Dr. Prof. Vahan Simonyan,
PhD Quantum Physics and Mathematics

- Professor of Bioinformatics & Biostatistics, George Washington University
- Chief Scientist, DNA-HIVE
- CO-Founder/President, WHISE-Embleema

Education

Dr Simonyan has a solid scientific background in varied academic disciplines:

- MS in Physical Organic Chemistry,
- Ph.D. in Physics and Mathematics,
- Dr. Sci. in Quantum Physics,
- post-doctoral training in Nanotechnology and Quantum Statistical Thermodynamics.

Experience

His recent expertise is in biotechnology and biomedical informatics and he served as a:

- Lead Architect at US National Institute of Health,
- R&D Director of Bioinformatics and Lead Scientist in Genetics at the US Food and Drug Administration
- Chief Scientist at a healthcare IT enterprise DNA-HIVE
- President at WHISE-Embleema global healthcare data marketization enterprise.

Research and Academic

Vahan Simonyan is a prolific author of +100 scientific publications in physics, chemistry, quantum mechanics, nanotechnology, biotechnology, population dynamics, and bioinformatics. Recipient of multiple awards, and multimillion-dollar grants for excellence in number of health informatics and biomedical informatics projects. Additionally, he holds an adjunct professor position at the George Washington University, where he teaches and develops curriculums for biomedical big data informatics and biostatistics research and development courses.

Advisory

Vahan Simonyan is an advisory board member for several biotech companies, and advisor to national governments in digital healthcare. Dr. Simonyan is also advising US FDA in scientific computing efforts, novel technologies, gene and cell therapies and modernization of digital healthcare.

Operations

Dr Simonyan's accomplishments in academic and R&D technology carriers have been complemented with the success of technology leadership roles in government, academia and industry where he establishes large-scale and complex, science-heavy R&D infrastructures capable of serving worldwide communities for research and regulatory purposes. Currently Dr. Simonyan leads large scale projects around health-IT and biomedical informatics. The subjects include but are not limited to:

- large scale data secure archival, analytics in genomic, clinical, and real-world evidence domains
- consulting in regulatory analytics in precision medicine
- infrastructure support for registries on cancer, autoimmune diseases, rare diseases, robotics, wearable medical devices
- standardization, harmonization and ontology development efforts for biomedical informatics and healthcare data standards
- patient advocacy, data privacy and ownership
- digital health policy consulting in national and international arena
- R&D in artificial intelligence and modern bioinformatics approaches to support healthcare

Strategic development and investment advisory

Dr. Simonyan provides medical product evaluation services to healthcare investment enterprises during due diligence procedures. Additional services are provided for existing investment vehicles to assist funded businesses in strategy development for regulatory positioning, and long-term sustainability. Subject matter expertise includes but is not limited to:

- evaluation of scientific merit of the primary concept,
- evaluation of risks for early stage scientific R&D,
- research protocol feasibility analysis,
- business alternatives and market competition analysis,
- evaluation of risks in the context of market dynamics,
- accessible market evaluation, epi-analytics
- regulatory feasibility in US market (FDA),
- evaluation of FDA submission packages (IND, BLA, NDA, 510K),
- regulatory pre-meetings, and meeting positioning,
- post-market evaluation strategy development,
- acquisition value estimates
- product licensing value estimations,
- assessment of digital relevance,
- health IT compliance, privacy, and security aspects (part 11, HIPAA, GDPR, etc),
- Artificial Intelligence and Machine Learning (AI/ML) strategies.

Subject matter expertise covers the following areas in precision medicine and medical devices industry:

- cell and gene therapies: CAR-T, allogeneic and autologous gene edited products, microbiome adjustment therapies, oncology, immune oncology, stem cell therapies
- molecular diagnostics panels (-omics),
- monitoring and wearable devices, ablation, spine, orthopedic devices
- software as a device,
- vaccine manufacturing consistency,
- target discovery and lead optimization.

Due diligence and strategy development services are priced as follows:

- for scientific and R&D evaluation ($1000/hour)
- market epi-analytics ($550/hour)
- digital ecosystem and digital compliance assessment ($550/hour)
- analytics strategy development ($1000/hour)
- regulatory analytics ($1500/hour)
- regulatory meetings, submission ($2000/hour)
- presentations and tutorials ($1500, max 2 hours per lecture)
- development services contract (mid/high level – $250-$300/hour, SME - $400/hour)