



Artificial Intelligence in Drug Development and the Impact on the Future Workforce

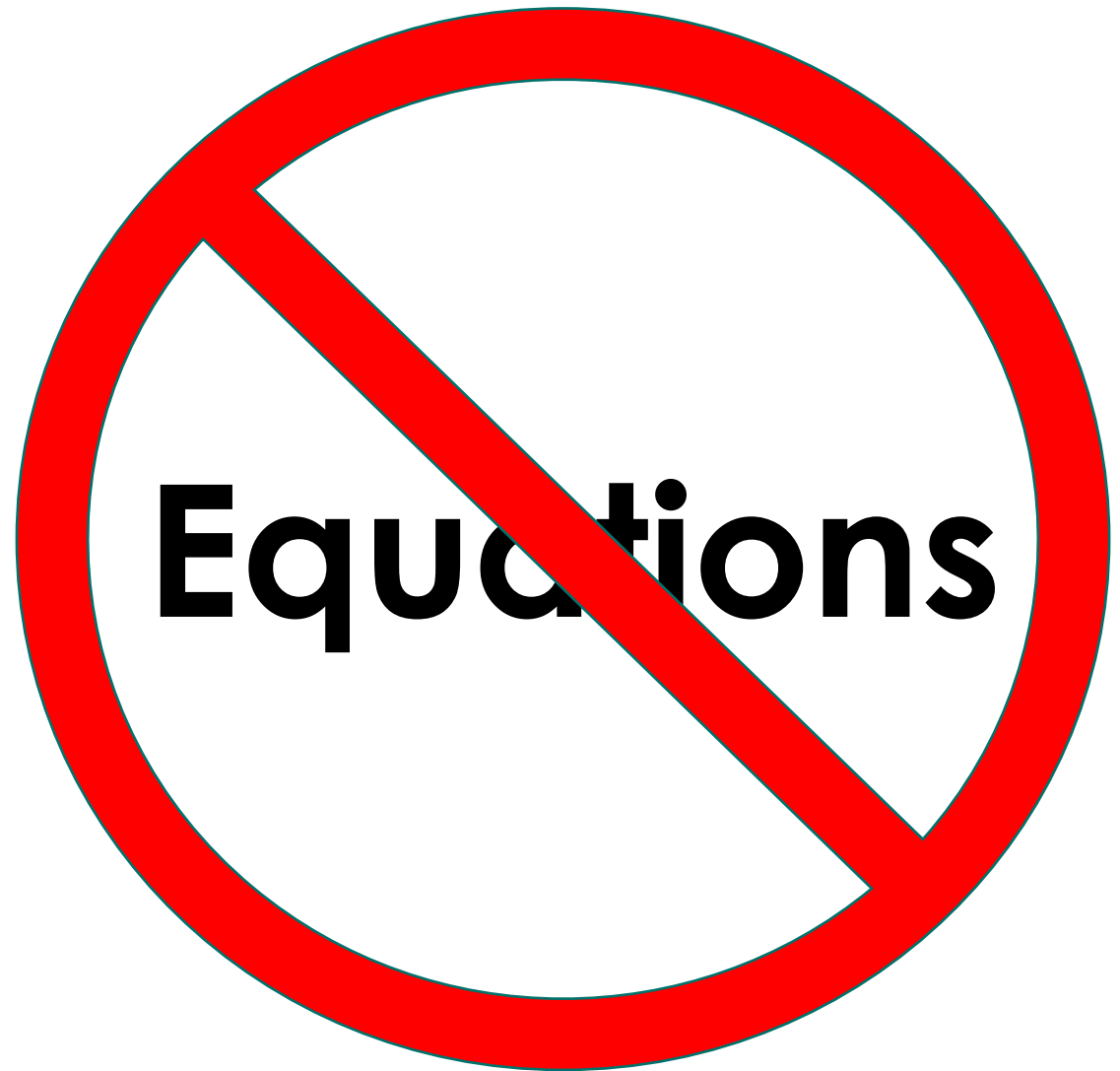
October 25, 2023

Brandon Higgs, PhD
VP, Head of Translational Data Science



Background on AI

