The Big TMF Battle: AI Versus the Geek

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Presented by:
Jacki Petty – Study Resourcing & Consulting Lead, Cencora
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Meet the Speakers

Jacki Petty (representing the Geek)

Title: Study Resourcing & Consulting Lead

Organization: Cencora

A TMF guru with an aptitude for turning complex projects into success stories. As a Study Resourcing & Consulting Lead, Jacki shines in managing large teams, developing innovative processes, and delivering user-friendly training. With a BSc in Psychology and a wealth of experience, she's an expert for all things TMF combined with effective people management. Known for her creativity, attention to detail, and ability to thrive under pressure, Jacki has a proven track record of boosting project health and customer satisfaction.

Rob Jones (representing Artificial Intelligence)

Title: TMF Product Manager

Organization: Cencora

In the industry for over 15 years, Rob has experience working across Sponsors, CROs and Vendors. After starting off in a white lab coat working with all manner of bodily fluids, he left the boring world of pipettes and entered the thrilling and exciting ride of documents, data, and records. Most recently Rob has been working at Cencora managing a team of 60 TMF experts working across a dozen sponsors before taking on ownership of the eTMF solution offered as well as supporting the other services offered by the TMF Practice Area.

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Agenda

1. The Evolving eTMF
2. The Traits of the TMF Geek
3. The Traits of Artificial Intelligence
4. The Battle
5. The Results

The Evolving eTMF

The Evolving World of eTMF

1996: ICH GCP E6 (R1)

2008: Trial Interactive launches

2010: TMF Ref Model V1.0

2011: VeevaVault launches

2012: TMF Ref Model V2.0

2015: TMF Ref Model V3.0

2016: PhlexEview V4.0 launches (SaaS model)

2016: ICH GCP E6 (R2)

2020: PhlexTMF introduces AI capabilities

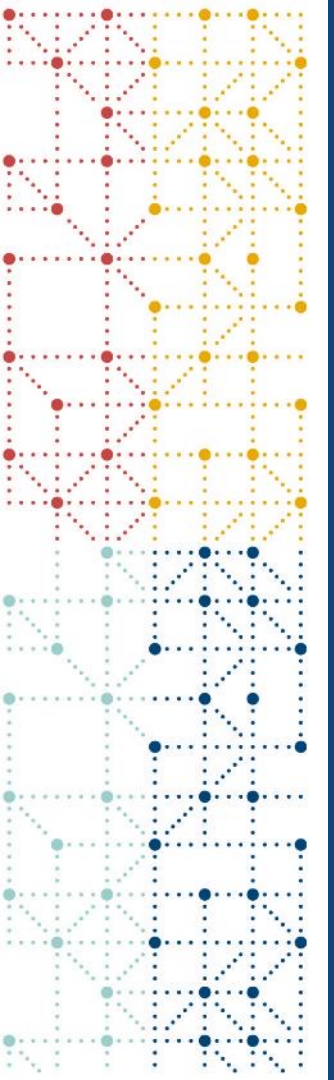
2022: PhlexTMF introduces AI QC features

2025: ICH GCP E6 (R3)

From paper and documents…

…to records and data!

- What makes a good TMF SME?
- What common traits do we share?
- How do these traits make us successful?
- How do these balance with evolving technology?



The Traits of a TMF Geek

* https://bigfive-test.com/

Quantifying the Geek

How do we define the TMF Geek?

- Anonymous data collected from 72 participants.
- Asked to complete the Big Five Personality Test* and select their current TMF-related role.

Participant Sample

Role	Count
Doc Specialist	32
TMF Admin	5
TMF SO	12
Snr TMF SO	9
Team Lead/Manager	9
Deputy/Department Head	5

