multinational studies, and supporting the construction of pan-European disease-oriented networks (e.g. WP2 expansion, capacity building and funding).

Business or sector Not-for-profit organisation / Clinical trials

Feb 2013 – Oct 2014 Advisory Board Member

European Society for Translational Medicine (EUSTM) (https://eutranslationalmedicine.org/)

Business or sector Not-for-profit organisation / R&D

Sep 2008 – Apr 2010 Therapeutic Area Leader Oncology & Hospital Care

AstraZeneca (https://www.astrazeneca.com/)

- Manages the Therapeutic Area Unit in order to perform the studies in a reliable, productive and cost effective way. Selects, proposes, and develops relevant international & local clinical studies, based on scientific, strategic and commercial criteria.
- Builds and maintains visibility and excellent long-term professional relationships with universities, opinion leaders and key investigators. Provides high-quality medical advice and assistance to other departments (Marketing, Sales, and Public Affairs).

Business or sector Pharmaceutical industry

Dec 2006 - Sep 2008

Therapeutic Area Leader Oncology

AstraZeneca (https://www.astrazeneca.com/)

- Manages the Therapeutic Area Unit in order to perform the studies in a reliable, productive and cost effective way. Selects, proposes, and develops relevant international & local clinical studies, based on scientific, strategic and commercial criteria.
- Builds and maintains visibility and excellent long-term professional relationships with universities, opinion leaders and key investigators. Provides high-quality medical advice and assistance to other departments (Marketing, Sales, and Public Affairs).

Business or sector Pharmaceutical industry

Jul 2003 - Nov 2006

Medical Manager Cardio-Metabolic Diseases

Merck Sharp & Dohme (MSD) (https://www.msd.com/)

- Actively create and maintain relationships with major national and international opinion leaders.
- Contribute to achieve the approved profit plan for the cardiovascular portfolio products through scientific support in the development of Marketing Strategy and Marketing Plan.
- Contribute to product and disease-related knowledge of Sales Forces. Ensure medical support on the cardiovascular portfolio products to internal and external customers.

Business or sector Pharmaceutical industry

Jan 2003 - Jul 2003

Product Medical Manager CV & NSAIDs

Innovex (former Quintiles Innovex and currently IQVIA: https://www.iqvia.com/)

- Develop and execute marketing programs for CV & NSAIDs products portfolio.
- Ensure disease-related and product knowledge for Sales Forces
- Coordinate activities in production, sales, advertising, promotion, marketing research, purchasing, distribution, package development, and finance.

Business or sector Pharmaceutical industry

Oct 1999 - Jan 2003

General Practitioner, MD

Self-employed / Private clinic / Hospital Business or sector Healthcare professional

Education and training

Q2 2023 Strategy Execution for Public Leadership

Harvard University

Q3 2022

02 2022	Benefit-Cost Analysis: Valuing Life and Health Harvard T.H. Chan School of Public Health Center for
Q3 2022	Executive and Continuing Professional Education
Q2 2022	Neuroscience for Business MIT Sloan School of Management
Q2 2021	Big Data for Social Good Harvard Business School Online
	Driving Health Care Strategy: Business Insights from Inside the Ecosystem Harvard Medical School
Oct 2020	Inquiry-Driven Leadership MIT Sloan School of Management
Q3 – Q4	HMX Fundamentals/Pro online certificate program: Immunology - Immuno-oncology, Medicine Harvard Medical School
Q3 – Q4 2020	HMX Fundamentals/Pro online certificate program: Genetics - Cancer Genomics, Medicine
	Harvard Medical School
Q3 – Q4 2020	HMX Fundamentals/Pro online certificate program: Genetics - Essentials, Medicine Harvard Medical School
Q3 – Q4 2020	HMX Fundamentals/Pro online certificate program: Pharmacology - Essentials, Medicine Harvard Medical School
Sept 2018 – Sept 2020	Master of Business Administration - MBA
2020	Luxembourg School of Business • Leadership and general management
Q1 – Q2 2019	Artificial Intelligence: Implications for Business Strategy MIT Sloan Executive Education
2000 - 2002	Public Health Specialisation Diploma (MSc) Université Catholique de Louvain, Belgium
1990 - 1999	MD + Specialisation GP, Faculty of Medicine Université Catholique de Louvain, Belgium

Additional information

Publications

• Vahid F, Hoge A, Hébert JR, Bohn T; ORISCAV working group*.. Association of diet quality indices with serum and metabolic biomarkers in participants of the ORISCAV-

