TA02
Future-Proofing Clinical Data Sciences:

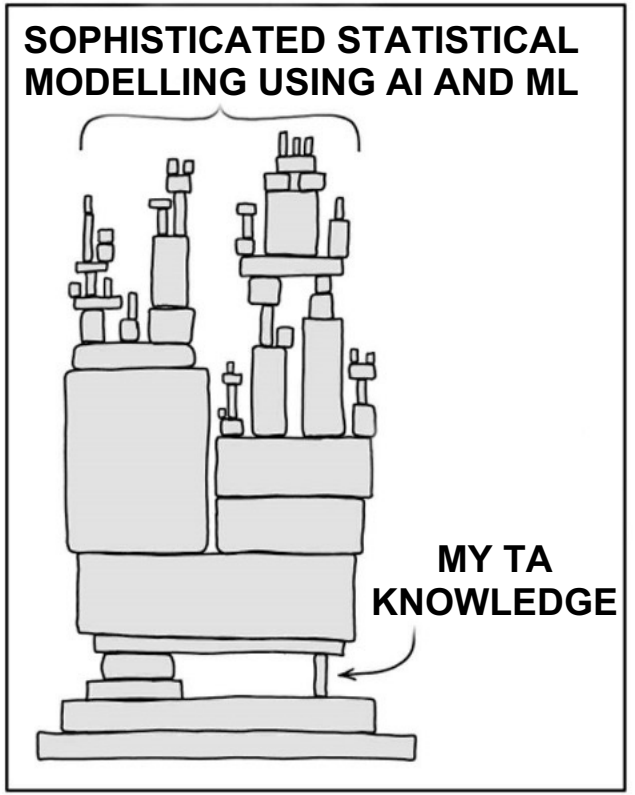
The Pivotal Role of Therapeutic Area Proficiency

Sascha Ahrweiler
PHUSE Educations Director

phuse·education

Agenda

- Importance of TA knowledge
- Acquiring TA knowledge via AI
- Do‘s and Don‘ts of promping AI Tools
- Follow PHUSE Educations TA Cluster
  - Description of Disease
  - Demographic & Baseline Characteristics
  - CDISC Data Standards and TAUGs
  - Agency Guidelines
  - Study Design & Clinical Trial Endpoints
  - Data Challenges
- Conclusion

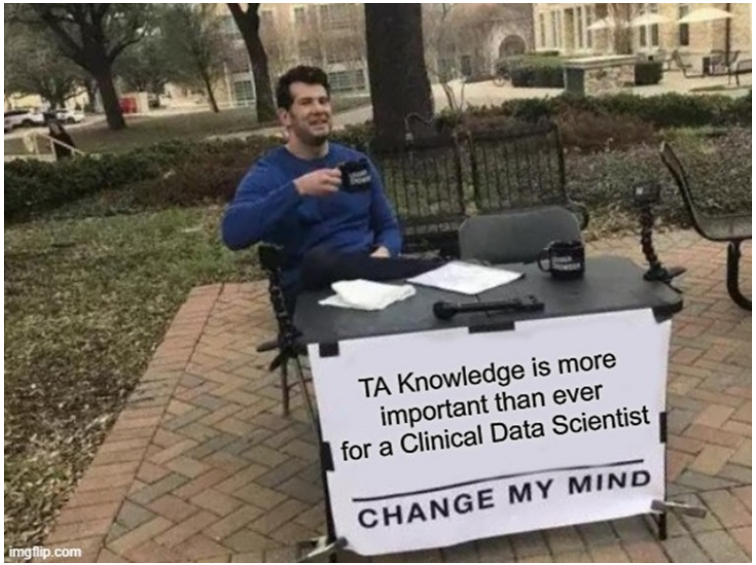


Importance of TA Knowledge

Therapeutic Area (TA) knowledge includes **understanding of disease** mechanisms, patient demographics, treatment landscape and evolving scientific insights

TA understanding not just and asset but a **distinguishing necessity** for designing and analyzing clinical trials and ensuring regulatory compliance

Continuous acquisition of TA knowledge are **imperative to future-proof** our practices in clinical data science



Acquire TA knowledge using AI?

