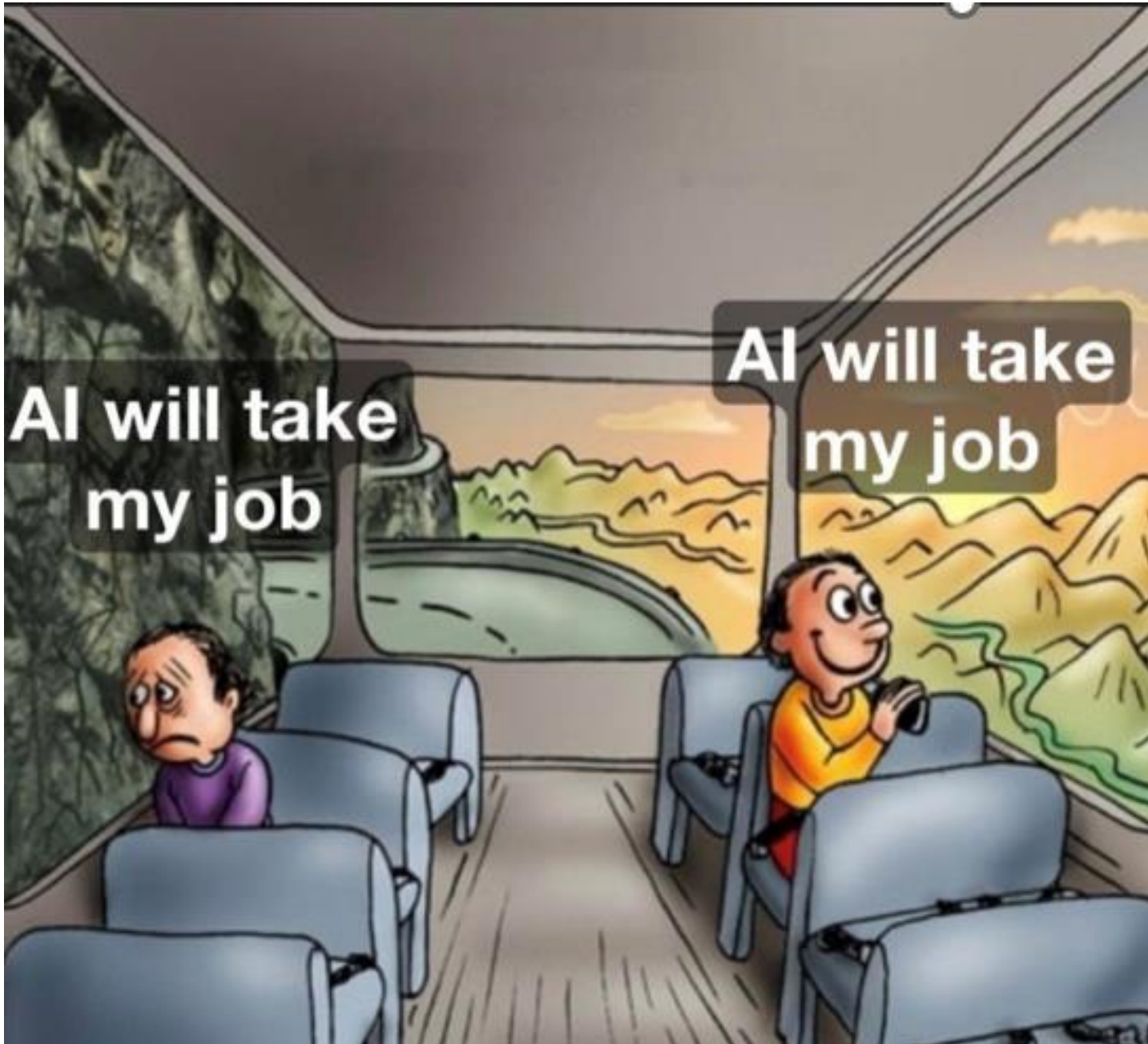




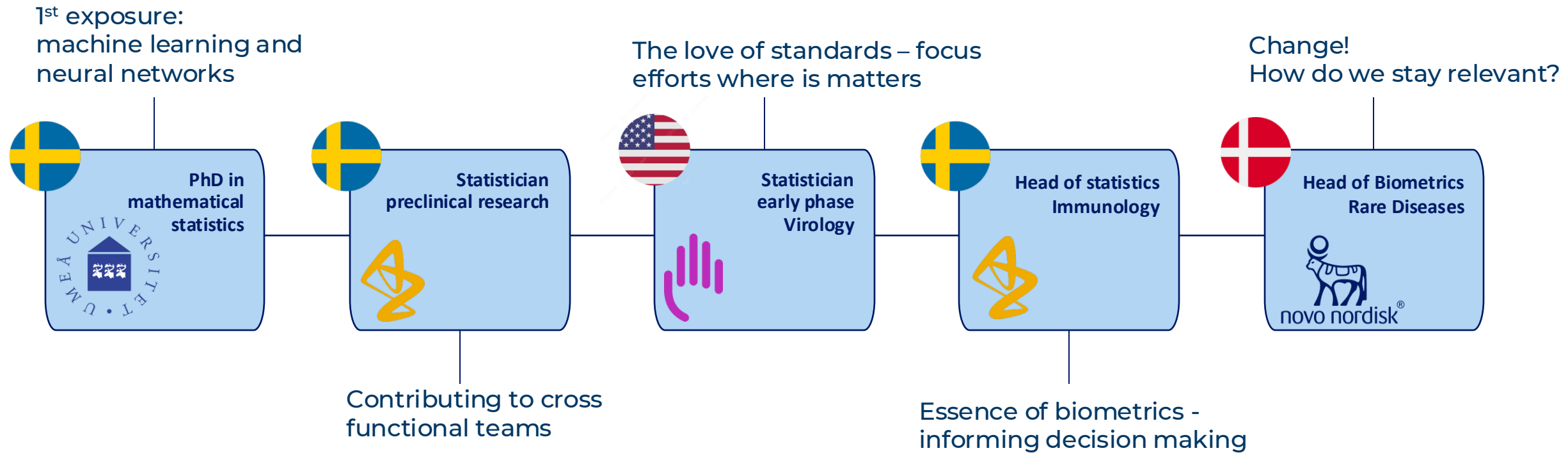
Mindset Matters

Embracing Change in the Role of Statistical Programmers

Anna Berglind, PHUSE SDE Copenhagen

23 Oct 2025

My personal journey



What is the ~~role~~ of the Statistical Programmer?

tasks

- **programming specifications**
- **datasets** e.g., SDTM, ADaM
- **Tables, Listings, Figures** for reports
- **Quality control:** Review datasets/outputs; ensure audit readiness