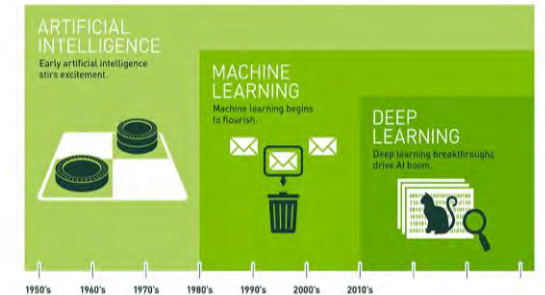
A brief primer



Introduction to AI

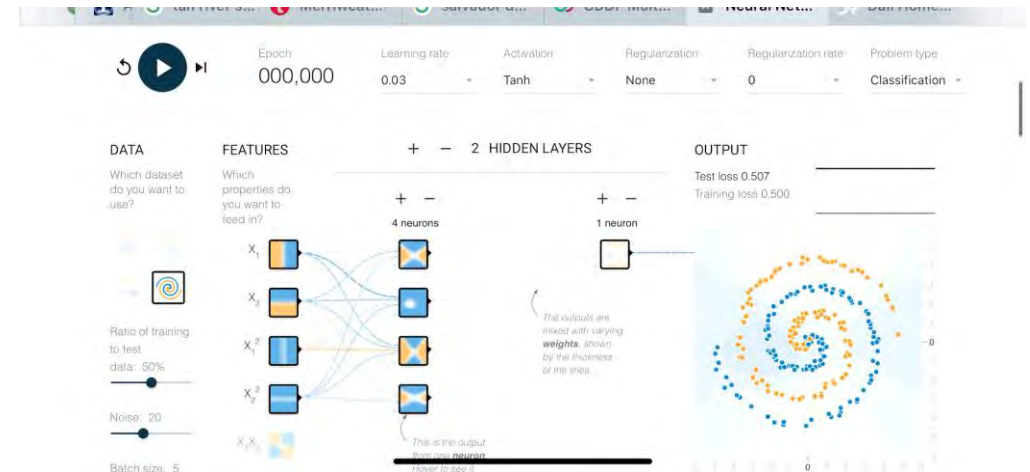
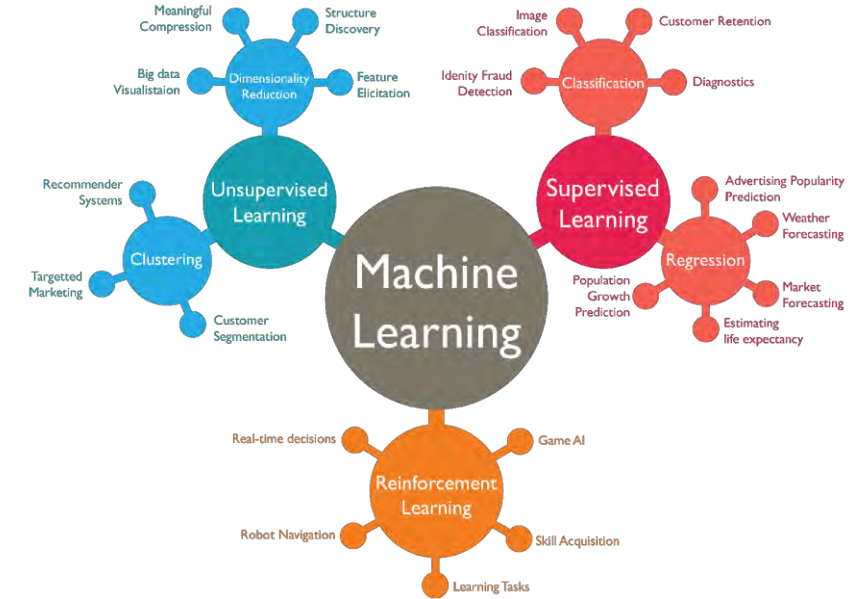
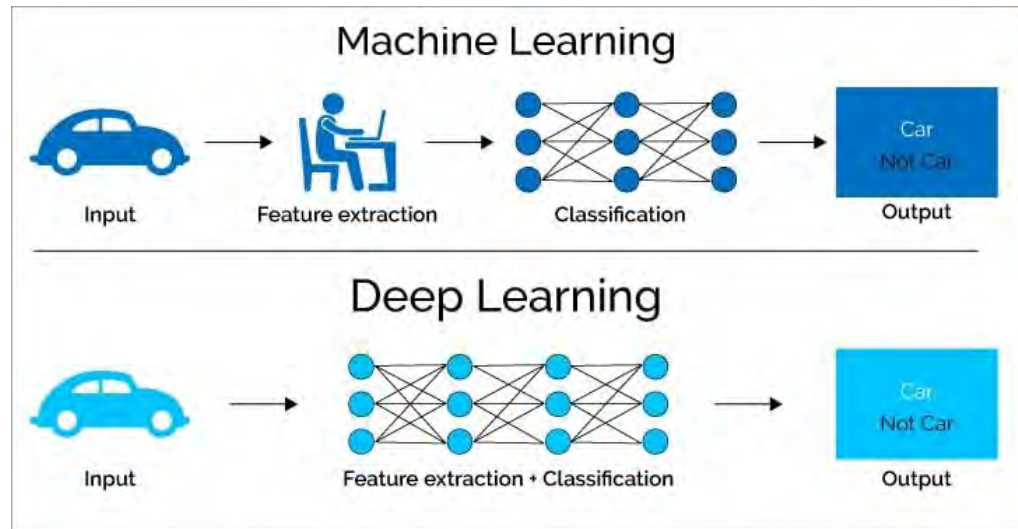
A brief background

