

MIRA HLEYHEL

PhD Epidemiology | PharmD

Founder & Research Director, Evidascience LLC

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PROFILE

PharmD and PhD epidemiologist with over ten years of experience spanning academic research, real-world evidence generation in the CRO industry, and independent scientific consulting. Founder and Research Director of Evidascience, combining rigorous epidemiological methodology with hands-on operational management of observational studies, from protocol design through to peer-reviewed publication and study reporting. Author of 25+ peer-reviewed publications, with proven expertise in study design, medical writing, biostatistics, and the coordination of multi-country research programs and stakeholder relationships.

CORE EXPERTISE

Epidemiology & RWE observational study design, protocol development, real-world evidence generation

Medical & Scientific Writing clinical study reports (CSR), protocols, manuscripts, abstracts, posters

Regulatory Support ethics submissions and clinical study reporting and evidence synthesis for regulatory deliverables

Biostatistics Statistical analysis planning, oversight of data analyses, data quality review and control, and interpretation of study findings

Study oversight end-to-end delivery on time and on budget, client and vendor relationship management

PROFESSIONAL EXPERIENCE

Founder & Research Director

June 2026 – Present

Evidascience LLC — Independent scientific consulting (epidemiology, medical writing, clinical research)

- Founded an independent consultancy delivering epidemiological expertise combined with operational project management to pharmaceutical, biotech, and CRO clients.
- Provide senior-level scientific leadership on observational research, real-world evidence, and medical writing.
- Engaged to draft a clinical study report (CSR), applying regulatory writing standards to observational study deliverables.

Real World Evidence Research Manager

June 2022 – May 2026

Oracle Life Sciences (formerly Cerner Enviza)

- Provided end-to-end oversight of observational and real-world evidence studies from inception through final reporting, ensuring adherence to timelines and budgets across multi-country programs.
- Provided methodological expertise on study design, contributed to statistical analysis plans, and oversaw data quality control and analysis.
- Authored and supervised delivery of protocols, study reports, peer-reviewed manuscripts, abstracts, and posters.
- Oversaw protocol implementation, ethics/regulatory submissions, data collection and study conduct to ensure compliance with company SOPs and applicable regulations with the support of regulatory departments.
- Led cross-functional study teams, coordinating sponsors, data collection vendors, statisticians, and other stakeholders to ensure timely study execution.
- Led sponsor communications, providing regular status updates and strategic recommendations.
- Selected and evaluated appropriate patient-reported outcome (PRO) measures based on study objectives, target population, and regulatory considerations.
- Interpreted PRO data and collaborated with multidisciplinary teams to ensure clinically meaningful integration of patient-centered endpoints into study design, analysis, and reporting.
- Liaised with PRO instrument copyright and licensing holders to obtain permissions, manage licensing agreements, and ensure compliant implementation of validated questionnaires across international studies.
- Conducted targeted literature reviews to identify evidence gaps, inform study design, and support the development of study materials, including protocols, questionnaires, and patient-facing documents.

- Synthesized published evidence to support endpoint selection, questionnaire development, eligibility criteria, and other methodological aspects of observational and real-world evidence studies.
- Supported the development of research proposals and study concepts for pharmaceutical and healthcare clients, including study design, methodology, feasibility assessments, timelines, and budget inputs.

Freelance Epidemiologist

2016 – 2022

Independent consultancy — concurrent with academic teaching

- Advised on the methodology, design, and implementation of observational research studies.
- Conducted statistical analyses (SAS) and interpreted findings for scientific communication.
- Developed manuscripts for submission to peer-reviewed journals.

Lecturer

2014 – Present

Institut Supérieur de Santé Publique, Saint Joseph University, Beirut (2021–present); Faculty of Public Health, Lebanese University, Fanar (2014–2022); Faculty of Health Sciences, University of Balamand, Beirut (2019–2021)

- Delivered courses in Epidemiology, Research Methods, Methodology of Clinical Trials, Biostatistics, and Public Health.
- Mentored Master of Public Health students on the design, conduct, analysis, and dissemination of their research projects.

Post-Doctoral Researcher

2014 – 2016

CESP INSERM U1018, Kremlin-Bicêtre, France

- Analyzed and interpreted data from the French Perinatal Cohort; conducted literature reviews.
- Developed scientific abstracts and manuscripts; presented at national and international conferences.