- **Documentation:** Prepare regulatory submissions (e.g., CSRs, submission documents)
- **Compliance:** Adhere to CDISC and regulatory standards
- **Communication:** Collaborate with cross-functional teams
- **Continuous Learning:** Stay updated on programming and regulations

The DIKW pyramid

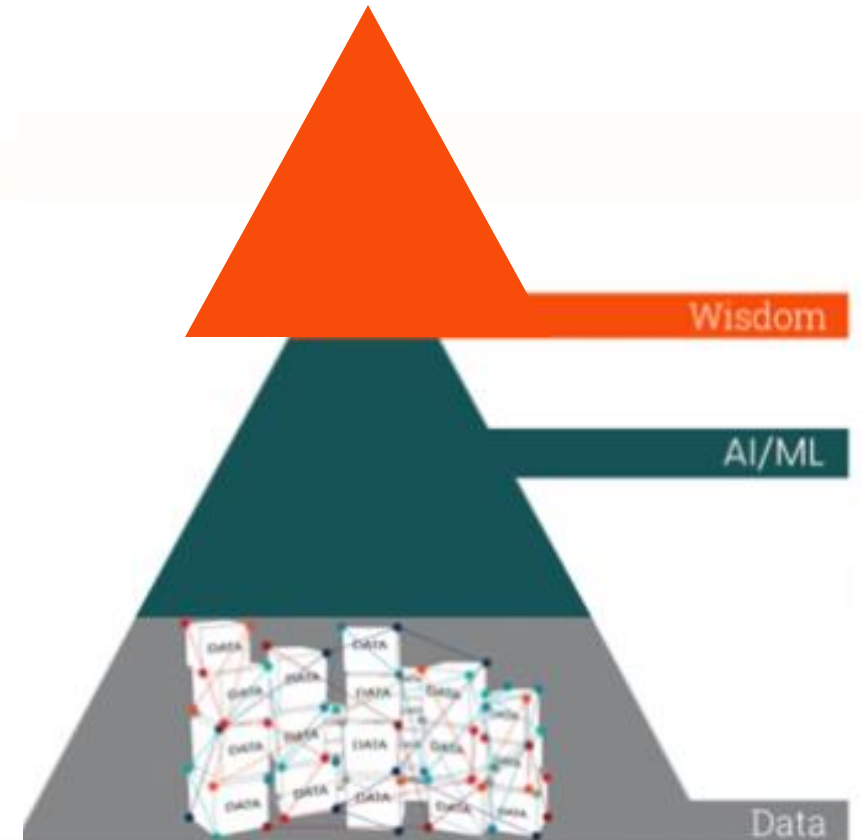
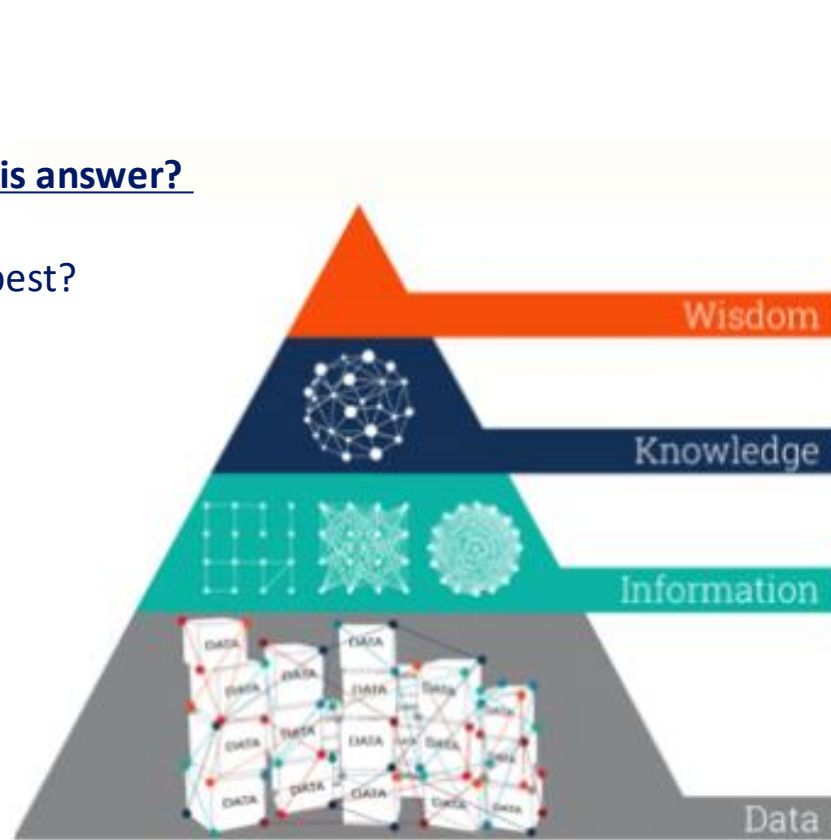
What question does is answer?