- $LUX-2\ study\ [published\ online\ ahead\ of\ print,\ 2023\ Mar\ 14].\ Eur\ J\ Nutr.\\ 2023; 10.1007/s00394-023-03095-y.\ doi:10.1007/s00394-023-03095-y$
- Collings PJ, Backes A, Aguayo GA, Malisoux L; ORISCAV-LUX study group. Device-measured physical activity and sedentary time in a national sample of Luxembourg residents: the ORISCAV-LUX 2 study. Int J Behav Nutr Phys Act. 2022;19(1):161. Published 2022 Dec 29. doi:10.1186/s12966-022-01380-3
- Backes A, Aguayo GA, Collings PJ, et al. Associations Between Wearable-Specific Indicators of Physical Activity Behaviour and Insulin Sensitivity and Glycated Haemoglobin in the General Population: Results from the ORISCAV-LUX 2 Study. Sports Med Open. 2022;8(1):146. Published 2022 Dec 12. doi:10.1186/s40798-022-00541-9
- Metabolically healthy and unhealthy weight statuses, health issues and related costs: Findings from the 2013-2015 European Health Examination Survey in Luxembourg. H Samouda, M Ruiz-Castell, M Karimi, V Bocquet, A Kuemmerle, A Chioti, F Dadoun, S Stranges. Diabetes Metab. 2019 Apr;45(2):140-151.
- Challenges and benefits of integrating diverse sampling strategies in the observation of cardiovascular risk factors (ORISCAV-LUX 2) study. A Alkerwi, J Pastore, N Sauvageot, G Le Coroller, V Bocquet, M d'Incau, G Aguayo, B Appenzeller, D Bejko, T Bohn, L Malisoux, S Couffignal, S Noppe, C Delagardelle, J Beissel, A Chioti, S Stranges, J-C Schmit. BMC Med Res Methodol. 2019 Feb 4; 19(1):27.
- Comparative analysis of the association between 35 frailty scores and cardiovascular events, cancer, and total mortality in an elderly general population in England: An observational study. GA Aguayo, MT Vaillant, A-F Donneau, A Schritz, S Stranges, L Malisoux, A Chioti, M Guillaume, M Muller, D R Witte. PLoS Med 2018 Mar 27;15(3): e1002543.
- Geographical variation of overweight, obesity and related risk factors: Findings from the European Health Examination Survey in Luxembourg, 2013-2015. Samouda H, Ruiz-Castell M, Bocquet V, Kuemmerle A, Chioti A, Dadoun F, Kandala NB, Stranges S. PLoS One. 2018 Jun 14;13(6): e0197021.
- Comparative analysis of the association between 35 frailty scores and cardiovascular events, cancer, and total mortality in an elderly general population in England: An observational study. Aguayo GA, Vaillant MT, Donneau AF, Schritz A, Stranges S, Malisoux L, Chioti A, Guillaume M, Muller M, Witte DR. PLoS Med. 2018 Mar 27;15(3):e1002543.
- Metabolically healthy and unhealthy weight statuses, health issues and related costs:
 Findings from the 2013-2015 European Health Examination Survey in Luxembourg.
 Samouda H, Ruiz-Castell M, Karimi M, Bocquet V, Kuemmerle A, Chioti A, Dadoun F,
 Stranges S. Diabetes Metab. 2017 Dec 1. pii: S1262-3636(17)30581-5.
- 1986-2016: 30 years of pregnancy outcomes surveillance in HIV-Positive women in Luxembourg. A Fischer, V Etienne, JC Schmit, V Arendt, T Staub, R Hemmer, C Michaux, M Gantenbein, A Chioti. European Journal of Public Health, Volume 26, Issue suppl_1, 1 November 2016.
- Advice on lifestyle changes (diet, red wine and physical activity) does not affect internal carotid and middle cerebral artery blood flow velocity in patients with carotid arteriosclerosis in a randomised controlled trial. Droste DW, Iliescu C, Vaillant M, Gantenbein M, De Bremaeker N, Lieunard C, Velez T, Meyer M, Guth T, Kuemmerle A, Chioti A. Cerebrovasc Dis 2014; 37:368–375.
- A daily glass of red wine associated with lifestyle changes independently improves blood lipids in patients with carotid arteriosclerosis: results from a randomized controlled trial.
 Droste DW, Iliescu C, Vaillant M, Gantenbein M, De BN, Lieunard C, Velez T, Meyer M, Guth T, Kuemmerle A, Gilson G, Chioti A. Nutr J 2013; 12:147-155.
- A Daily Glass of Red Wine and Lifestyle Changes Do Not Affect Arterial Blood Pressure
 and Heart Rate in Patients with Carotid Arteriosclerosis after 4 and 20 Weeks. Droste
 DW, Iliescu C, Vaillant M, Gantenbein M, De Bremaeker N, Lieunard C, Velez T, Meyer
 M, Guth T, Kuemmerle A, Chioti A. Cerebrovascular Diseases Extra 2013; 3:121-129.
- Lifestyle counseling in patients with carotid arteriosclerosis from Luxemburg should focus more on the reduction of sugar, sodium and saturated fat consumption Droste DW, Iliescu C, Vaillant M, Gantenbein M, De Bremaeker N, Lieunard C, Velez T, Meyer M, Guth T, Kuemmerle A, Chioti A. Bull Soc Sci Med Grand Duche Luxemb. 2013; (1):2838.