We usually use AI for data analysis and predictive modelling

Can we utilize **generative AI to acquire TA knowledge?**

Method:

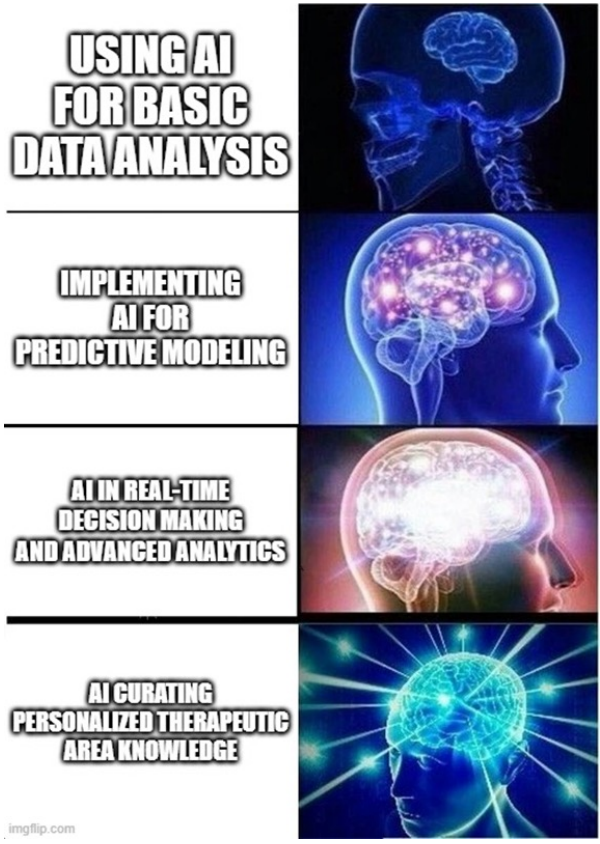
Using **PHUSE Educations structure** to write TA article

Take use case **Parkinson Disease**

ChatGPT 4 with Plus Subscription

CDISC membership

PHUSE Educations Parkinson's Disease



Do‘s and Don‘ts of prompting AI tools

Avoid Vague Requests
Generic questions will lead to generic answers, which might not be useful.

Don’t Overlook Verification
Always cross-check the information provided by AI with reliable sources.

Don't Rely Solely on AI
Use AI as a supplementary tool, not as the sole source of your therapeutic area knowledge.

Avoid Misinterpretation
Be cautious of how you interpret the information provided by AI; misunderstandings can lead to incorrect applications in your work.

Be Specific
Clearly define the TA and the specific information you need

Ask for Sources
Request the AI to provide sources or suggest readings

Update Requests
Keep your queries current by asking for the latest research.

Check for Relevance
Ensure that the information provided by AI is relevant and correct

Check my paper TA02 for a **detailed initialization prompt**

Description of Disease

„Tell me about Parkinson‘s Disease“

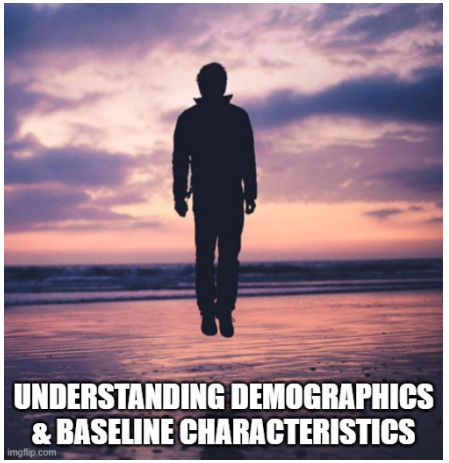
*“Provide a detailed overview of Parkinson's Disease, focusing on **aspects relevant to clinical data science**. Include information on epidemiology with high-level statistics on affected populations, typical progression of the disease, and common data types used in clinical trials for Parkinson's research. Also, suggest links to **trustworthy sources** for in-depth understanding, suitable for someone with a **basic medical background**.”*