Agreeableness: Compassionate, cooperative, trustworthy

Strengths = Teamwork, empathy

Conscientiousness: Organized, responsible, reliable

Strengths = Efficiency, planning

Extraversion: Sociable, energetic, outgoing

Strengths = Networking, leadership

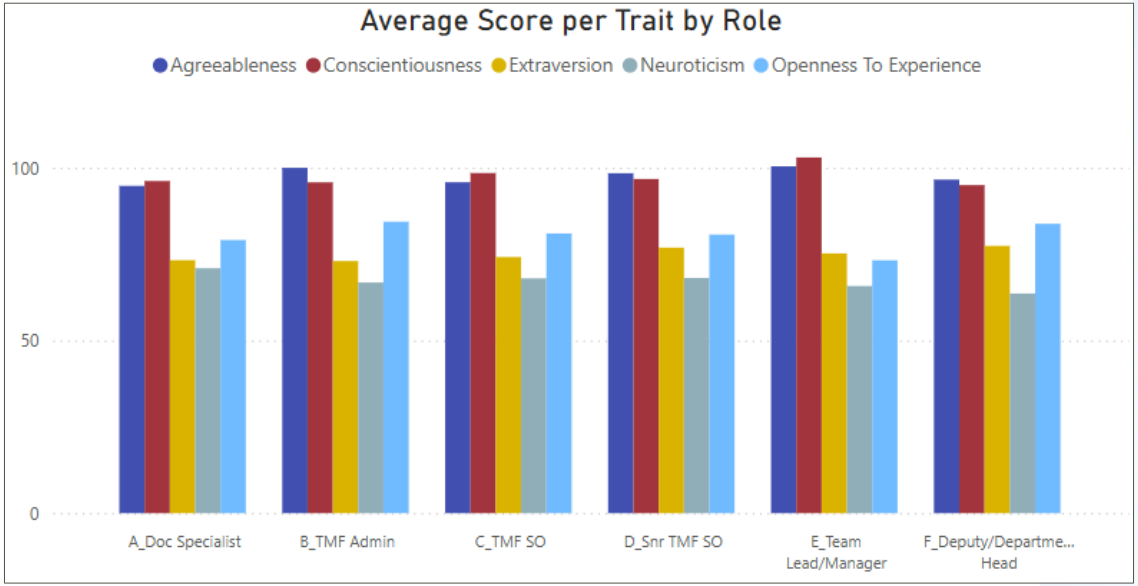
Neuroticism: Emotionally sensitive, reactive to stress

Strengths = Self-awareness, resilience

Openness to Experience: Curious, inventive, open to new ideas

Strengths = Creativity, adaptability

With Fascinating Results

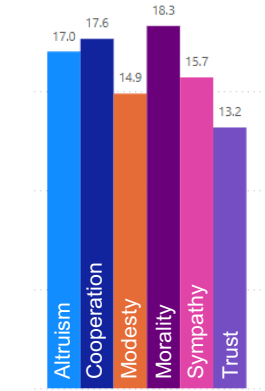


- The pattern seen across average scores of personality traits was almost identical, irrespective of the individual's role!

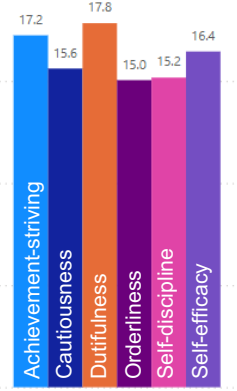
Is this the personality profile for TMF success?

Stand-out Traits

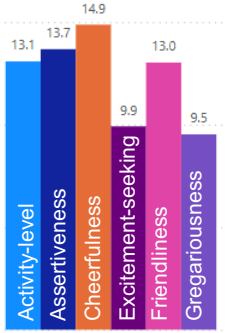
Within each of the Big 5 traits, we can also see what individual aspects stood out the most…



