



## *Use of Data Science & Digital Technologies in Regulatory Affairs*



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# Agenda

- Opportunity of Data Science & Digital Technologies
- Digital Technologies in Drug Development – selected case studies



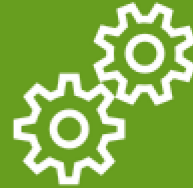
# Opportunity of Data Science & Digital Technologies



# Advances in data science and digital technologies are contributing to a changing landscape in pharma



Mobile Apps



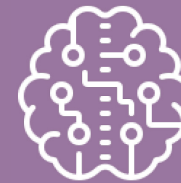
Automation



Digital Diagnostic Tools



Wearables

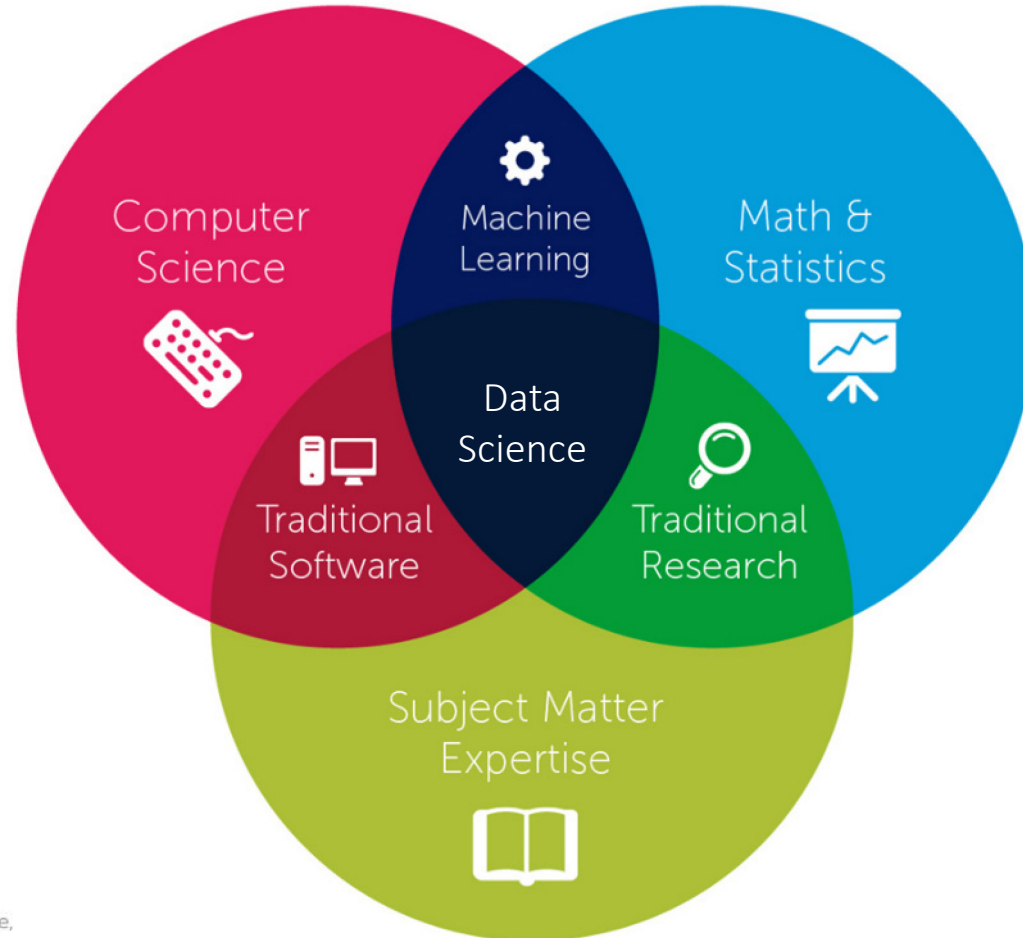


Artificial Intelligence



# What is data science?

Interdisciplinary field focused on extracting insights from data



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# Data science uses a range of technologies to solve increasingly complex challenges in a data-driven manner









