

Introduction



In the pharmaceutical industry, the role of the statistical programmer is critical to transforming clinical trial data into reliable insights thus facilitate quality evidence-based decision making. Indeed, statistical programmers are responsible for creating and providing statistical results at each interim decision-making point, as well as for the conclusion of each clinical trial. They are also responsible for electronic submission of data to regulatory authorities. This role has already evolved (and continues to evolve) over the years, with the **rapid changes in technologies** (multilingual, visualization) and the **regulatory landscape** (CDISC).

How the emergence of the Artificial Intelligence rescans the cards and can help the statistical programmer in this new adventure?

A constant evolution

Over the years, we have already seen significant changes of this job. Indeed, Clinical trials are evolving rapidly, with more focus than ever on time and budget



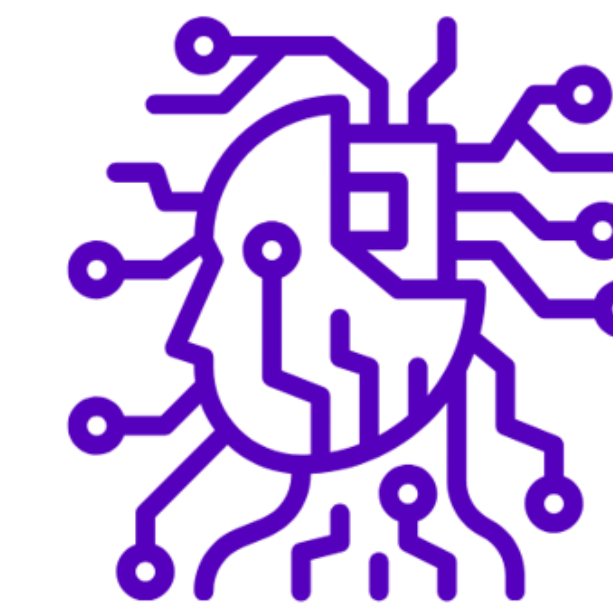
- **Data standards** (CDISC)
- **speed-up in the evolution of health agencies requirements** (like RTOR or Orbis projects)
- **Appearance of new type of parameters** to analyze (such as biomarkers)
- **Emergence of other languages (like R) and data visualization** (like R Shiny)
- In term of drugs, **new technologies are available** (such as antibodies: mono, bi-specific, multi; proteins; nanobodies; enzymes; genetic therapy; RNA; vaccines)
- **New technologies to support the data collection** (devices, wearables, RWE, de-centralization): volume, data quality.
- **Innovative statistics approaches** (Umbrella, Platform, Basket, adaptive design) for better answers to scientific questions and accelerated decision making.

All these changes have required statistical programmers to adapt the way of working, to be less behind theirs screens for only program. These changes have allowed statistical programmers to have more responsibilities, such as leading the electronic submission of the data

The emergence of the Artificial Intelligence (AI)

The impact of artificial intelligence (Natural Language Processing; and particularly Large Language Model) in each job cannot be ignored! The advent of artificial intelligence (AI) has introduced new **opportunities** (and **challenges**) to help us in the race of evolution of the clinical trials. Indeed, AI has the potential to automate some of the tasks performed by statistical programmers (mostly ones in open source, pre-trained models that we can fine-tuned). Nevertheless, **it cannot replace the human/domain expertise and contextual understanding** that statistical programmers bring. The generated content should still be validated by an expert. Statistical programmers still play a crucial role in designing analyses, interpreting results proposed by the machine, and ensuring the validity and context of statistical findings. **The synergy between human judgment and AI capabilities can lead to more robust and insightful outcomes.**

To fully leverage the benefits of AI while addressing the associated limitations, it's important to approach AI development and implementation **with careful consideration of ethical, societal, and practical implications**. Collaboration between all stakeholders (developers, regulatory agencies, business, etc.) is essential to navigate these challenges, limit them and create AI systems that are beneficial and responsible.

