



PHUSE EU Connect

# *New Starters Session Regulatory Environment*



**Academia to Industry**

November 2021 / Amrit Singh / v0.1





# Agenda

// Past Life

// **Transition to Industry**

// Contrast with academia

// Repurposing skillset for new purposes

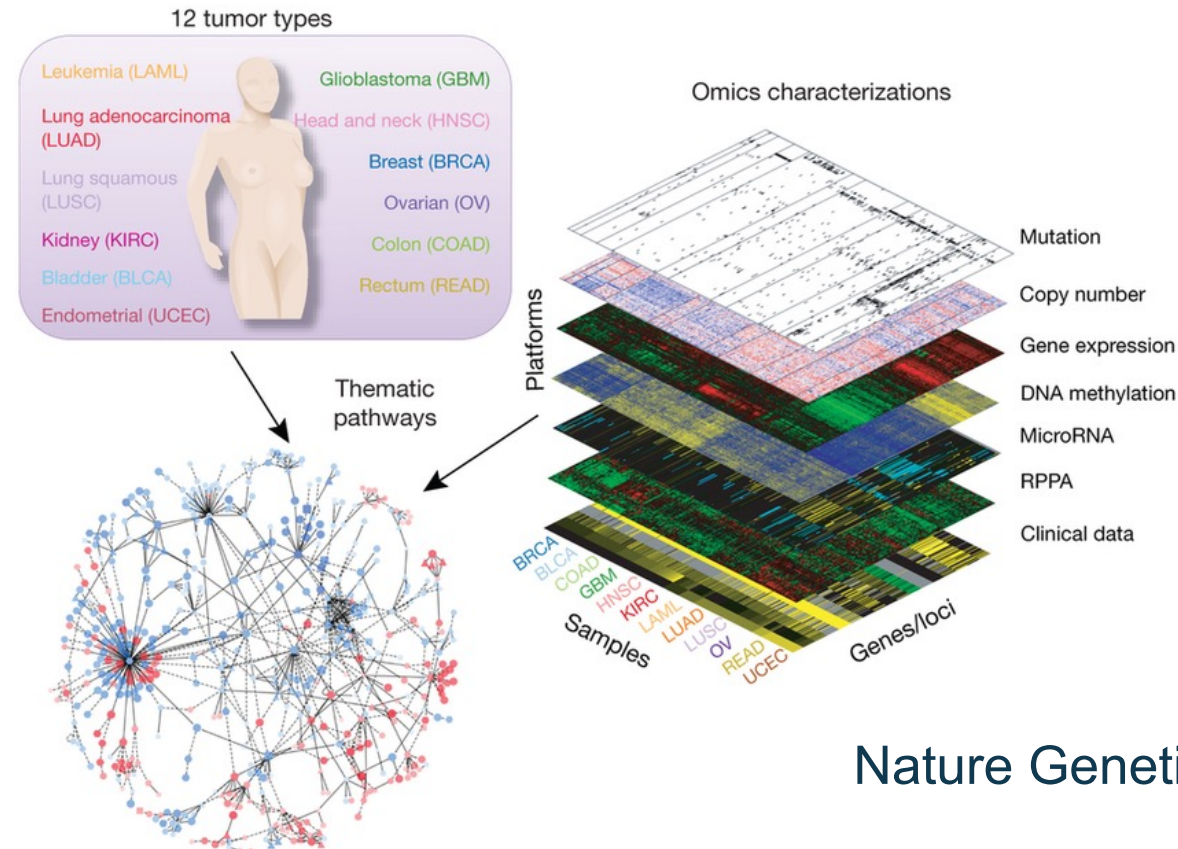
// Looking forward...

# Academic Life

BSc (Biology and Mathematics) and PhD (Experimental Medicine)

// Computational Biology background

// Programming, web development technologies, cloud services, biomedical data science, experimental techniques, reproducible research



Nature Genetics 2013 45(10):1113-20.