“Is there anything I can do to make the good prompt even better? Ask me 5 more questions to further clarify the context.
Once you are completely sure about the context, provide the perfect prompt to reach our goal”

Demographic and Baseline Characteristics

"What are the Demographic and Baseline Characteristics for Parkinson's Disease?"

*"Provide a detailed analysis of the demographic and baseline characteristics of Parkinson's Disease patients, which are **usually measured in clinical trials**. Focus on aspects relevant to **clinical data science**. Include information on variables, which are acquired in a clinical trial to describe the **study population**. Also, describe **typical baseline characteristics** to describe the study population as detailed as possible. This should include the **primary and secondary variables** measured at study screening or study start. Suggest **authoritative sources** for in-depth demographic data and baseline characteristics suitable for **statistical analysis** in Parkinson's Disease research."*



CDISC Standards and TAUGs

CDISC Standards and TAUGs **require membership for full access**!

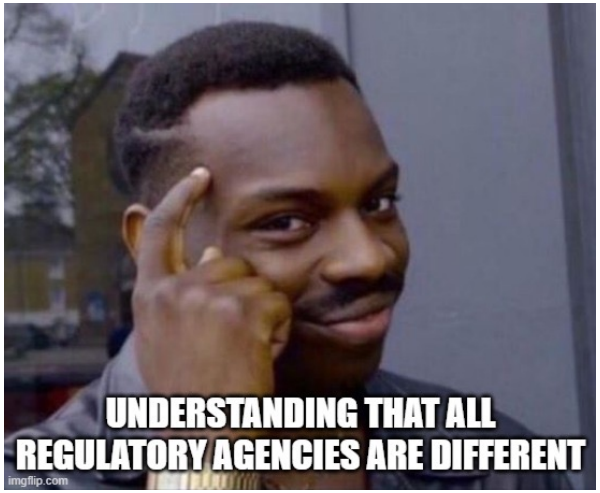
Download documents and **upload to ChatGPT**

"Briefly explain what the CDISC Standards and Therapeutic Area User Guides (TAUGs) for PD are. Provide links to the CDISC website where the standards and TAUGs can be accessed. Discuss the challenge of CDISC Standards being behind a firewall and accessible only to members. The ***attached documents contain information about Parkinson's Disease*** *specific therapeutic are user guides, focusing on their application in clinical trials for clinical data science. Highlight* ***key sections of the uploaded documents that are particularly relevant to PD research****. Explain how these standards guide data management and analysis in PD clinical trials, and provide examples or case studies if available. The* ***PD specific SDTM domains are described in Section 2****. Provide a bullet point list for each domain and add a high-level description about the importance and the content of this SDTM domain."*

Agency Guidelines

Understand that regulatory agencies across the globe might have **different guidelines available**

Understand that a **disease specific guideline might not be available, but the overarching TA might be**.



"Provide an overview of global agency guidelines relevant to ***neurodegenerative disorders****, with a specific focus on Parkinson's Disease. For each agency,* ***extract the three most important points*** *to consider for a clinical data scientist. Discuss if there are any* ***PD-specific guidelines*** *or those applicable to neurodegenerative disorders as a whole from agencies like the* ***US FDA, European EMA, Japanese PMDA, and Chinese health authorities****. Explain how these guidelines might vary and their implications for clinical data management and trial design in PD research."*

Study Design and Clinical Trial Endpoints

Read, understand and verify the demographics and baseline section!

Understand basics in clinical trial design!