## Advanced Analytics



## Machine Learning



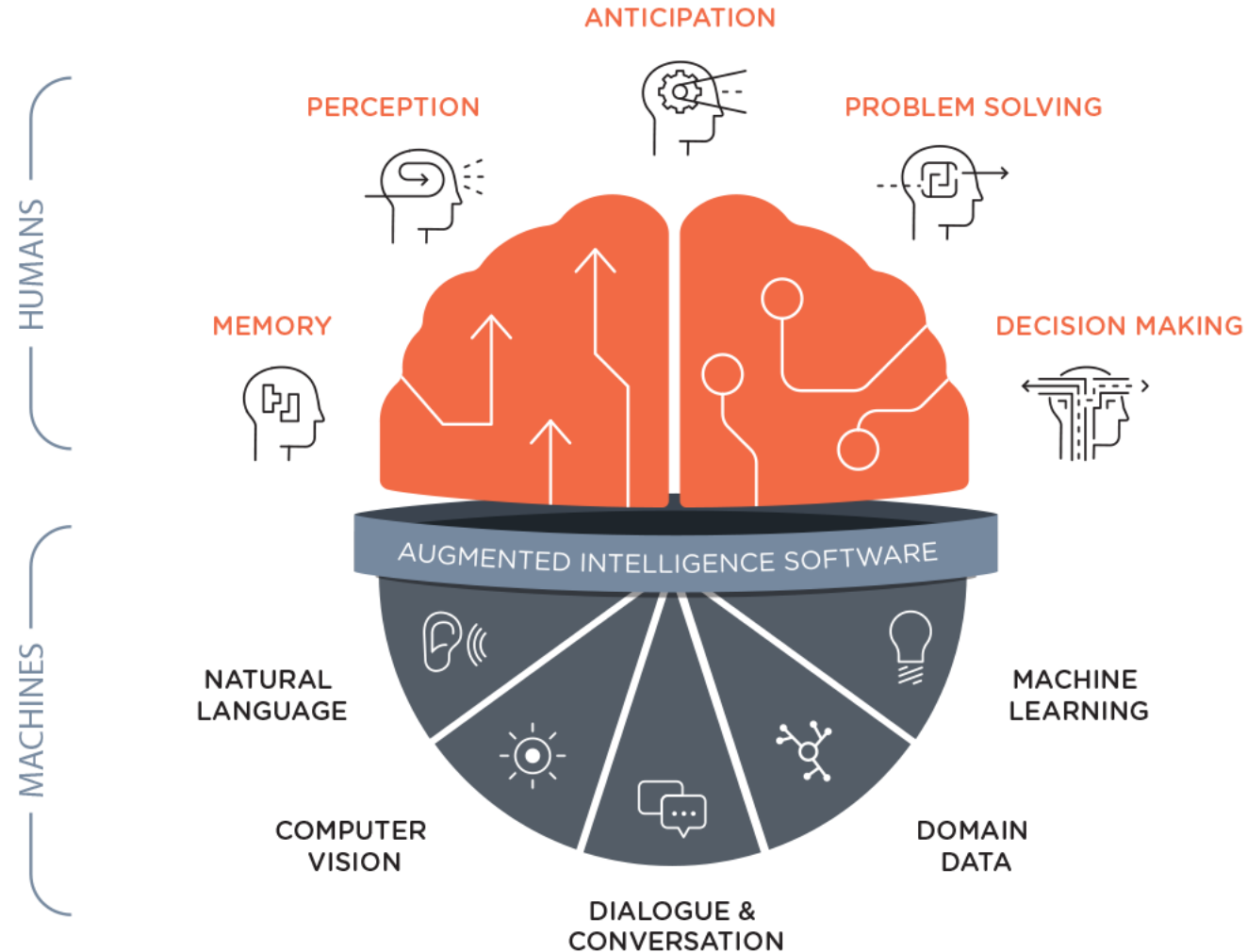
## Artificial Intelligence

Definition	Data science is an interdisciplinary field of scientific methods, processes, algorithms and systems to extract knowledge or insights from structured or unstructured data <sup>1</sup>	Machine learning is a field of computer science that gives computer systems the ability to “learn” (i.e., progressively improve performance on a specific task) with data, without being explicitly programmed <sup>2</sup>	The study and design of intelligent (computer) systems which perceive their environment and take actions which maximize their chance of success <sup>3</sup>
Example	The analyst/statistician will tell how many percent of patients with identified symptoms have specific disease	Based on patient symptoms, the system will predict the type of disease. Prediction gets more accurate over time	Based on patient symptoms, the system will predict the type of disease and suggest suitable treatment to patient
Final Outcome/ Application	 Insights 	 Prediction 	 Action 



