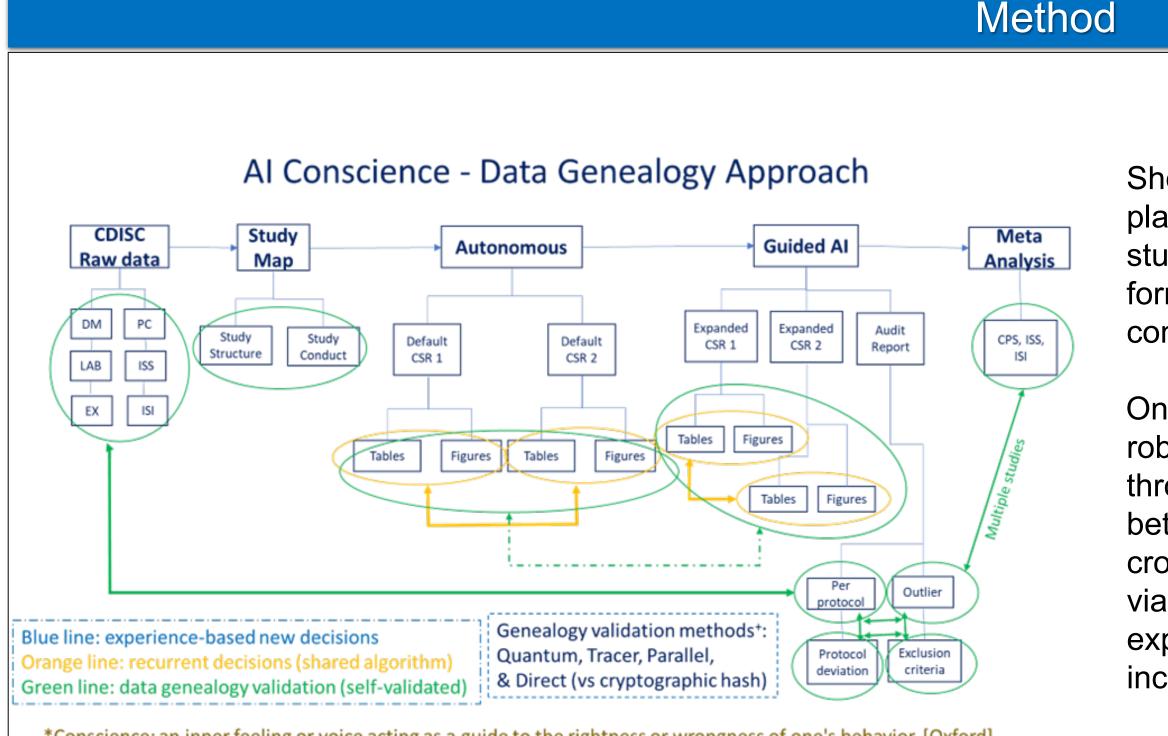


Add conscience to a Generative AI platform, achieving Responsible AI for clinical R&D Peter Lee, Le Wang, Gunjan Gugale, Urvashi Somani, Nayeem Hossain OCP, OTS, CDER, FDA