- Definition of Artificial Intelligence (AI):
 - The simulation of human intelligence in machines that are programmed to think, learn, and perform tasks independently
 - Strive towards consciousness and sentience
- Origins of AI:
 - Dartmouth Conference in 1956, AI pioneers Alan Turing and John McCarthy
- Key Milestone:
 - IBM's Deep Blue defeating Garry Kasparov in chess, 1996-97



Machine learning vs. Deep learning

Related, but distinct disciplines

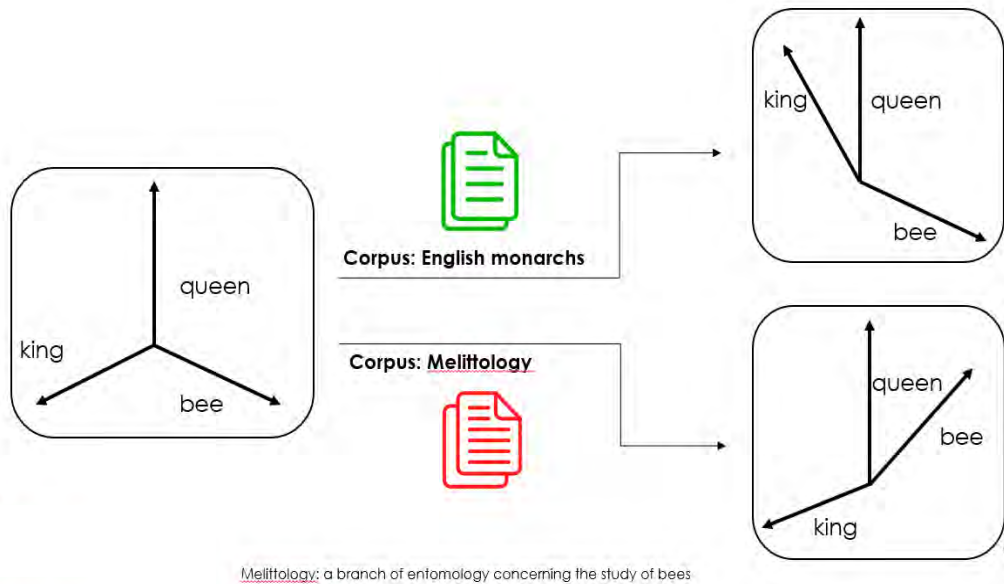




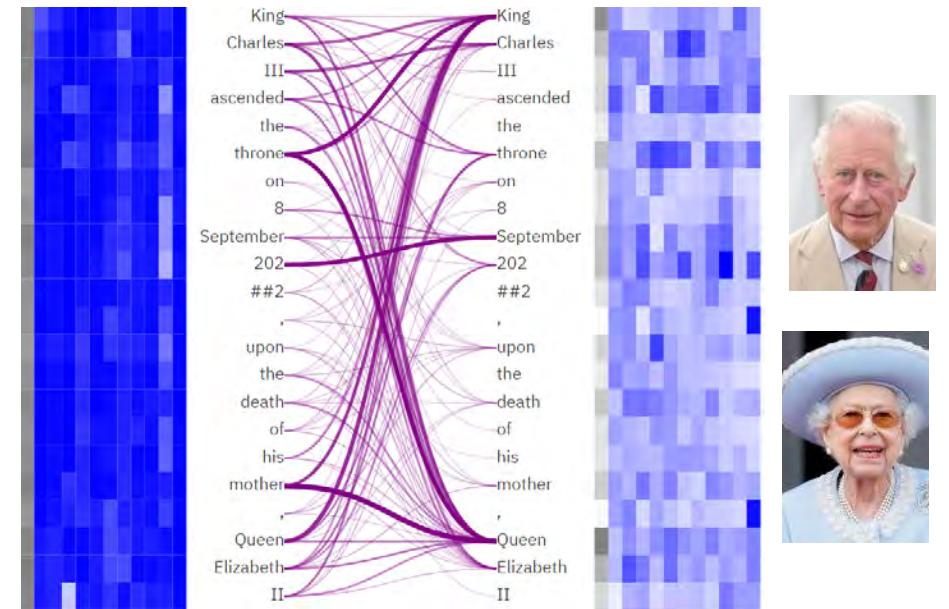
Large Language Models (LLMs): A very quick introduction

Sentence: “King Charles III ascended the throne on 8 September 2022, upon the death of his mother, Queen Elizabeth II”