# Transition from Computational Biology to Statistical Programming

From open-source to commercial software (SAS, PowerBI)

## Academia

- Best practices are up to the individual labs/researchers
- Coding practices are variable
- Data management best practices are variable
- Currency is publications

- Adoption of open-source technologies
- Educational initiatives (PHUSE)

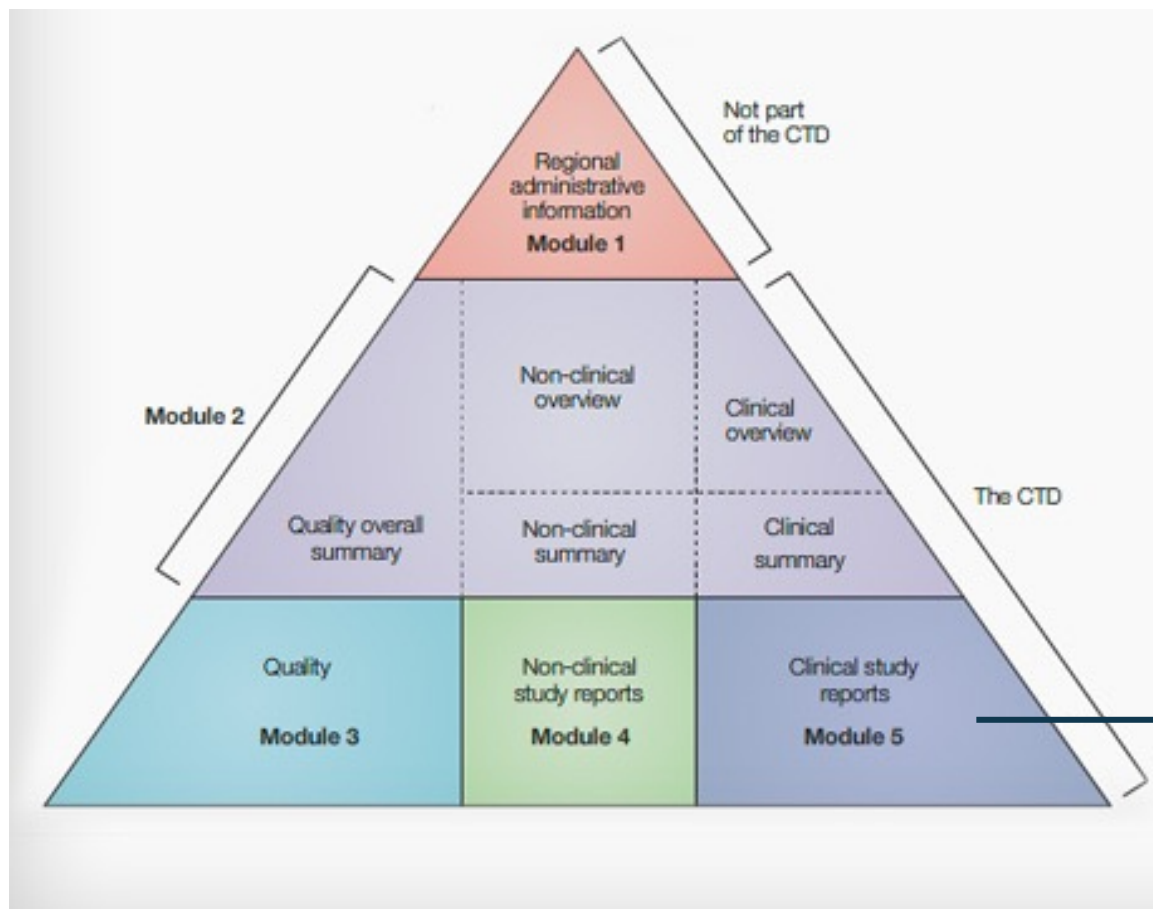
## Pharma

- Standardized project structure and protocols for various stages throughout the study
- Double programming practices
- Data tabulation models (SDTM, ADAM)
- Currency is use cases to improve efficiency, automation *etc.*