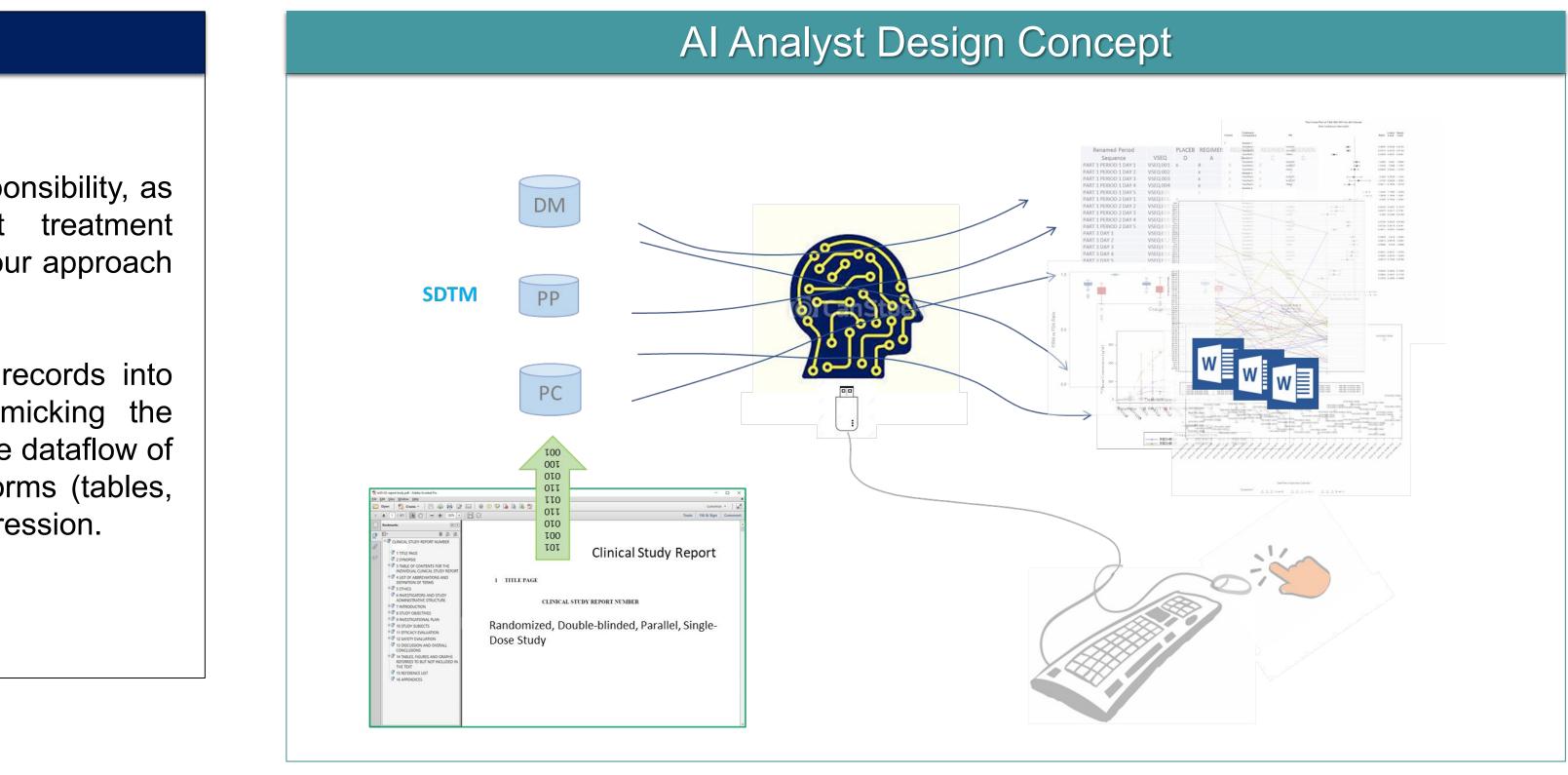
Introduction

For the past few years, we have been developing solutions to address AI responsibility, as clinical decisions based on Al-generated results could affect treatment the recommendations for many patient populations. In this poster, we will share our approach to achieve Responsible AI by adding "conscience" to a Generative AI platform.

The AI Analyst platform autonomously transcribes millions of clinical data records into comprehensive reports summarizing the clinical study outcomes, by mimicking the clinician's thinking process. A data genealogy chart can be used to illustrate the dataflow of the AI platform, where each data block consists of different morphological forms (tables, figures, and reports) to express the raw data, a concept analogous to gene expression.



*Conscience: an inner feeling or voice acting as a guide to the rightness or wrongness of one's behavior. [Oxford]



Shown on the right is the data genealogy chart of the AI Analyst platform, which generates clinical reports autonomously from study raw data. Each block consists of different morphological forms (tables, figures, and reports) to express the raw data, a concept that is analogous to gene expression.

One approach of creating AI conscience is to ensure the robustness of data genealogy, i.e. the data integrity is preserved throughout all decision-making steps (blue line in the chart) between raw data and final reports. In addition, the AI should cross-validate (green line in the chart) different reports generated via separate workflow paths, which can be thought of as different expression of the raw data. The validation methods we adopted include Quantum, Tracer, Parallel, Direct, and Cryptographic.

- generate the reports.
- experiences.
- capacity of conscience.





Conclusion

> The AI platform has been utilized for hundreds of drug submissions and more than 1200 clinical studies to dated.

 \succ Each submission is a brand-new experience for the AI, and it would use its accumulated SME thinking learned and programmed from the previous cases to

 \succ Inevitably, some new scenarios would not fall into any of the previous

 \succ In these cases, the AI is able to tell the right or wrong outputs and identify the potential issues, hence possessing some