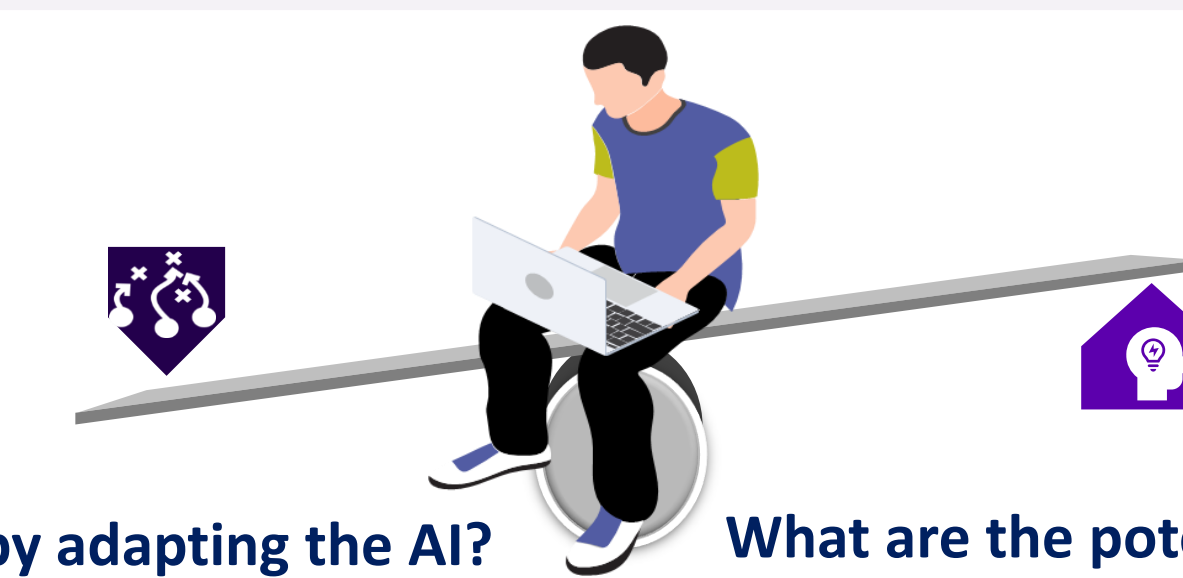


Which type of BENEFITS can we win by adapting the AI?

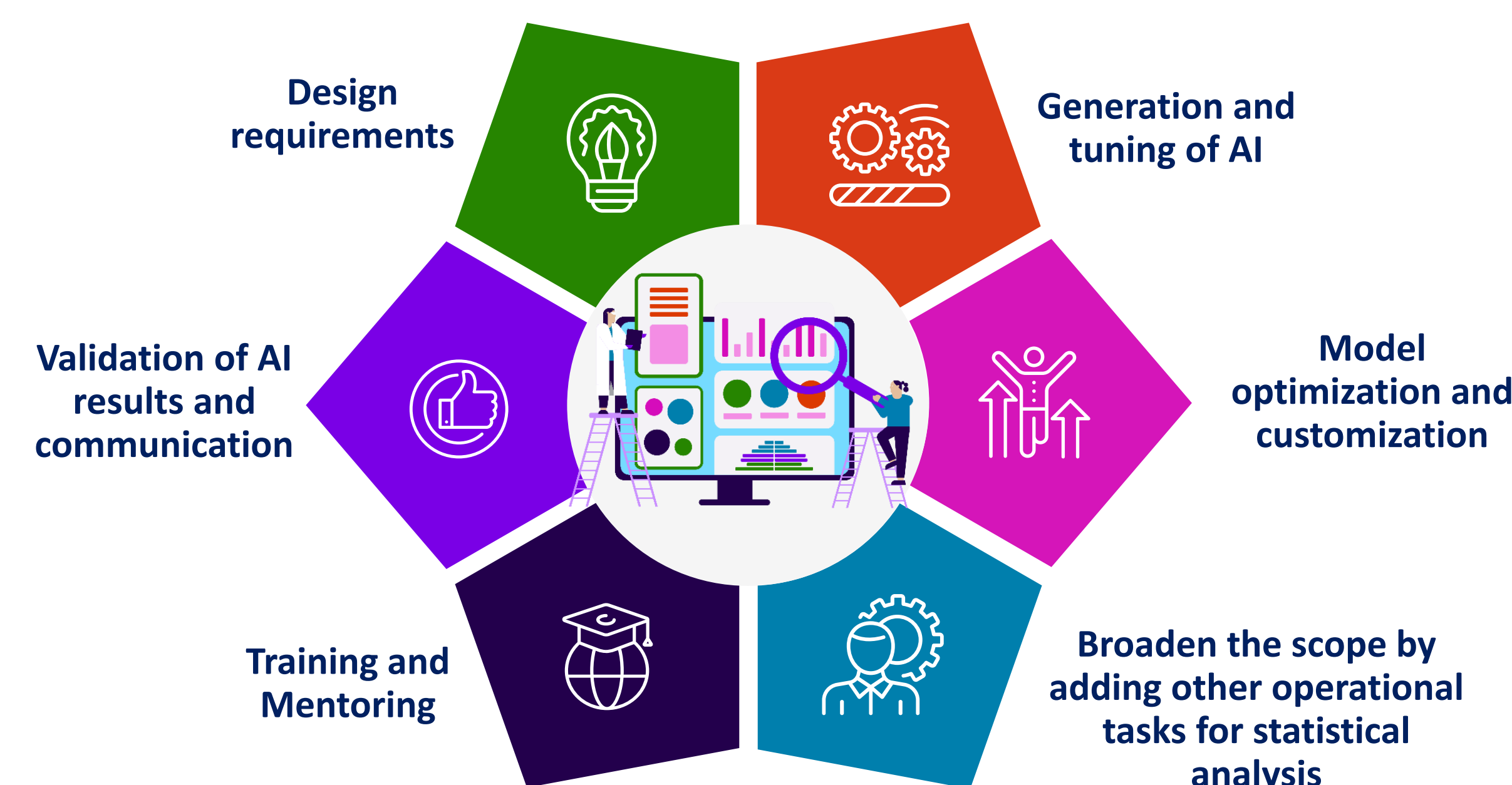
- Automating Repetitive Tasks
- Faster Insights (analyze vast amounts of data)
- Extract information
- Data Visualization and Reporting
- Error Detection and Quality Control
- Efficient Code Generation