Why do? or What is best?

How? Or Why?

What?

Nothing



What makes us come into the office every day?

Example from the Novo Nordisk RareD Biometrics team

Purpose:

Our reason for being:

In Biometrics Rare D, we improve the lives of patients with unmet medical needs, leading strategic and informed, data-driven decisions

Vision:

The position or status we aspire to achieve within a reasonable timeframe:

By September 2026, we will be widely acknowledged as a leading innovative and patient-centric partner, known for data-driven, scientific and operational insights to accelerate product development and maximise impact

What is the ~~role~~ of the Statistical Programmer?

tasks

- **programming specifications**
- **datasets** e.g., SDTM, ADaM
- **Tables, Listings, Figures** for reports
- **Quality control:** Review datasets/outputs; ensure audit readiness
- **Documentation:** Prepare regulatory submissions (e.g., CSRs, submission documents)
- **Compliance:** Adhere to CDISC and regulatory standards
- **Communication:** Collaborate with cross-functional teams
- **Continuous Learning:** Stay updated on programming and regulations

What is the role of the Statistical Programmer?

tasks

standardization

automation

- **programming specifications**
- **datasets** e.g., SDTM, ADaM
- **Tables, Listings, Figures** for reports
- **Quality control**: Review datasets/outputs; ensure audit readiness
- **Documentation**: Prepare regulatory submissions (e.g., CSRs, submission documents)
- **Compliance**: Adhere to CDISC and regulatory standards
- **Communication**: Collaborate with cross-functional teams
- **Continuous Learning**: Stay updated on programming and regulations

standardization

automation

AI

purpose

- **Enable decision-making**
 - Regulatory **decisions** to approve drugs
 - Company **decisions** on what to invest in
 - Prescription **decisions** for Doctors

Jonathan Bi: I No Longer Fear AI Replacing Me, I Welcome It

<https://www.youtube.com/watch?v=n6KJASQ7kw&pp=0gcJCesJAYcqIYzv>

AI will **not** replace people but people who use AI **will** replace people who don't

Upgrade!

Learn the art of the prompt
Learn how to help AI – reduce bias and errors
Work with AI – you complement each other

Where do we add the most value?

Enable decision making!
Create – innovate
Strategic – not tactical
Integrated knowledge – clinical / quantitative
Provide integrity and rigor

Mindset matters

This is happening – embrace it!
Be in the driver's seat – take responsibility

Stay curious!

Thank you!