



Navigating the New Frontier of Clinical Data Management....or should we call it Data Science?

Gail Kniveton
5th March 2024

Quick introduction Gail Kniveton

I started my career with a Bachelor of Science (BSc) focused in Biochemistry from Coventry University

Worked in Clinical Research Organisations (CRO) for 5 years in clinical data management including SAS programming.

Worked in CRO and recruitment agencies where I developed operational expertise in recruitment, global project management including clinical trials, functional service models and recruitment ramp ups for innovating SMEs.

Recruiting diverse and inclusive teams is key to success in all the businesses I have worked with.

For the last 12 years I own and run 2 recruitment companies called Pop Science and Innovo Associates, working across life science technology and clinical trials including data science. My specialisation is working in new areas where there are limited talent pools.

Where are we seeing the biggest AI ML impact on jobs roles in Pharma?

- Slido – Words - where are you seeing the biggest AI and ML impacts in Pharma and Drug Development?

slido



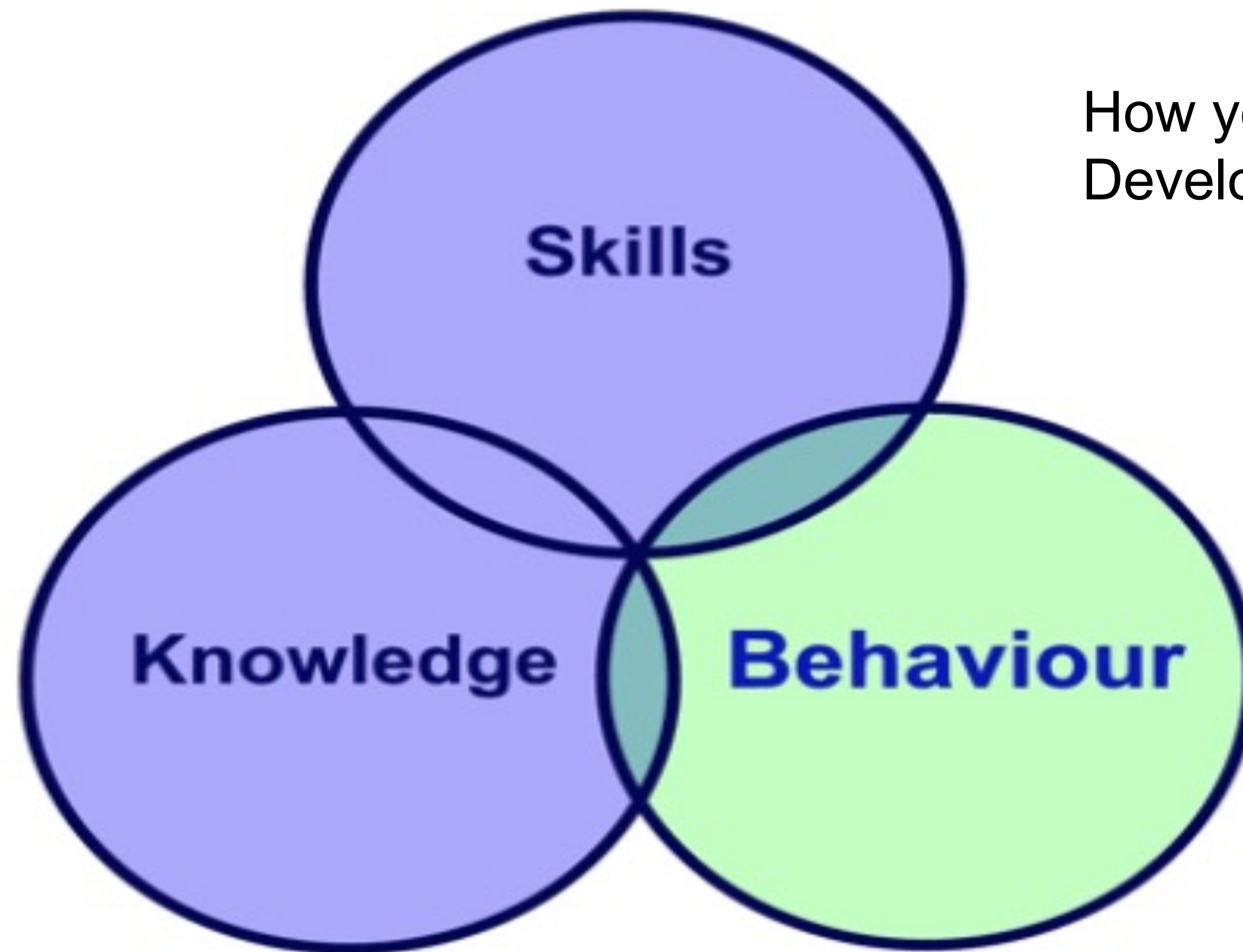
Where are we seeing the biggest AI ML impact on jobs roles in Pharma?