What are the potential LIMITATIONS?

- Data dependence (Bias and Fairness)
- Interpretability and Explainability
- Lack of Common-Sense Understanding
- Ethical and Legal Concerns
- High Computational Resource & Cost Requirements
- Unemployment Concerns
- Environmental Impact



What are the possible future tasks?



In essence, the **role of the statistical programmer will evolve into more strategic, creative, and high-impacted activities** where human expertise is crucial for making informed decisions, communicating with other stakeholders, and ensuring the effectiveness and ethics of statistical analysis.

The 12 steps to be prepared

Generative AI comes with a plethora of opportunities to transform our ways of working and enhance our practices. That said, **this disruptive technology would require significant adaptation** : upskilling, engaging, and educating all employees but also supporting change and culture shift; assess and seize any relevant opportunities using thoughtful risk-taking approach:

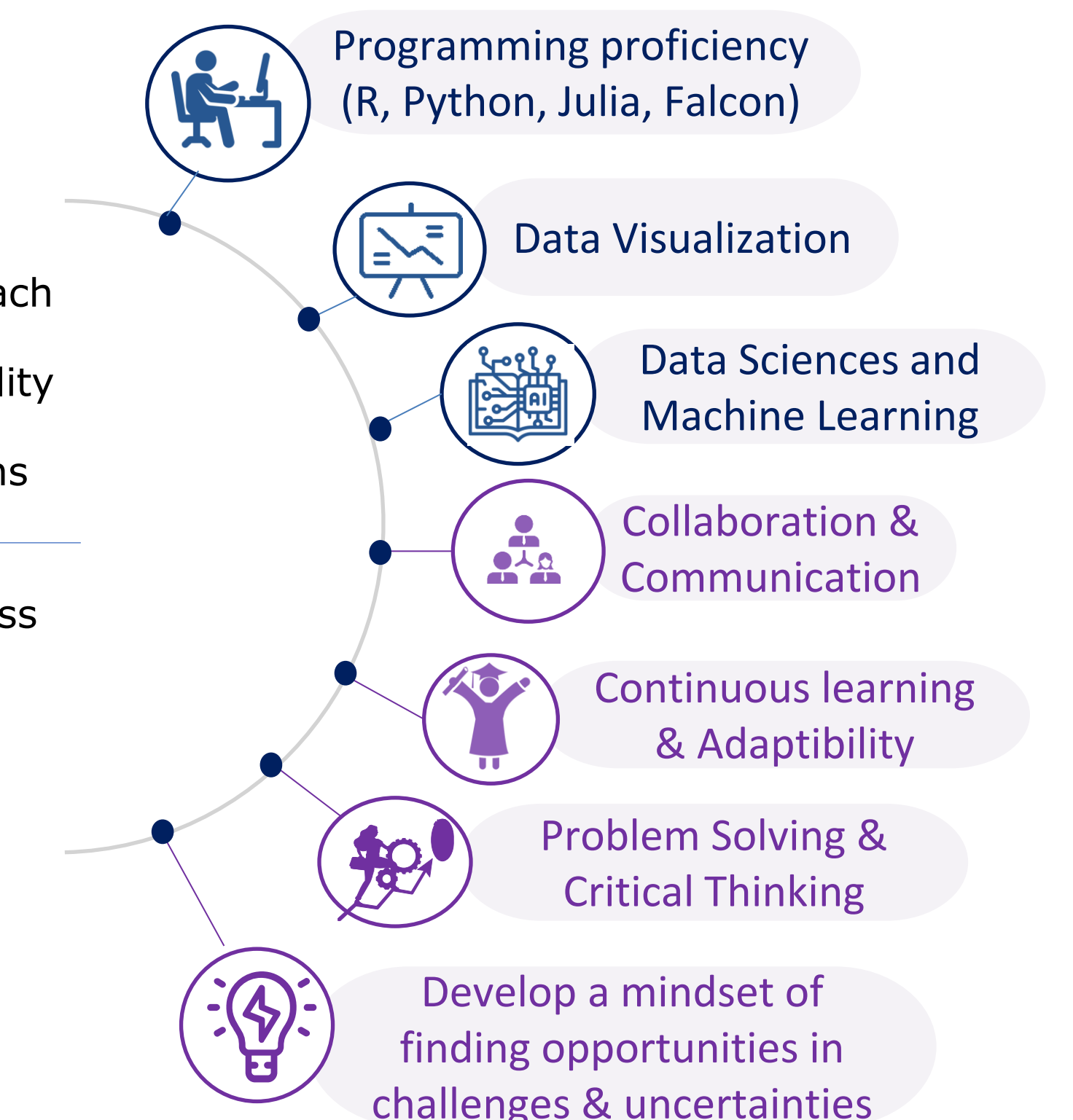
what are the main challenges of AI? How do we think we can maximize its benefits while minimizing risk? Helping a team evolve their jobs in the context of artificial intelligence, especially AI generative technologies, requires a combination of strategic planning, skill development, open communication, and a supportive work environment. Here are some steps a manager and a team can take to facilitate this evolution



By embracing these skills and actively contributing to the data analysis process, statistical programmers can continue to play a valuable role

