U.S. FOOD & DRUG ADMINISTRATION

Leveraging Generative AI (GenAI) to Support Regulatory Assessment

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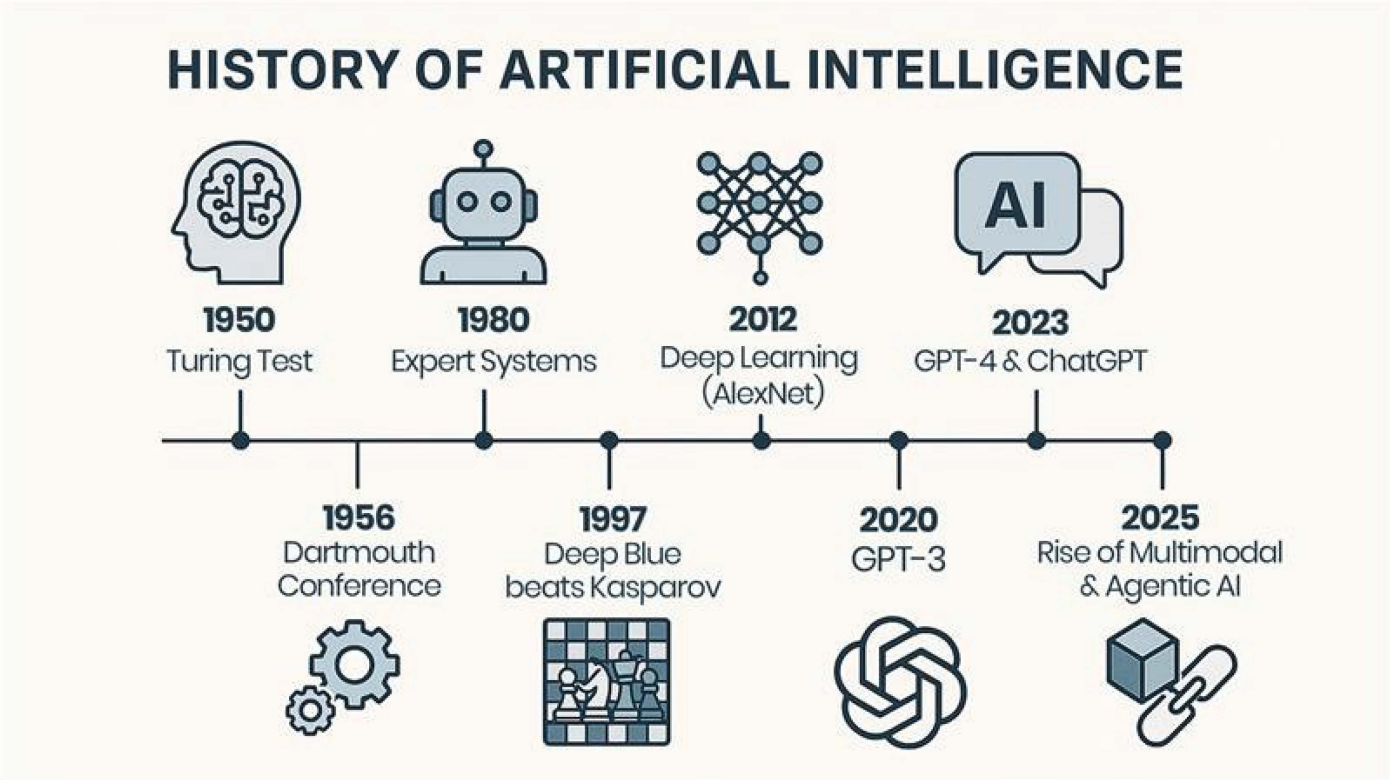
AI is NOT a New Concept