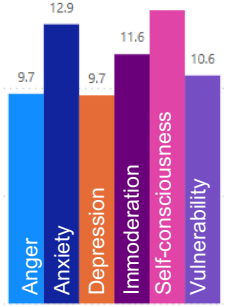
Agreeableness



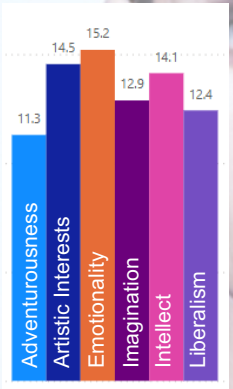
Conscientiousness



Extraversion



Neuroticism

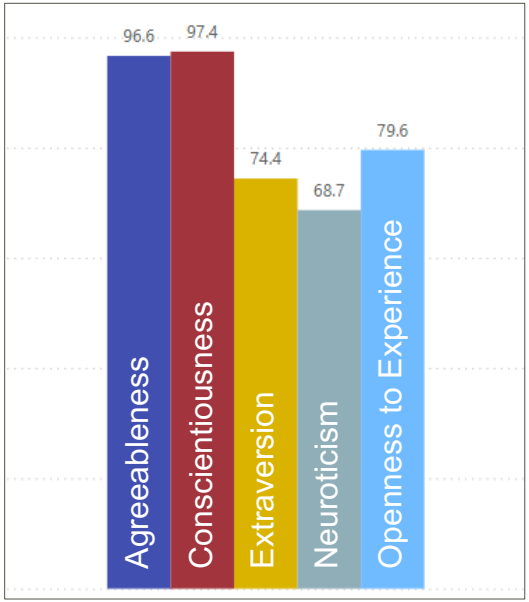


Openness

So, what does being a cooperative, moral, dutiful, cheerful, emotional and self-conscious TMF geek mean in practice?

Defined by Personality…

The average TMF Geek profile:



Agreeableness

- **High** - Compassionate, empathetic and cooperative. Enjoys helping others and value harmonious relationships.

Conscientiousness

- **High** - Organized, reliable and disciplined. Sets goals and works diligently to achieve them, paying attention to detail.

Extraversion

- **Low** - Prefers solitude and smaller groups, to large gatherings. Often introspective and prefers quiet activities.

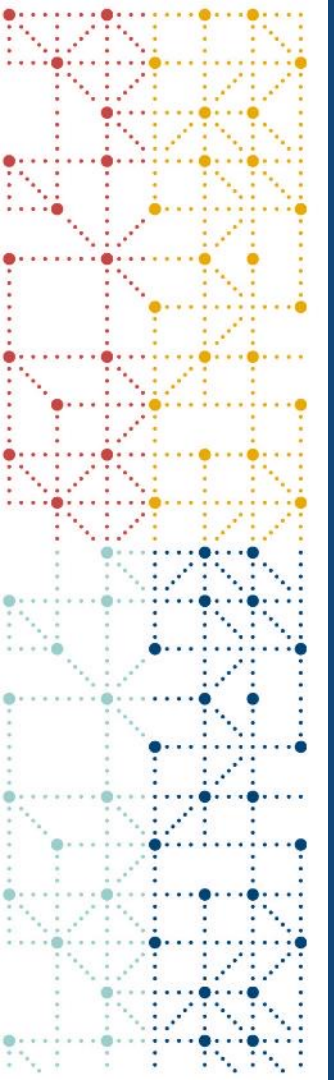
Neuroticism

- **Low** - Emotionally stable and resilient. Handles stress well and generally stays calm and composed.

Openness to Experience

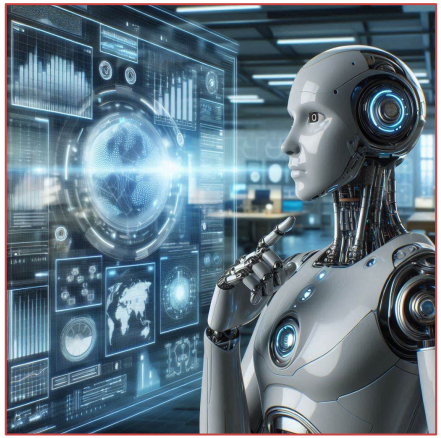
- **Medium** - Balanced approach to new experiences and ideas. Open to change but also appreciates routine and convention.

… Enhanced by Experience!



