

Experience Sharing

Evanthia Koukouli, PhD EFSPI Stats Leaders Meeting 2023 May 23, 2023



Disclaimer

- This presentation is based on publicly available information (including data relating to non-Novartis products or approaches).
- The views presented are the views of the presenter, not necessarily those of Novartis.

My journey



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Academic Experience:

- BSc in Mathematics, National & Kapodistrian University of Athens, Greece
- MSc and PhD in Statistics, Lancaster University, UK
- PhD Thesis (2022): "Statistical Methods for Modelling Complex Longitudinal Data with Applications in Cancer Pharmacogenetics and Ageing"
- Graduate Teaching Assistant for the duration of my PhD Working in Industry:
- Biostatistics Internship at Roche (2020)
- Principal Biostatistician at Novartis since March 2022 (London, UK)
 - Joined the UK & Ireland Virtual Analytics Network (VAN): complete three 5month rotations before getting assigned to my permanent role (July 2023)

My VAN rotations

Renal

- Trial Statistician to design a Ph3b study
- Protocol & SAP writing
- Side projects included performing code validations, handling ADaM datasets, performing data explorations of precedent trials
- Meetings & collaboration with CTT members

Neuroscience

- Research project where I handled external data sets to inform decision making for the design of a Ph2 trial
- Very close collaboration with clinicians; open discussions where statistical outputs drove team's decisions for the design of the trial

Statistical Methodology (Oncology)

- Support Oncology through investigating a variety of statistical methodologies to address key trial issues
- Consultation meetings with internal and external experts
- Collaboration with very senior statisticians

Understanding the decision making process from a business perspective



Perception of our role as statisticians

Before I joined pharma...

- ✓ Strong **technical background**, including coding
- √The statistician is the one who derives data driven conclusions to inform the scientific community (or stakeholders)

After 1 year working within pharma...

- ✓ Critical role of statisticians in drug development
- ✓Our role is not only limited to implementing complex statistical methods but also getting actively involved into the decision making process to drive strategic business decisions
- ✓ Communication & collaboration skills, adaptability, resilience and problem solving skills are key



Becoming influential

How can our structured thinking and quantitative skills be utilized to support drug development?

Communication skills

(presenting to a diverse audience, communicating ideas to clinicians, etc.)

Business knowledge (deep understanding of drug development)

Technical skills

(the fundamentals are usually provided through our education; company courses help to stay current in the field)

Leadership skills



Support ideas

- Allow junior statisticians to gain diverse experiences early
 - Increase junior statisticians' visibility within the company, may create new collaboration opportunities, increase their appreciation and recognition of colleagues' work; also, will broaden their perspective
 - Can help to get the right talent in the right role
 - Getting experience from working at different stages of drug development or disease areas is critical
- Opportunities for direct collaboration with statistical leaders
- A structured mentorship
- Create open channel of communication with leaders; "frequent" meetings (e.g., twice/three times per year) for experience sharing

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Thank you