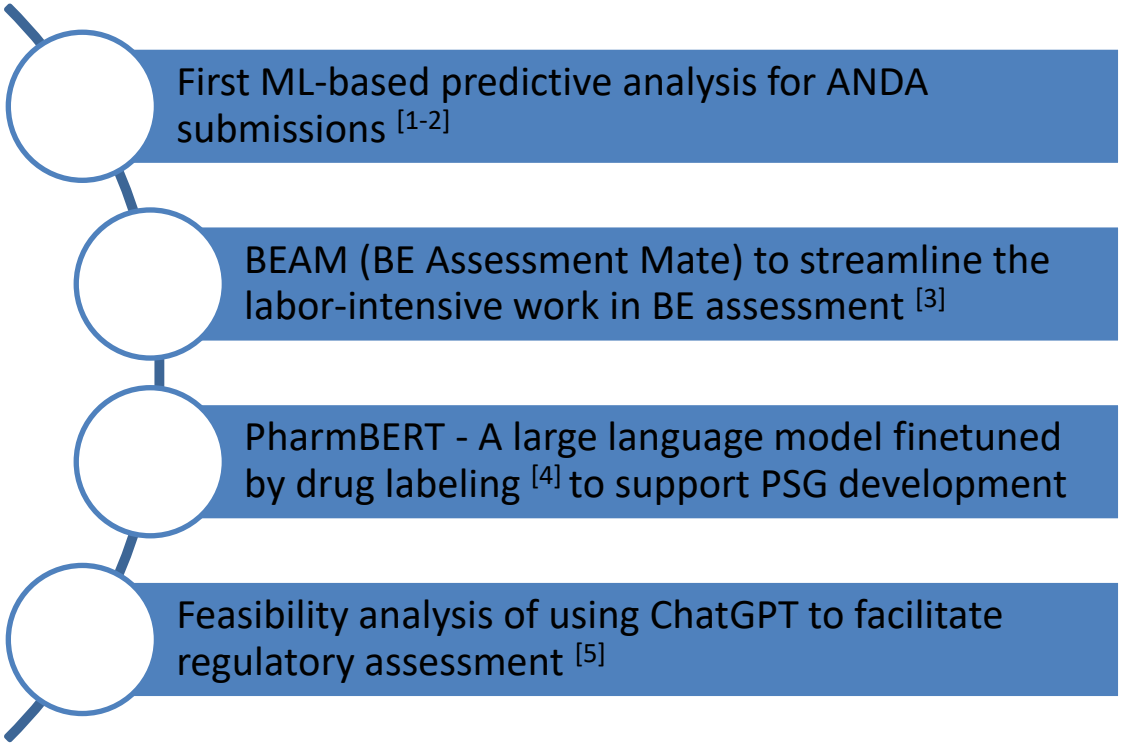


Geoffrey Hinton

https://en.wikipedia.org/wiki/Geoffrey_Hinton

Previous AI Efforts in OGD

Highlighted AI Research Projects



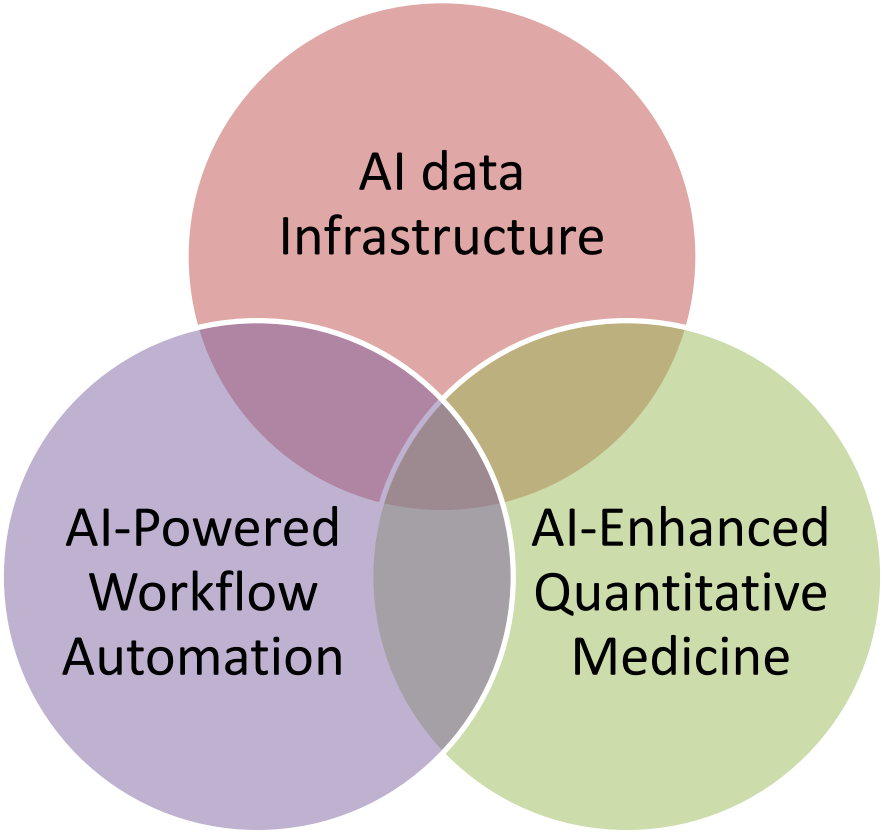
ML – Machine Learning
PSG – Product-Specific Guidance

[1] Gong, et al. Clin Transl Sci (2018) 11, 305–311; [2] Hu, et al. Clin Pharmacol Ther. 2019;106(1):174-181; [3] OGD 2021 Annual Report; [4] ValizadehAslani, et al. Briefings in Bioinformatics, 2023, 1–10; [5] Shi, et al. Journal of Biomedical Informatics 148 (2023)104533.