# Data science can augment human intelligence

Leveraging strengths of machines and humans results in increased effectiveness



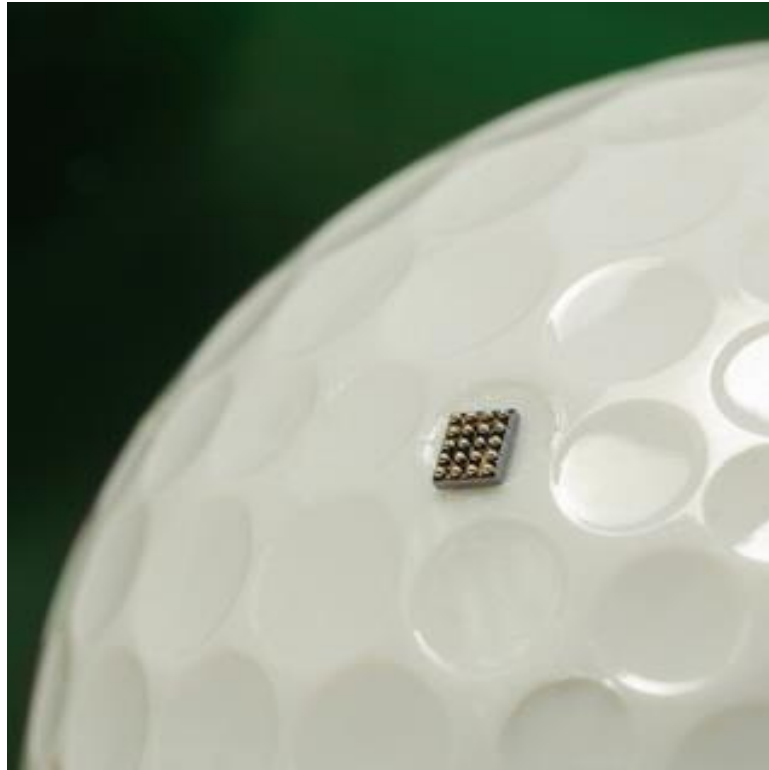


# Why now?

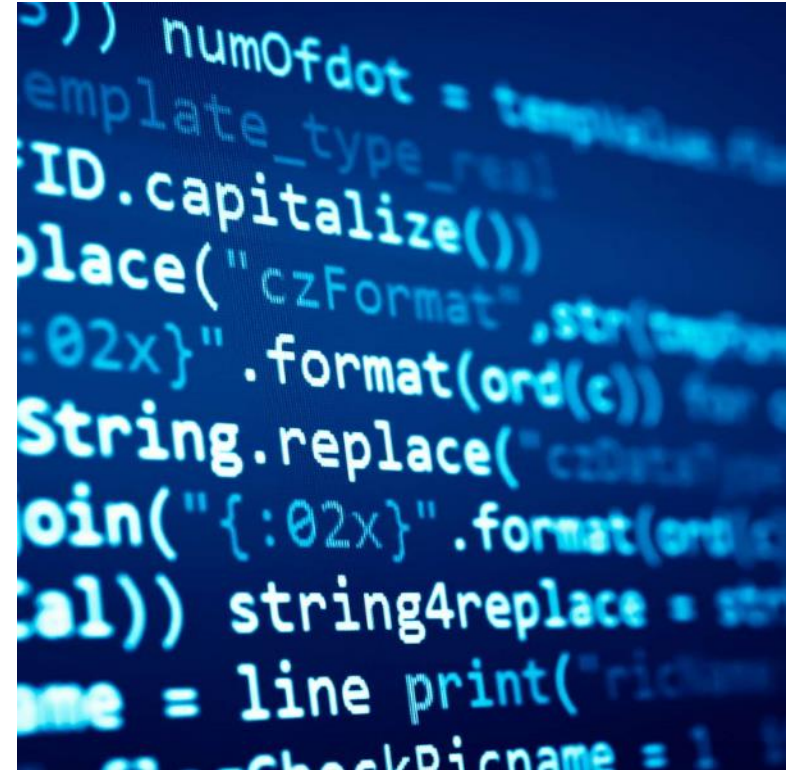
Several factors fueling recent advances in artificial intelligence



Increasing volume of data



Faster, cheaper processing



Smarter algorithms





# Digital Technologies in Drug Development – selected case studies



Technology is helping drug development stakeholders in several ways:

1

**PHYSICIANS**

supporting diagnosis of diseases through image analysis

2

**PATIENTS**

facilitating use of drugs by providing information and reminders

3

**REGULATORY AFFAIRS**

supporting development strategies and compliance by analyzing regulatory environment and decisions