EDUCATION

PhD, Public Health: Epidemiology & Biomedical Information Sciences

2014

Pierre et Marie Curie – Sorbonne University, Paris

Diploma, Statistics, Clinical Research & Epidemiology (CESAM)

2012

Pierre et Marie Curie – Sorbonne University, Paris

Master's, Research Methods in Environment & Health

2011

Joseph Fourier University, Grenoble

Doctor of Pharmacy (PharmD)

2009

Lebanese University, Beirut

SCHOLARSHIPS & HONOURS

- Young Investigator Scholarship — Conference on Retroviruses and Opportunistic Infections (CROI), Boston.
- Predoc Scholarship Program, Grenoble.

SELECTED PUBLICATIONS

Author of 25+ peer-reviewed publications. Selected recent and senior author work below; full list available on [ORCID](#) / [Google Scholar](#).

1. Fiocchi A, Worm M, Wing-Kin Wong G, Mnif T, Reed S, **Hleyhel M**, Dritsa S, LeCalvé P, Moussallem A, Vincent B, Tassinari P, Marvel J, Gupta R. Prevalence of IgE-Mediated Food Allergies in Children and Adults: Results from the Multinational ASSESS FA Study. *J Allergy Clin Immunol Pract*. 2026 Apr 30:S2213-2198(26)00346-6.
2. Gupta R, Mnif T, Reed S, **Hleyhel M**, Dritsa S, LeCalvé P, Moussallem A, Tassinari P, Marvel J, Fiocchi A. Methodology of the international cross-sectional prevalence and severity study of pediatric and adult IgE-mediated food allergies (ASSESS FA). *World Allergy Organ J*. 2025 Aug 22;18(9):101105.
3. **Hleyhel M**, Popovici O, Leuştean M, et al. Prevalence of chronic hepatitis C infection in the general population: results from a national survey, Romania, 2020 to 2023. *Euro Surveill*. 2024;29(30):2300663.

4. **Hleyhel M**, Geller J, Sadou A, et al. Prevalence of chronic hepatitis C infection in the general population: results from a national survey, Estonia, July to December 2022. *Euro Surveill.* 2024;29(30):2300651.
5. El Khoury J, Saleh N, Lahoud N, Maison P, **Hleyhel M**. Compliance to international guidelines and rational use of antibiotics in urinary tract infections in a country without national guidance: a cross-sectional study. *BMJ Open Qual.* 2024;13(4):e003027.
6. Grabar S, **Hleyhel M**, Belot A, et al. Invasive cervical cancer in HIV-infected women: risk and survival relative to those of the general population in France (FHDH-ANRS CO4). *HIV Med.* 2019;20(3):222–229.
7. **Hleyhel M**, Goujon S, Sibiude J, et al. Risk of cancer in children exposed to antiretroviral nucleoside analogues in utero: the French experience. *Environ Mol Mutagen.* 2019;60(5):404–409.
8. **Hleyhel M**, Goujon S, Delteil C, et al. Risk of cancer in children exposed to didanosine in utero. *AIDS.* 2016;30(8):1245–1256.
9. **Hleyhel M**, Belot A, Bouvier AM, et al. Trends in survival after cancer diagnosis among HIV-infected individuals between 1992 and 2009 (FHDH-ANRS CO4). *Int J Cancer.* 2015;137(10):2443–2453.
10. **Hleyhel M**, Bouvier AM, Belot A, et al. Risk of non-AIDS-defining cancers among HIV-1-infected individuals in France between 1997 and 2009. *AIDS.* 2014;28(14):2109–2118.

SELECTED ORAL COMMUNICATIONS

- International Workshop on HIV Observational Databases (18th, Sitges, Spain; 17th, Cavtat, Croatia).
- Conférence internationale francophone sur le VIH et les hépatites, Montpellier, France (2014).
- 8ème Conférence Francophone d'Épidémiologie Clinique (EPICLIN), Bordeaux, France (2014).
- 11th International Congress on Drug Therapy in HIV Infection, Glasgow, United Kingdom.
- Lebanese Order of Pharmacists — 26th Annual Congress, Beirut, Lebanon (2018).

TECHNICAL & LANGUAGE SKILLS

Software: SAS, statistical analysis and data management tools

Languages: Arabic (native), French (fluent), English (fluent)