Where are we seeing the biggest AI ML impact on jobs roles in Pharma?

- EVERYWHERE!
 - Drug Discovery and Drug Repurposing
 - Diagnostics
 - Patient Recruitment and Retention
 - Protocol Optimisation
 - Data Analysis and Real Time Monitoring
 - Drug Safety and Pharmacovigilance
 - Regulatory Compliance and Documentation
 - Predictive Modeling and Forecasting
- How does this impact our roles?
- Is this really helping patient treatment and medical advancement?

What do we need to do to evolve? Skills, Knowledge and Behaviours

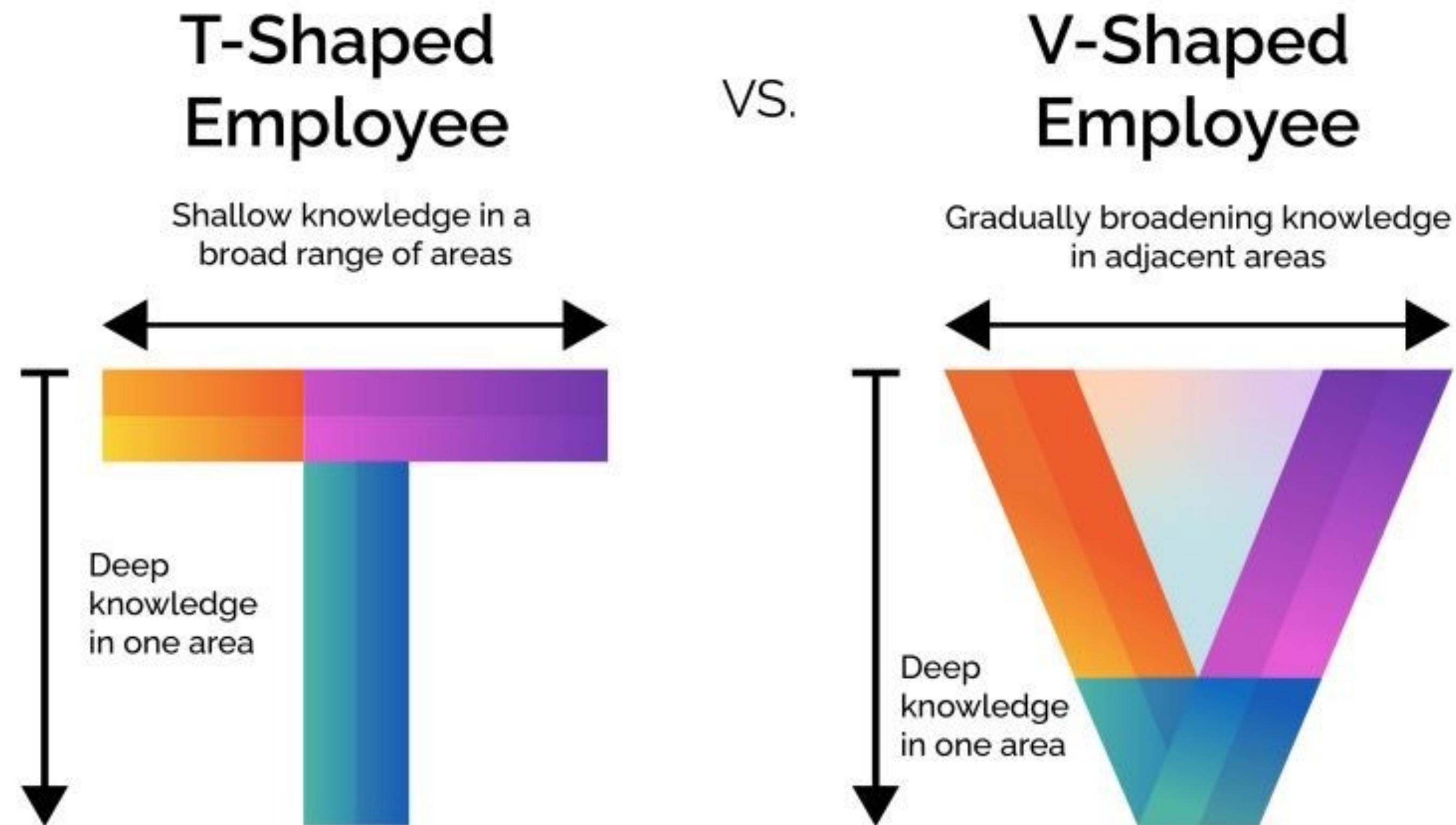
What you know?
e.g. Python
Regulations



How you apply this to work?
Developed with experience

Your mindset and approach

Where are we seeing the biggest AI ML impact on jobs roles in Pharma?



© Visual Jeroen Kraaijenbrink

What skills, knowledge or behaviours do you think you need to develop for AI and ML?

- Slido – words – what skills, knowledge or behaviours do you think we need to see?

slido



What skills, knowledge or behaviours do you think you need to develop for AI and ML?

Skills demands to support AI and ML

- Technology skills + science or medicine (bi-lingual)
- AI and ML language and tools Python in addition to SAS
- RWE data scientists or Clinical Trials Statisticians who understand data ontology beyond CDISC and including Science Data, SciPy, eHR etc
- Use of OpenSource or LLM
- Federated learning models
- Validation experts for AI and ML
- Regulatory experts for AI and ML
- Data acquisitions experts for AI and ML data
- Project and Product Managers with T shaped skills to oversee delivery

Behaviour demands to support AI and ML

- Learning to broaden skill base (T shaped models)
- Academics transition into commercial companies
- Rapidly changing organisational structures including reskilling and redundancy for some traditional roles