*"Provide a **detailed exploration of various study designs** commonly employed in PD research, including randomized controlled trials and observational studies. Discuss the rationale and implications of each design, with an emphasis on control groups, blinding, and study duration.*

Delve into the selection and significance of study endpoints in PD trials. Cover both primary endpoints,
*like **motor symptom evaluation** through scales like the **Unified Parkinson's Disease Rating Scale**, and secondary endpoints, such as **non-motor symptom assessment** and **quality of life measurements**. Address the challenges in measuring, interpreting, and statistically analyzing these endpoints.*

*Highlight the emerging role of **digital biomarkers** in PD research. Discuss the **integration of wearable technologies** and mobile applications for continuous **symptom monitoring**, their impact on study designs, and the statistical considerations for data analysis.*

*Examine the use of **neuroimaging techniques (MRI, PET scans)** and biomarkers in understanding PD pathology, progression, and treatment response. Explore the statistical methods and challenges in analyzing neuroimaging and biomarker data.*

*Conclude by discussing the **future directions in PD clinical trial design**, focusing on patient-centered approaches, adaptive trial designs, and the incorporation of real-world data."*

Data Challenges

Understand all you have created so far to have a thorough understanding of what kind of data is collected and what can go wrong

Better get a mentor and create notes what could be challenging from your point of view.
Then use these **notes for AI to digest**.

*"Provide a detailed analysis of **common data challenges** encountered in Parkinson's Disease (PD) clinical trials as described **in the attached document**. Focus on specific issues such as **inaccurate or incomplete medication history**, **variability in disease progression**, subjectivity in symptom assessment, the integration of data from wearable devices, handling missing data, dose-response relationships, and comorbidities.*

*Discuss **sophisticated statistical methodologies** and **best practices for addressing these challenges**, ensuring data validity, and maintaining the integrity of the study. Highlight the importance of collaboration with clinicians and healthcare professionals in overcoming these obstacles."*

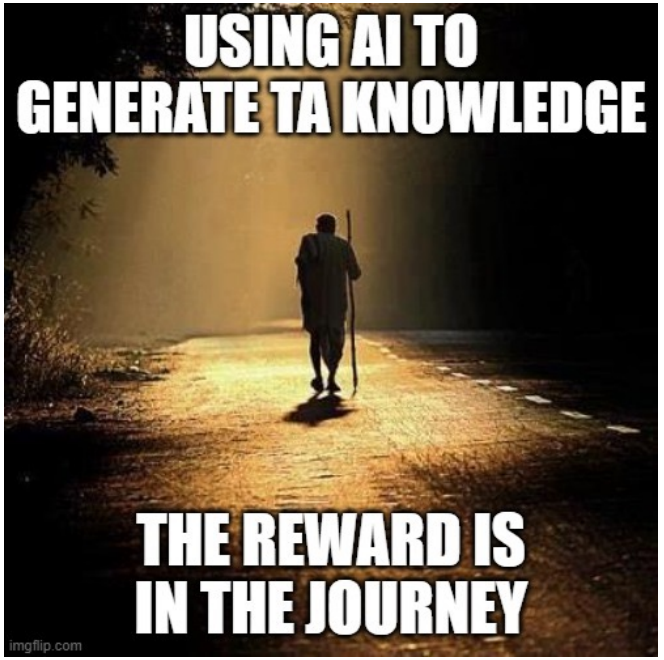
Conclusion

TA knowledge is **critical to future proof** our profession

Using **generative AI is (not yet) as easy** as asking for clinical data science relevant TA knowledge

Following the **PHUSE Educations structure** with the aim to write a TA article will bring you on a TA journey

Utilize mentorship such as PHUSE Educations to optimize your TA knowledge



Thank you!
Any Questions?

PHUSE Educations
Parkinson's Disease

The Global Healthcare
Data Science Community

Contact Channels
UK +44 1843 609600
office@phuse.global
phuse.global

Social Media
@phusetwitta
/phusebook
/phusetube
/company/phuse

All memes in this presentation were generated with imgflip.com/memegenerator