# Bayer is developing artificial intelligence software to help physicians diagnose CTEPH through pattern recognition



- Software will use deep learning to support radiologists by identifying signs of CTEPH in computed tomography pulmonary angiography (CTPA) scans
- Software processes image findings of cardiovascular, lung perfusion and pulmonary vessel analyses in combination with the patient's history of pulmonary embolism
- Software could be deployed via Bayer's Radimetrics™, an informatics technology platform that connects contrast medium with injector and scan information to provide important insights
- Received FDA's Breakthrough Device Designation in 2018



# An alternate solution to help women manage a flexible dosing regimen for contraception

2



- Contraceptive with a flexible dosing regimen
- App guides women through the flexible regimen, allowing women to decide when to have their menstrual bleeding and what to do in case of missed pills
- Contains complete labeling of product
- Package refers patients to download the app



# Technology is helping Bayer monitor the regulatory context and requirements

3



Updates on regulatory context & requirements

- News (press, speeches, etc.)
- Laws, regulations, guidance



Communicated through a dashboard & newsletter

- Automatic monitoring of relevant sources and topics



Can increase efficiency

- Reduced manual effort for monitoring
- Improved information flow for users

# Technology is also helping Bayer better understand regulatory decision making



## Analysis of regulatory precedents

- Clinical trial information
- Regulatory assessment reports
- Competitor labels



## Supported by a data science research tool

- Designed to answer many types of questions



## Can enable faster & better decision making

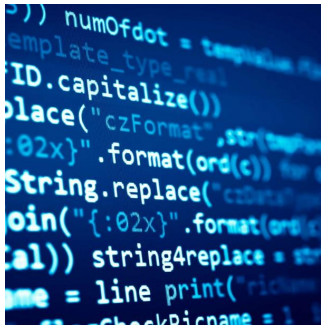
- More efficient search
- New insights can help increase efficiency of drug development
- Improved prediction of challenges and regulatory approval



## Future outlook



**Data** from an even broader range of data sources will be utilized to inform decision making



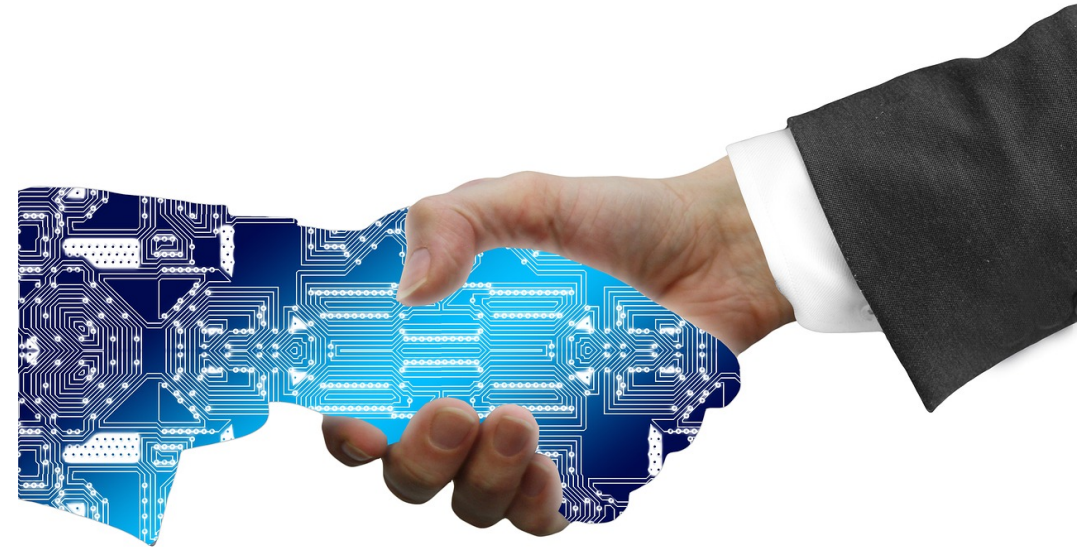
**Algorithms and processing power** will continue to advance rapidly



Data science and digital technologies will be applied to additional use cases, which will help bring **innovative treatments to patients faster**