- Defining new processes
- Resistance to AI and ML internally (change management) and from users (training and support)

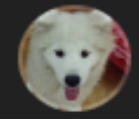
Knowledge demands to support AI and ML

- Technology skills + science or medicine
- High demand for python applied to science
- High demand for RWE data scientists who understand data ontology beyond CDISC
- Academics transition into commercial companies
- Rapidly changing organisational structures including reskilling and redundancy for some traditional roles

Challenges – the opportunities for you

- Data Quality – looking at how we ensure great data quality for AI and ML models
- Algorithm transparency – how do we assure that we can unpick what is created?
- Data Privacy and security – looking at compliance.
- Federated learning - what can we share back? Doctors and patients
- Regulatory understanding and oversight
- Patient preference, safety and efficacy – does it work and does it add value?
- Lack of people with this range of experience – how can you upskill quickly and effectively?
- How can you be the human in the machine?

Make yourself a Data Scientist



You

What is a data scientist?



ChatGPT

A data scientist is a professional who analyzes and interprets complex data to inform decision-making processes, solve problems, and discover insights. They possess a combination of skills in statistics, mathematics, programming, and domain expertise to extract meaningful patterns and trends from large datasets. Data scientists utilize various tools and techniques such as machine learning, data mining, and data visualization to derive actionable insights and build predictive models. Their work spans across industries including technology, healthcare, finance, marketing, and many others, where data plays a crucial role in driving business strategies and innovation.