"In the middle of every difficulty lies opportunity." - Albert Einstein

- 1 Identify Opportunities
- 2 Clear Communication
- 3 Long-term vision
- 4 Experimentation & pilot projects
- 5 Feedbacks loops
- 6 Support & Recognition
- 7 Collaborative approach
- 8 Adaptability & flexibility
- 9 Ethical considerations
- 10 Education & Awareness
- 11 Continuous learning
- 12 Skill Development



Conclusion

The statistical programmer role is undergoing significant evolution, and we **must be proactive in adapting to these changes**. It is essential to stay informed, upskill ourselves and prioritize effective communication and time management. **Evaluating the impact of AI on a job requires a holistic approach that considers both quantitative and qualitative aspects**. It's essential to involve everyone in the evaluation process and maintain open communication to address any challenges or concerns that arise during the transition

We are at the beginning of the AI area, **a lot of challenges, questions are there**.

Lastly, **humans must be in the loop and use their judgement**. Users must be able to identify when a response is erroneous as using outputs without verifying the contents can result in potentially dangerous misinformation. **Generative AI is not a replacement for critical thinking**. Statistical programmer must be trained in how to engineer prompts, identify bias in content generate, and in the traceability and accountability of the use of generative AI-created content. **Up-skilling and partnerships will be needed to successfully adopt generative AI**.

My wish: human will develop an AI eco-responsible, without destroying ourselves