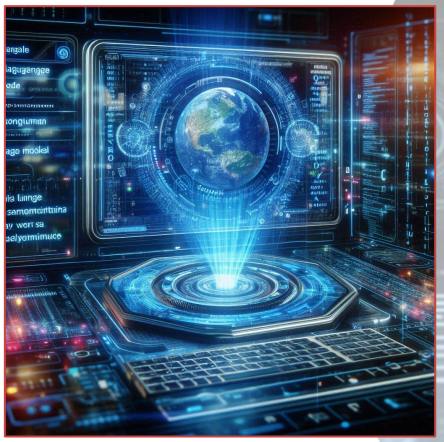
The Traits of Artificial Intelligence

The “Experience” of AI



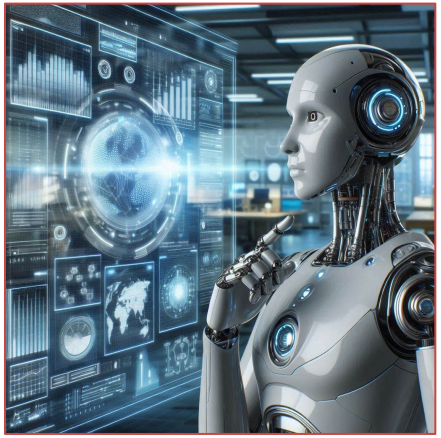
Machine Learning

VS



Large Language Model

Machine Learning



Machine Learning

Use Case

- Repetitive tasks you wish to automate to varying degrees

Development

- Must be designed for the exact task you want to automate

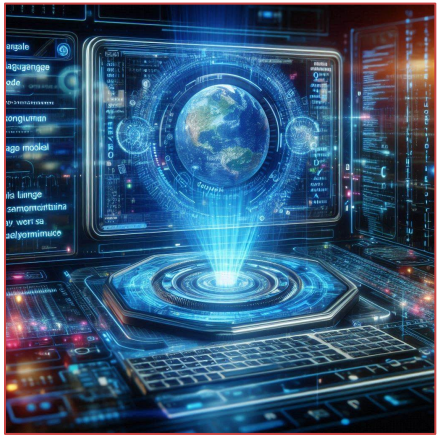
Training

- Uses data and algorithms to identify patterns, can be updated with new data and instructions

Interaction

- Users do not often have direct interaction, they have inputs and outputs

Large Language Model



Use Case

- Use as a knowledge base users interact with, can understand and generate text

Development

- Once the core model is created, its use can be defined by the user

Training

- Masses amounts of data in all formats to learn from and evolve

Interaction

- Direct interaction from the user with the model, providing request in human language

Quantifying Artificial Intelligence

- How do you define AI in relation to the Big 5 Personality Traits?
- We asked AI…

Agreeableness

- AI can be programmed to be cooperative, helpful, and supportive, which can mimic agreeableness. However, this is based on algorithms and programming rather than genuine empathy or social bonding.

Conscientiousness

- AI can be very conscientious in terms of reliability and efficiency. They follow programmed instructions meticulously and can handle repetitive tasks with high accuracy. However, they lack the intrinsic motivation and ethical considerations that human conscientiousness entails.

Extraversion

- AI does not experience social interactions or emotions, so it doesn't exhibit extraversion in the human sense. However, AI can be designed to engage in frequent and effective communication, simulating extraverted behavior in customer service or social media contexts.

Neuroticism

- AI does not experience emotions, stress, or anxiety, so it does not exhibit neuroticism. AI systems operate based on logic and data, without the emotional variability that characterizes this trait in humans.

Openness

- AI systems can be highly open in terms of their ability to process and generate a wide range of information and ideas. They can learn from diverse datasets and adapt to new tasks, showing a form of intellectual curiosity and creativity.

The Battle

Artificial Intelligence

Bio: A super-efficient, data-loving machine with an excellent ability for organizing chaos, provided they've received extensive training. Can engage in two-way conversation on demand, but don't always trust everything you hear. Copes brilliantly in high-stress situations, always focussed on the end goal and without empathy for external factors that might get in the way.

VS

TMF Geek

Bio: An amicable and attentive subject matter expert, forever focussed on Inspection Readiness. Can adapt to the most awkward of studies and tricky of teams, while staying calm and collected under pressure. Has exceptional organizational skills, and the capacity to resolve the most challenging queries – all within the constraints of forever-changing regulations.

Round 1: TMF Document Processing

Import, classification and quality checking of TMF records.

	DESIRED TRAITS	
Neutral, unbiased and can reliably and efficiently apply rules based on algorithms.		Works well with others with empathy and understanding, helping boost team dynamics when completing repetitive or challenging tasks.
Exceptional attention to detail, ensuring records are processed accurately and systematically.		Meticulous nature ensures records meet compliance expectations, while also identifying unexpected nuances in record content.
Quickly processes and organizes information, making it available on request.		Effectively engages with stakeholders when required to provide insights and updates, helping support project success.
Maintains performance under high pressure, while also scaling easily to cope with fluctuating workloads.		Effectively manages stress, using expertise to navigate challenges and maintain consistent high-quality deliverables.
Trained to handle a wide range of record formats and data structures.		Provides creativity and innovation, using knowledge to develop strategies and solutions for more complex problems.