# Regulatory Environment (Where do I fit in?)

Preparation of regulatory documents (electronic Common Technical Document, eCTD)



## Statistical Programming & Analysis

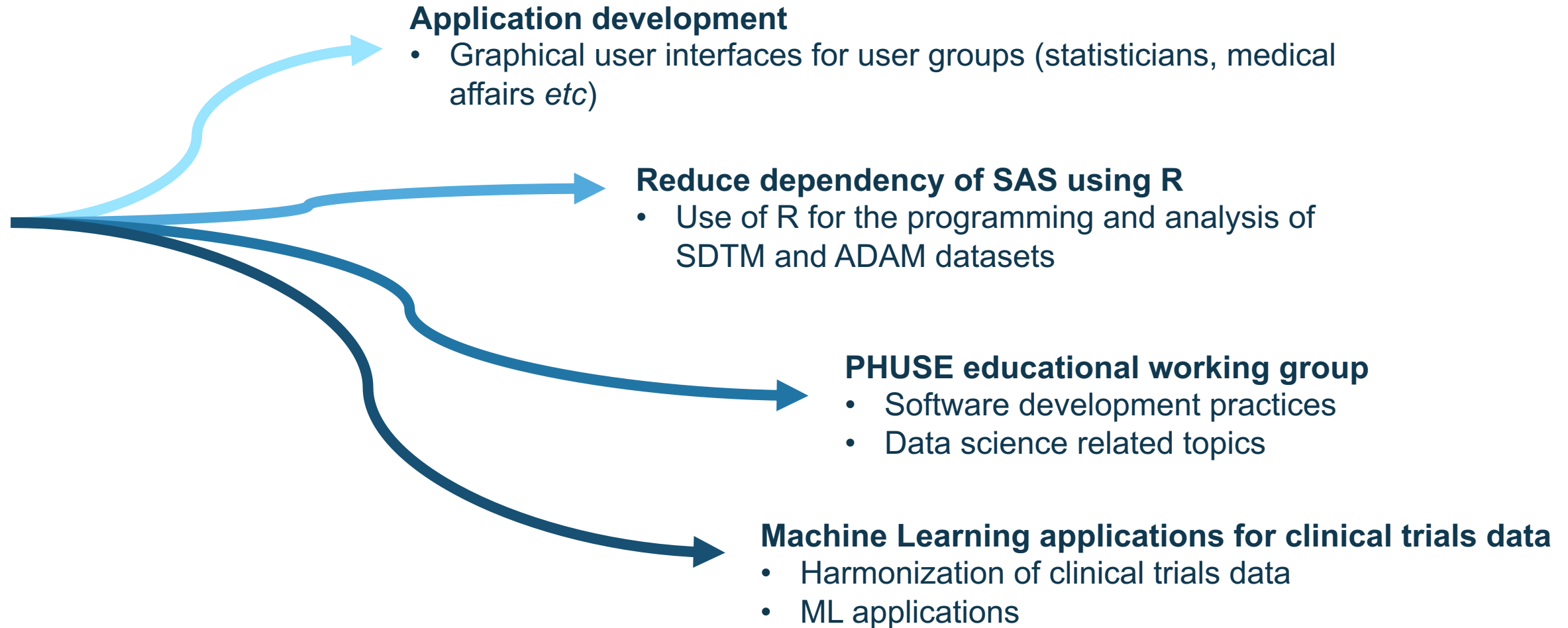
- Table, listings and figures
- applications for:
  - Viewing safety data
  - Viewing of listings
  - Automated generation of TLFs



[https://www.accessdata.fda.gov/cder/eCTD/backgr/backgr/fd\\_02\\_01\\_0030.htm](https://www.accessdata.fda.gov/cder/eCTD/backgr/backgr/fd_02_01_0030.htm)



# Looking forward...





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*Thank you!*



**Questions?**

