

# Alex Bica MD, MPH, FRSPH

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## Profile

Board-certified physician and senior pharmacovigilance leader with 15+ years of global experience in drug safety, clinical development, and regulatory strategy across pharma, biotech, and public health. Proven track record of advancing oncology, immunology, vaccines, rare diseases, and infectious disease programs from early clinical research through approval and post-marketing. Expert in signal detection, benefit–risk management, regulatory submissions (IND, BLA, MAA, NDA), and global compliance (FDA, EMA, PMDA, TGA). Recognized for building and leading high-performing PV teams, shaping safety governance, and ensuring patient protection while enabling innovation.

## CORE COMPETENCIES

Pharmacovigilance (PV) & Drug Safety Strategy
**Professional**

Clinical Development Leadership (FIH to Phase IV)
**Professional**

Oncology, Immunology, Vaccines, Rare Diseases
**Professional**

Safety Surveillance, Signal Detection & Case Management (SAE, SUSAR)
**Professional**

Risk Management Plans (RMP), Aggregate Safety Reports (DSUR, PBRER)
**Professional**

Regulatory Submissions (IND, BLA, MAA, NDA)
**Professional**

Translational Safety & Benefit–Risk Assessment
**Professional**

Global Compliance (ICH, GCP, FDA, EMA, PMDA, TGA)
**Professional**

Safety Governance & Inspection Readiness
**Professional**

Cross-Functional Leadership & Team Development
**Professional**

## EDUCATION

2015 – 2016
Siena, Italy

**Vaccinology & Pharmaceutical Clinical Development | Executive Master of Science (MSc)**
**Università degli Studi di Siena**

2008 – 2012
Iasi, Romania

**Medical Epidemiology and Infectious Diseases | Specialist**
**University of Medicine and Pharmacy “Gr. T. Popa,” Iasi**

2006 – 2008
Iasi, Romania

**Public Health | Master of Public Health (MPH)**
**University of Medicine and Pharmacy “Gr. T. Popa,” Iasi**

2000 – 2006
Iasi, Romania

**General Medicine | Medical Doctor**
**University of Medicine and Pharmacy “Gr. T. Popa,” Iasi**

## PROFESSIONAL EXPERIENCE

08/2024 – present
Marburg, Germany

### HEAD OF TRANSLATIONAL and EARLY DEVELOPMENT SAFETY
**CSL**

- Built and led CSL's first Early Development & Translational Safety organization, bridging pre-clinical and early clinical development.
- Defined the strategic vision and operating model, aligning safety across hematology, immunology, cardiovascular, renal, transplant, immunoglobulins, and vaccines.
- Recruited and developed a high-performing global safety team, fostering innovation and operational excellence.
- Introduced novel translational safety approaches (modeling, simulation) to reduce early development risk and accelerate decision-making.
- Provided strategic PV leadership for first-in-human and proof-of-concept studies, ensuring patient protection, signal detection, and regulatory compliance.
- Partnered with senior R&D leadership and FDA/EMA to guide benefit–risk strategy and portfolio progression.

03/2023 – 08/2024
Marburg, Germany

### GLOBAL THERAPEUTIC AREA HEAD, IMMUNOLOGY
**CSL**

- Directed global safety and risk management strategy for CSL's Immunology portfolio (pre- and post-approval).
- Led a team of 10 physicians across global sites, embedding proactive signal detection and benefit–risk assessments.
- Oversaw all safety activities enabling the regulatory approval and launch of Andembry, including submissions, inspections, and HA interactions.
- Acted as CSL's primary liaison with FDA, EMA, PMDA, and TGA, managing complex safety discussions.
- Represented Global Safety & Pharmacovigilance in cross-functional teams, integrating safety into development, regulatory, and commercialization.
- Championed proactive safety science, introducing innovative methods for risk mitigation and regulatory readiness.