GenAI – Ushering in a New Era of Creativity

- Bridges the gap between humans and machines
- Ignites fresh ideas while eliminating repetitive tasks
- Drives workflow automation for greater efficiency, consistency, and quality

AI strategy and initiative



AI Data Infrastructure

- Reliable data as the foundation of AI success
  - Ensuring accuracy, completeness, and consistency
  - Data standardization and seamless integration across varied sources
- Advanced information retrieval methods to quickly access relevant datasets and knowledge
  - Efficient indexing and metadata tagging
  - AI-powered knowledge extraction
  - User-friendly query interfaces

A Pilot PK Data Warehouse (PDW)

- Curated and executable PK datasets
  - Metadata
  - Sufficient supportive information from multiple data sources
- Ongoing efforts
  - Historic old applications
  - Newly submitted applications

Use Cases
(significant time- and labor-intensive work reduction)

Data integrity check: gathering all PK datasets for the drug product of interest to understand the data patterns within and cross the applications, potentially flagging out suspicious data and signals.

Meta analysis to support regulatory assessment: efficiently providing requested PK datasets to address regulatory needs or questions, such as
- Cross-study analysis
- BE criteria examination

PDW: Potential Queries or Uses

Query by ***specific formulation design***

Ex: Compiling in vitro dissolution and PK data of products using a certain formulation design?

