MIRA HLEYHEL

PhD Epidemiology | PharmD | Epidemiologist & RWE Consultant

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PROFESSIONAL PROFILE

PharmD and PhD epidemiologist with 10+ years of experience across real-world evidence (RWE), observational research, academic epidemiology and independent scientific consulting. Experienced in providing methodological and scientific leadership throughout the research lifecycle, from research question development and study design to protocol and statistical analysis plan development, oversight of analyses, interpretation, reporting and publication. At Oracle Life Sciences (formerly Cerner Enviza), provided end-to-end scientific and operational oversight of multi-country observational and RWE studies for pharmaceutical clients, working closely with sponsors, statisticians, vendors and multidisciplinary teams. Founder of Evidascience, providing flexible epidemiology, RWE and scientific writing support. Author of 25+ peer-reviewed publications, including work in cancer epidemiology and large observational cohorts.

CORE EXPERTISE

Epidemiology & RWE	Observational study design; evidence generation; research questions; epidemiological methods
Scientific & Methodological Leadership	Protocol development; methodological advice; study oversight; scientific quality
Statistical Planning & Interpretation	Statistical analysis plans; analysis oversight; data quality review; interpretation of findings
Scientific & Medical Writing	Study reports; protocols; manuscripts; abstracts; posters; evidence synthesis
Project & Client Management	Multi-country delivery; sponsor communication; timelines and budgets; vendor coordination
Cross-functional Collaboration	Biostatistics, analytics, medical, regulatory, data collection and external stakeholders
Academic & Research Leadership	Teaching; research supervision; mentoring; publications; conference presentations
Therapeutic & Research Experience	Cancer epidemiology; HIV; infectious diseases; allergy; perinatal and public health research

PROFESSIONAL EXPERIENCE

Founder & Research Director | June 2026 – Present

Evidascience LLC — Independent epidemiology, RWE and scientific consulting

- Founded an independent consultancy providing epidemiological expertise, RWE support and scientific writing to pharmaceutical, biotech and CRO clients.
- Provide scientific leadership and flexible consulting support for observational research, study methodology, evidence generation and medical/scientific writing.
- Led the scientific reporting of a longitudinal observational study assessing real-world treatment effectiveness through the analysis and interpretation of patient-reported outcomes (PROs) collected at baseline and across multiple follow-up assessments.

Real World Evidence Research Manager | June 2022 – May 2026

Oracle Life Sciences (formerly Cerner Enviza) — International RWE and observational research

- Led scientific and operational oversight of observational and RWE studies from study concept and design through implementation, analysis oversight, interpretation and final reporting across multi-country programs.
- Provided methodological input on epidemiological study design and contributed to statistical analysis plans; reviewed data quality and oversaw analyses in collaboration with statistical and analytical teams.
- Developed, authored and supervised high-quality study protocols, study reports, peer-reviewed manuscripts, abstracts and posters.
- Translated study objectives into practical research approaches, including literature reviews, evidence-gap assessments, endpoint selection, eligibility criteria and study-material development.
- Coordinated multidisciplinary teams, including sponsors, statisticians, data-collection vendors and other internal and external stakeholders, to maintain scientific quality and delivery timelines.
- Served as a key sponsor contact, communicating study progress, addressing methodological questions and providing recommendations to support project decisions.
- Oversaw protocol implementation, ethics and regulatory submission processes, data collection and study conduct in collaboration with relevant regulatory teams.
- Evaluated patient-reported outcome measures against study objectives, target populations and regulatory considerations; supported appropriate licensing and implementation across international studies.
- Contributed to research proposals and study concepts, including 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 epidemiological research.
- Conducted statistical analyses using SAS and interpreted findings for scientific communication.

- Prepared scientific manuscripts for submission to peer-reviewed journals.

Lecturer | **2014 – Present**
Saint Joseph University, Lebanese University and University of Balamand — Lebanon

- Teach Epidemiology, Research Methods, Clinical Trial Methodology, Biostatistics and Public Health at university level.
- Supervise and mentor Master of Public Health students in research question development, study design, methodology, analysis and dissemination.

Postdoctoral Researcher | **2014 – 2016**
CESP INSERM U1018 — Kremlin-Bicêtre, France

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

EDUCATION

PhD, Public Health: Epidemiology & Biomedical Information Sciences | 2014 | Pierre and Marie Curie University, Paris, France
Diploma, Statistics, Clinical Research & Epidemiology (CESAM) | 2012 | Pierre and Marie Curie University, Paris, France
Master's, Research Methods in Environment & Health | 2011 | Joseph Fourier University, Grenoble, France
Doctor of Pharmacy (PharmD) | 2009 | Lebanese University, Beirut, Lebanon

SELECTED PUBLICATIONS

Author of 25+ peer-reviewed publications. Selected publications demonstrating epidemiological and RWE expertise:

- Fiocchi A, Worm M, Wing-Kin Wong G, et al., including Hleyhel M. Prevalence of IgE-Mediated Food Allergies in Children and Adults: Results from the Multinational ASSESS FA Study. J Allergy Clin Immunol Pract. 2026.
- Gupta R, Mnif T, Reed S, Hleyhel M, et al. 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;18(9):101105.
- Hleyhel M, Popovici O, Leuștean 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.
- 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.
- 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.
- 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.
- 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.

SELECTED AWARDS & SCIENTIFIC COMMUNICATIONS

- Young Investigator Scholarship, Conference on Retroviruses and Opportunistic Infections (CROI), Boston.
- Oral presentations at the International Workshop on HIV Observational Databases; EPICLIN; International Francophone Conference on HIV and Hepatitis; and other scientific congresses.

TECHNICAL & LANGUAGE SKILLS

Statistical software: SAS; statistical analysis and data management tools.
Languages: Arabic (native); French (fluent); English (fluent).