05/2022 – 03/2023
Marburg, Germany

### SENIOR DIRECTOR, GLOBAL SAFETY LEAD
**CSL**

- Provided strategic PV leadership across immunology, transplant, respiratory, and infectious diseases.
- Served as SME in FDA Advisory Committees, EMA referrals, and Rapporteur discussions, strengthening global regulatory standing.
- Directed safety strategy and execution for multiple INDs, BLAs, MAAs, and first-in-human trials.Oversaw all COVID-19 clinical research safety activities, ensuring scientific rigor and regulatory compliance under accelerated timelines.
- Facilitated Data Monitoring Committee (DMC) reviews and unblinded safety analyses to guide risk–benefit decisions.
- Acted as key liaison with KOLs, license partners, and internal stakeholders for coordinated safety strategy.

08/2019 – 05/2022
Marburg, Germany

### DIRECTOR, GLOBAL SAFETY LEAD
**CSL**

- Directed end-to-end safety strategy and operations across therapeutic areas.
- Chaired Safety Management Teams, aligning PV, regulatory, clinical, and medical functions.
- Oversaw safety monitoring and contributed to major IND, BLA, and MAA submissions.
- Supported signal detection, labeling, and risk management planning.
- Represented safety in governance forums and external regulatory interactions.

## PROFESSIONAL EXPERIENCE

03/2019 – 08/2019
Frankfurt am Main, Germany

### DIRECTOR, GLOBAL CLINICAL LEAD PROPHYLACTIC VACCINES AND DRUG SAFETY
**CureVac AG**

- Directed clinical development and PV strategy for prophylactic vaccine projects.
- Oversaw safety surveillance, signal detection, and risk mitigation for oncology and infectious disease assets.
- Developed and maintained RMPs, SMPs, DEAs, and inspection readiness.
- Chaired Safety Committees and coordinated DSMBs to ensure patient safety.

12/2016 – 03/2019
Frankfurt am Main, Germany

### ASSISTANT DIRECTOR, GLOBAL CLINICAL LEAD PROPHYLACTIC VACCINES AND DRUG SAFETY
**CureVac AG**

- Provided medical leadership to clinical study teams, ensuring deliverables.
- Supervised global safety activities for oncology and vaccine assets, including risk management.
- Supported regulatory submissions and Health Authority interactions.

05/2015 – 12/2016
Siena, Italy

### Safety Evaluation and Risk Management Physician
**GSK Vaccines**

- **Conducted post-marketing safety analyses and benefit–risk evaluations.**
- **Performed signal detection, O/E analyses, and regulatory safety studies.**

09/2012 – 05/2015
Romania

### HEAD OF EPIDEMIOLOGY AND DISEASES CONTROL DEPARTMENT
**National Health Authority, Ministry of Health**

- Directed epidemiology, pharmacovigilance, and outbreak response programs.
- Managed Phase IV NIS, health budgets, and national safety policies.
- Served as national expert in bioethics and President of the Malpractice Committee.

09/2008 – 09/2012
Romania

### MEDICAL EPIDEMIOLOGIST
**Public Health Directorate**

- Oversaw public health programs, surveillance, and Phase IV NIS.
- Implemented regulatory guidelines at regional level for vaccine-preventable diseases.

## PUBLICATIONS, ABSTRACTS & POSTER/ORAL PRESENTATIONS

15+ peer-reviewed publications (PubMed indexed).
30+ international conference presentations (oral & poster).

## ADDITIONAL CREDENTIALS

**– TECHNICAL SKILLS**

Argus
**Professional**

Empirica Topics
**Professional**

Spotfire
**Professional**

Power BI
**Professional**

OFF-X
**Professional**

## ADDITIONAL CREDENTIALS

**– LANGUAGES**

English
**Professional**

Romanian
**Native**

Italian
**Professional**

German
**Professional**

French
**Limited**

## PROFESSIONAL DEVELOPMENT (LICENSURE/CERTIFICATIONS)

2016 — **ICH GCP**
**Royal College of Physicians, London, UK**

2016 — **Certificate in Global Health**
**Karolinska Institutet**

**Postgraduate Certificates in Nosocomial Infections, Influenza Surveillance, Vaccine Safety**
**World Health Organisation**

05/2025 — **Novel Clinical Trial Design in Translational Medicine**
**University of Cambridge**

## PROFESSIONAL AFFILIATIONS

Fellow of the Royal Society of Public Health, London, UK

Academic Fellow of the Academy of Science, Siena, Italy

Associate Professor and Faculty Member at the University of Siena, Italy

## INTERESTS

Family

Technology and AI

Literature and History