Query by ***CRO***

Query by a ***clinical study site(s)***

Query by a ***clinical study design***

Query by ……

CRO - Contract Research Organization

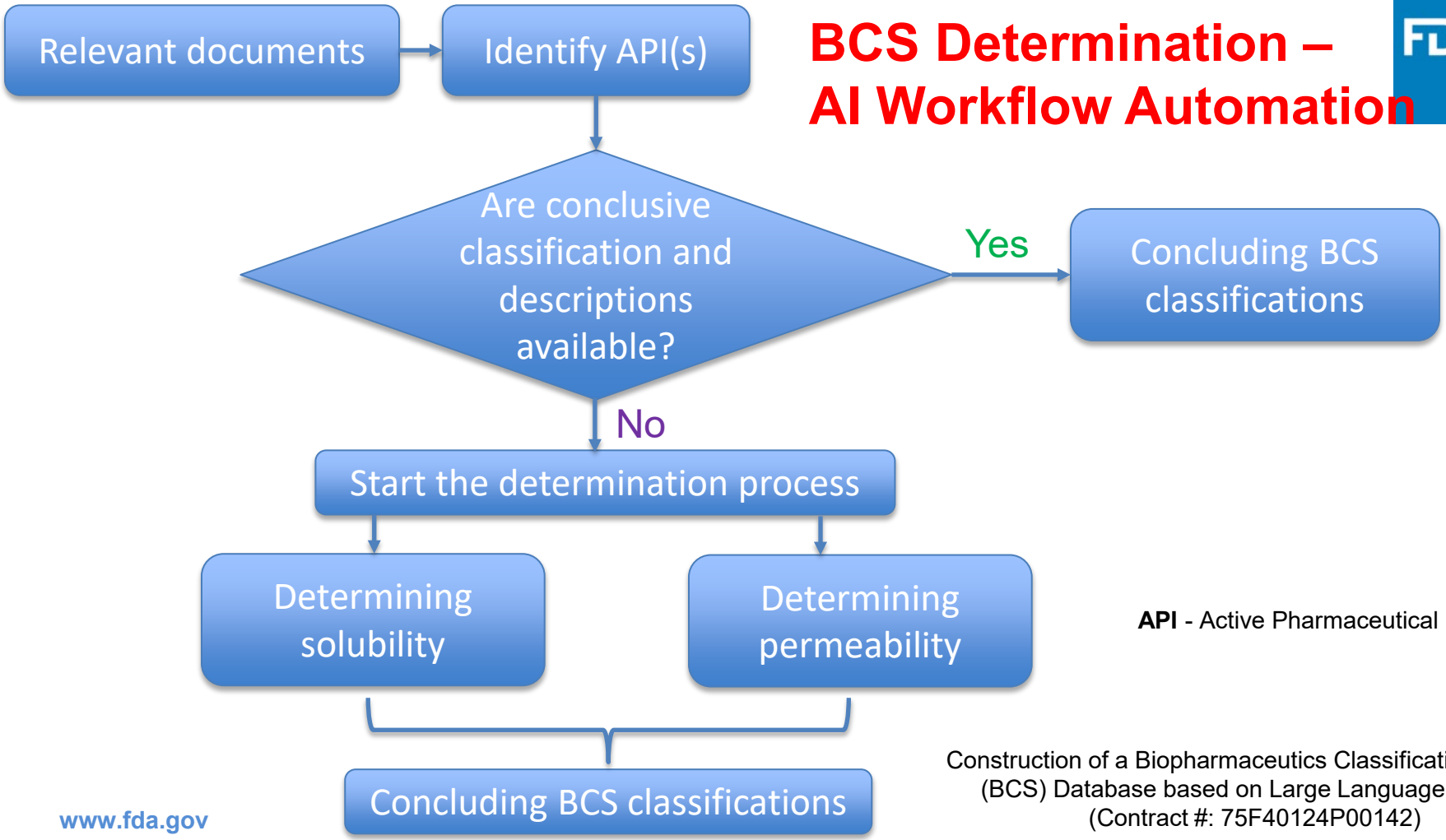
AI-Powered Workflow Automation

- Defining domain-specific workflows aligned with regulatory and scientific needs
- Translating workflows into clear business requirements to guide AI-driven automation
- Developing and deploying AI tools to implement workflows efficiently, consistently, and reliably

An AI Tool for BCS Determination

- BCS classification provides critical information for regulatory assessment and decision-making, including biowaiver considerations.
- No comprehensive BCS database currently exists to support generic drug assessment, and manual BCS extraction is time-consuming and labor-intensive.
- An AI-powered tool for automated BCS determination, with supporting references and reasoning, would greatly enhance regulatory assessment and accelerate the database construction.

BCS Determination – AI Workflow Automation



API - Active Pharmaceutical Ingredient

Construction of a Biopharmaceutics Classification System (BCS) Database based on Large Language Models (Contract #: 75F40124P00142)

Current Progress

- The developed AI tool is currently undergoing internal validation.
- The tool will be used to facilitate the construction of a BCS classification database.
- The extracted data supporting BCS determination will significantly enhance quantitative model development.

More Ongoing Projects for Workflow Automation

- Pre-ANDA review
- Formulation assessment
- PSG (Product-Specific Guidance) development
- CC (Controlled Correspondence) assessment

Performance Evaluation

- The AI automation tools are designed to support, **not participate in**, the decision-making process.
- They enhance workflow efficiency by automating labor-intensive steps.
- They accelerate the collection and curation of information to better support FDA reviewers.
- Their performance depends primarily on the accuracy and completeness of the information retrieved.

AI-Enhanced Quantitative Medicine

- Resource and expertise gaps in modeling and simulation (M&S) remain a challenge for the generic drug industry.
- AI is transforming quantitative medicine modeling through AI-assisted model development.
- AI can lower entry barriers by making advanced modeling approaches more accessible and less resource-intensive.
- AI-driven tools enhance efficiency and scalability, enabling broader adoption of M&S in generic drug development.

PyDarwin: a ML-Enhanced Automated Population PK Model Building Toolbox

- Traditional model selection often relies on stepwise methods that are trial-and-error and frequently miss the true optimal model.

- PyDarwin uses machine learning (ML) to conduct a robust, global search across large model spaces for model selection.
  - Reduces labor-intensive, trial-and-error modeling
  - Improves both speed and reliability
  - Released as an open-source Python package to promote broader adoption, transparency, and collaboration in both academic and industry settings.

Development of a model selection method for population pharmacokinetics analysis by deep-learning based reinforcement learning (1U01FD007355)

Takeaways

- The usability of AI tools relies on:
  - Data infrastructure
  - Information retrieval ability
  - Understanding of domain knowledge
  - Workflow automation by the agentic AI system

- Successful AI tools will significantly facilitate high-quality and efficient regulatory assessments.

THANK YOU