Round 2: Study Team Interactions

Collaborating with a cross-function team to help answer questions and facilitate TMF activities.

DESIRED TRAITS

Neutral entity, always remains fair and objective.		Demonstrates empathy and understanding, able to accommodate different viewpoints and competing priorities.
Helps track and report on progress, ensuring data presented is accurate and up-to-date, supporting decision making.		Ensures all key topics are covered, using expertise to have oversight of details and provide answers to complex questions.
Provides timely, organized and accurate information, able to answer logical questions based on available data.		Actively engages with the study team to foster collaboration, build strong relationships and open discussion.
Unaffected by stress or emotional fluctuations, provides stability and reliability.		Maintains composure under stress to help deal with challenging situations.
Can provide insights and data analysis to offer new perspective on large datasets.		Brings creativity and openness, able to contribute knowledge to team discussions.

Round 3: TMF Health and Metrics

Running reports and providing actionable insights based on the data returned.

DESIRED TRAITS

Unbiased and provides data-driven recommendations.	Understands and accommodates different viewpoints, ensuring insights are actionable and aligned with study team goals.
Meticulous attention to detail and can generate accurate and comprehensive reports.	Considers all aspects of data to ensure reports are accurate but also relevant and actionable.
Facilitates communication through clear and accessible presentation of data, in a timely manner.	Encourages discussion and collaboration of data, able to relate actions to the individual and their role.
Provides continuous and reliable monitoring of data with timely alerts for any issues.	Affectively manages stress to ensure the right information is available as needed – including in preparation for, and during, inspections!
Analyses vast amounts of data and identify trends not immediately apparent, suggesting relationships based on a given dataset.	Analyses data in the context of their experiences and innovative in presenting information to study teams.

Round 4: Learning & Development

Training on TMF processes and expectations, along with regulatory requirements.

DESIRED TRAITS

Provides neutral, unbiased training with an objective approach and data-driven feedback.	Accommodates different learning styles and tailor training to individual needs to provide best possible support.
Generates thorough and comprehensive training materials on a given topic or process.	Ensures training programmes are relevant and actionable, highlighting the key information for the target audience.
Organizes and presents training materials on a given topic and responds to questions based on learnt information.	Presents information in the most effective way for the target audience, managing group dynamics and facilitating discussion.
Ensures training is consistently provided on time and progress is monitored.	Creates a positive learning environment, remaining calm and composed under pressure.
Provides training materials and resources based on large datasets, adapted to the trainee's progress and understanding.	Contributes experience and knowledge to developing effective training, incorporating latest industry trends and changes.

Round 5: What comes next?

Consider where AI could be utilized to make a positive impact on your TMF processes

- Speed and efficiency – can you free up time for people to focus on more complex activities?
- Accuracy and consistency – can you minimize risks by taking out human error and subjective opinion?
- Scalability – can you improve management and efficiency of large projects and workload fluctuations?
- Cost-effectiveness – does the cost-benefit ratio make sense?

DESIRED TRAITS

- Subject matter expertise – is in depth knowledge, critical thinking and decision making required?
- Problem solving – is judgement and experience needed to handle complex situations and exceptions to the rule?
- Adaptability – can changes occur frequently requiring quick adjustments in strategy or training?
- Communication and Collaboration – do you need strong relationships to get the task done?

The Result

And the Winner Is…

Our personalities are what make us successful in the eTMF industry – at heart we are a group of TMF Geeks, and AI cannot replace our unique features.

However, AI offers improvements and efficiencies that we should encourage and embrace; acknowledging the benefits to individuals, study teams, and organizations.

It all comes down to having an effective implementation strategy.

Identify Tasks for Automation

- Determine which tasks can be effectively automated and supported by AI, for example document classification, data extraction and other routine checks.

Integrate AI with Human Expertise

- A hybrid approach is best – allowing AI to focus on the mundane, repetitive or routine tasks, allowing the TMF Geek to focus on complex and high-value activities.

Train and Adapt

- Train the TMF Geeks to work alongside the AI tools, ensuring they know how to leverage the outputs and how to integrate them into their day-to-day activities.

Continuous Improvement

- Frequently review and refine AI processes based on feedback from the TMF Geeks and other eTMF end users to ensure continuous improvement and alignment with regulatory changes.

Thank You!