# What impact will machine learning have on jobs?

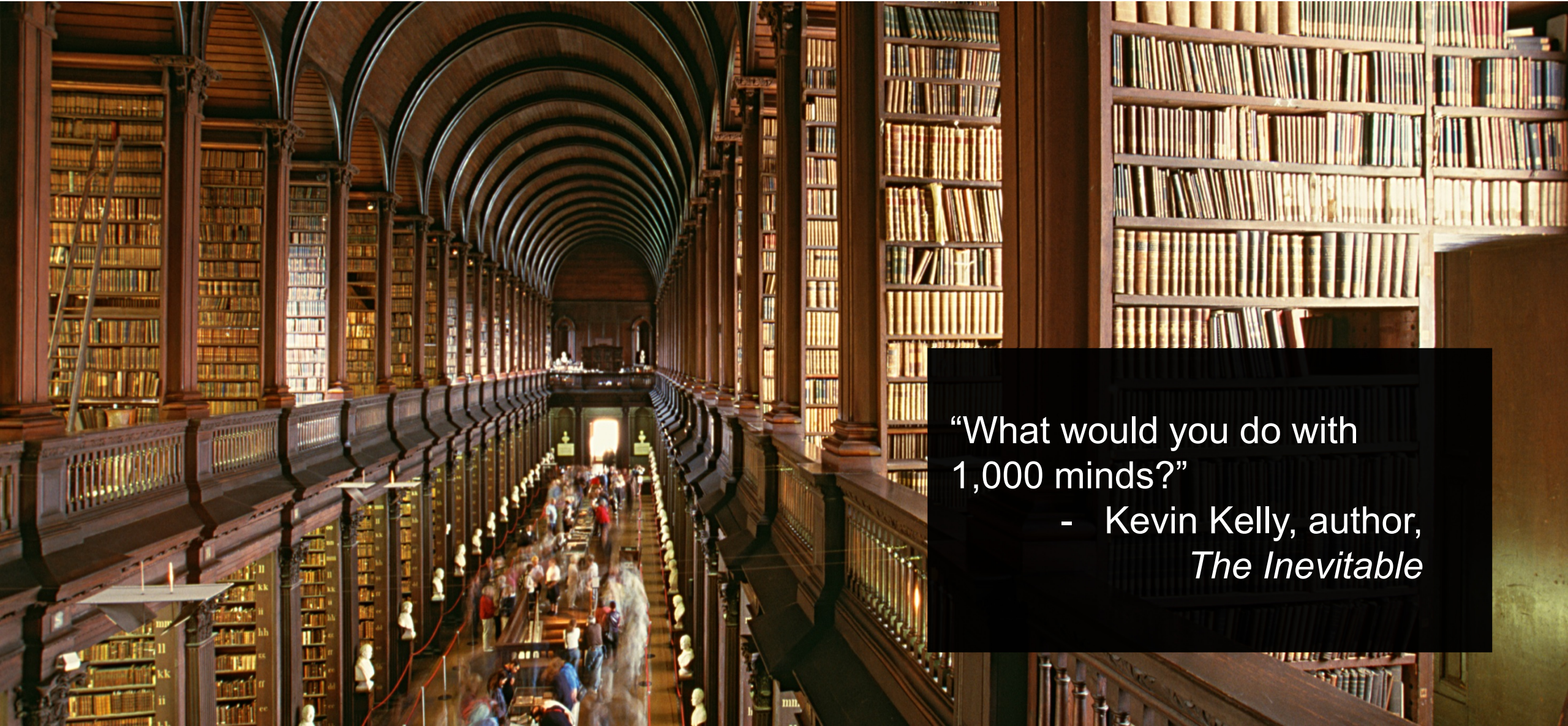
- Substitution – may **substitute for humans** in some tasks
- Price elasticity – may **lower cost of certain tasks**, which could impact spending
- Complementarities – demand for **other tasks may increase**
- Income elasticity – **compensation may increase** for tasks in high demand
- Elasticity of labor supply – as wages change for specific task, **number of workers changes**
- Business process redesign – **processes will change** to increase efficiency







# AI technology has potential to augment Regulatory Affairs knowledge, resulting in increased efficiency



“What would you do with  
1,000 minds?”  
- Kevin Kelly, author,  
*The Inevitable*



# Summary

- Data science uses a range of technologies to solve increasingly complex challenges in a data-driven manner
- Physicians, patients, regulatory affairs colleagues, and regulators are using digital technologies to transform how they engage at several stages of the drug development process. These technologies represent a significant opportunity to increase the efficiency and effectiveness of drug development.
- Collaboration & trust will be critical as stakeholders look to apply data science and digital technologies to address additional challenges in drug development



*Thank you!*