- Prevalence and treatment of anaemia in cancer patients in Luxembourg. Gantenbein M,
 Untereiner M, Chioti A, Rauh S, Berchem G, Jacob F, Plawny L, Dewilde S, Burie D,
 Frederick B. Poster Presentation at the 26th General Meeting of the Belgian
 Hematological Society, Liège, January 28-29, 2011.
- The Cariatide study: evaluation of the impact of educational material on the compliance and persistence rates to adjuvant aromatase inhibitor medication in postmenopausal breast cancer patients: baseline data. Neven P., Tanner M., Kreienberg R., Atkins L., Marty M., Chioti A., Markopoulos C. EJC Supplements 2010; 8 (3): 78.

Projects

- 15+ years of experience in clinical trials including operations and drug development (oncology, CNS, CV, diabetes, including diverse health registries,...); developed the Clinical and Epidemiological Investigation Center of the Luxembourg Institute of Health, along with advising on the research agendas of the institution: contribution to scientific position papers for Ministry of Higher Education and Research (research agendas), National research Fund (funding schemes), Ministry of Health (technical & regulatory) and Ministry of Economy (SMEs and innovation)
- Scientific Committee Member for the Innovative Medicines Initiative (Oct 2016
 Dec 2021)
- European Commission expert (EX2016D289244): 13 participations since August 2017 (H2020 IMI, H2020 Twinning and HADEA)
- EU COST external expert, European Cooperation in Science and Technology (since 2015)
- Advisor for Luxinnovation Fit4 Start Program in Luxembourg (2018 2020)
- Scientific & regulatory advisor for the Luxembourg National Plan on Rare Diseases (since 2017)
- Luxembourg National Cancer research strategy peer-review coordinator and rapporteur (since 2016)
- Health Research Board Ireland: panel review member (2011); panel review chair (2020)
- Luxembourg National Radiotherapy Centre: set-up of morbi-mortality registry + reviewer (2010- 2016)
- Evaluator of research awards: Luxembourg Healthcare Summit & Centre Hospitalier Luxembourg/LIH (2016)
- Regular reviewer for strategy papers for Luxembourg research institutions and University (latest work on Digital therapeutics and diagnostics)

Memberships

- European Clinical Research Infrastructures Network: Chair of network committee & ethics reviewer (2011 to 2015)
- European Forum for Good Clinical Practice: board member (2012-2018); cochair of position paper in medical technology (2015)
- Member of the working group on Dual-Career Solutions Programme, within the Gender Action Plan led by the University of Luxembourg; draft and review of position paper on dual careers (2016)
- Luxembourg Agency for Research Integrity (National Research Fund & LIH): founding member; draft and review scientific misconduct procedures
- International Consortium for Personalised Medicine (IC PerMed) Interim
 Executive Committee Member, in the challenge group dedicated to Shaping
 Sustainable Healthcare => role during EU Presidency of Luxembourg in 2015
- Advisory Board Member European Society for Translational Medicine (EUSTM)(2013-2014)
- Founding Board Member, Luxembourg Public Health Association (LUXPHA) (2017)

• Founding Board Member, EUPATI Luxembourg (2021)

Within current position: involvement in national advisory bodies (Social Security, Customs, Veterinary Services, National security, ...) and European and international instances (EMA, HMA, Beneluxa, IHSI, INCB, OECD, WHO,...).

Participated and collaborated in EU FP7, H2020 funded projects and COST actions, as well as projects funded through ECRIN, BBMRI, and EATRIS. In my role at LIH, I have assisted researchers in applying for funding on several occasions.

Other Relevant Information

Provided external regulatory advise and expertise to Luxembourg Ministry of Health since 2010:

- 2010 2012: alignment of EU and national clinical research regulations; development of quality manuals and GCP trainings
- 2011 2012: biomedical research regulation and disease/patient registries
- 2012: medicines agency concept paper
- 2014: pharmacovigilance (national implementation of EU regulation and development of PV training)
- 2015: medical devices; personalized medicine (programme of Luxembourg EU semester)
- 2015 2016 : regulatory procedures related to orphan medicines, compassionate use, medical need programs and off-label use
- 2017: inter-ministerial working group on implementation of GDPR in Luxembourg (related to Recital 54 - Processing of Sensitive Data in Public Health Sector)
- 2017 2018: led the GMP inspections quality framework leading to Luxembourg being recognized as capable by US FDA in June 2019 within the EU-US FDA mutual recognition of inspections of medicines manufacturers

Joined the Directorate of Health (Ministry of Health) in March 2018: leading the transformation of the current National Competent Authority (from Division of Pharmacy and Medicines to Luxembourg Agency for Medicines and Health Products) with a focus on the following strategic pillars: 1) Supporting the innovation ecosystem; 2) Shaping regulatory science; and 3) Creating smart HTA.

Internal regulatory expertise since 2018 in various areas: medicines lifecycle, medical devices, ATMPs, narcotics, medicinal cannabis, regulatory framework for borderline products, market access and market surveillance, pharmacovigilance, national implementation of Falsified Medicines Directive and relevant EU regulations (MDR, IVDR, CTR, NVR).

Since March 2020: regulatory advice on issues raised by COVID (national derogations, special authorizations, early access schemes related to the procurement and distribution of medical countermeasures, medicines and vaccines).

Monthly publications on regulatory matters for healthcare professionals since September 2019.