Words are related based on document context

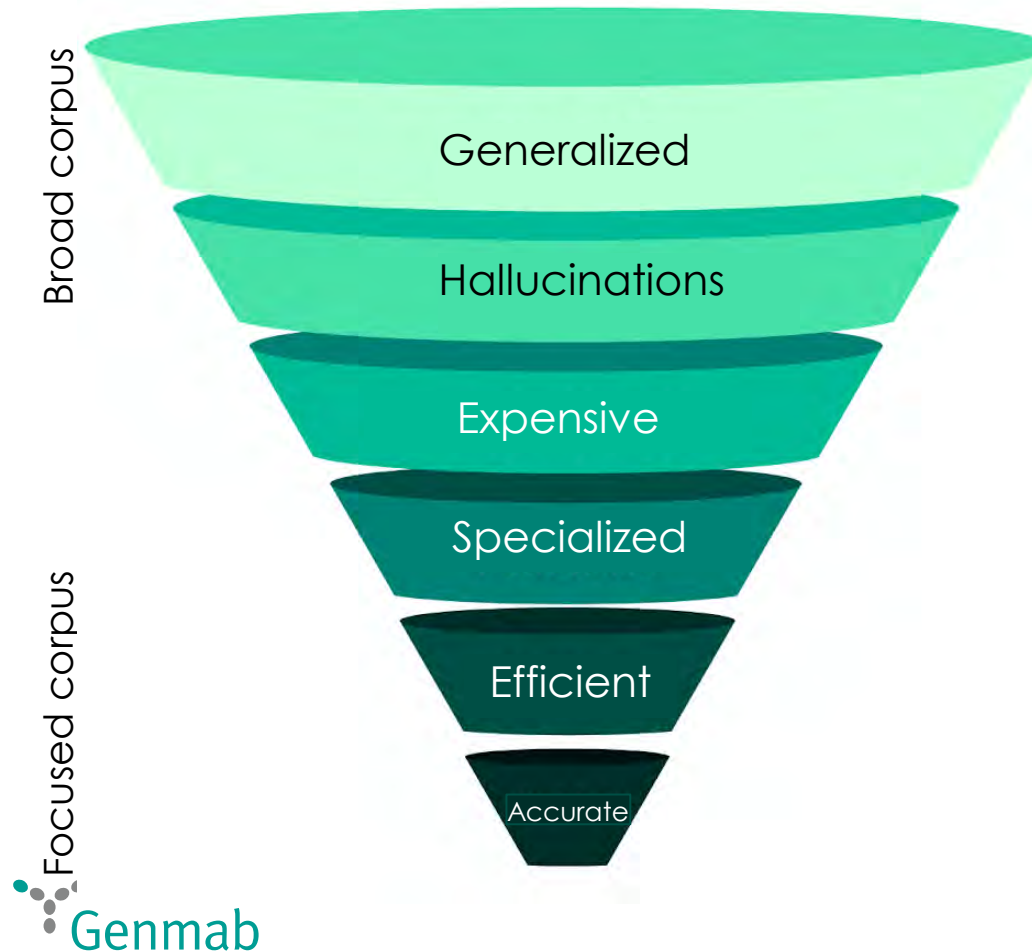


Words are related based on sentence context

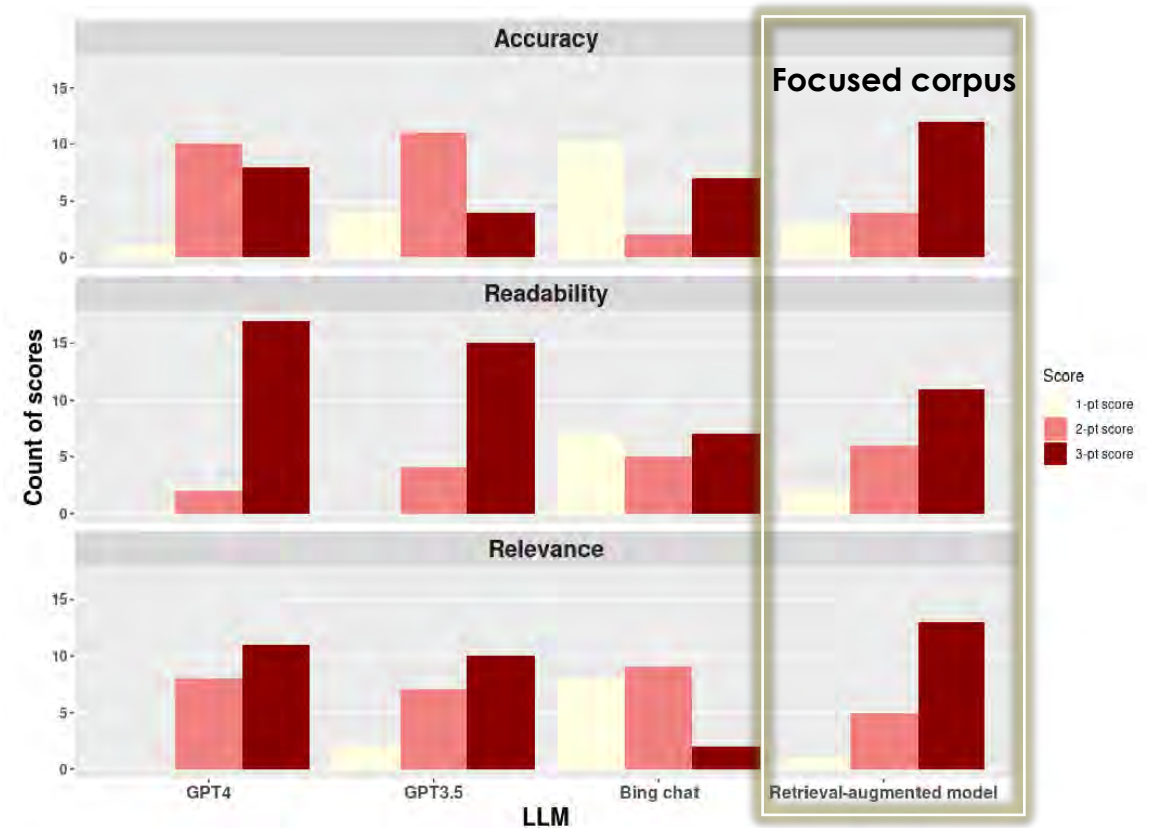


Context matters for training or fine tuning LLMs

A focused corpus versus a broad corpus



Comparison between GPT3.5, GPT4, Bing, and a focused corpus





Can a neural network learn to recognize doodling?

Help teach it by adding your drawings to the [world's largest doodling data set](#), shared publicly to help with machine learning research.

Let's Doodle!

AI
Experiment

Google

RTutor Home Data Report EDA Ask About

airquality No file selected Reset

Upload a file or use demo data. Then just ask questions or request analyses in English or other languages. For general questions, briefly explain the data first, especially the relevant columns. See examples above. If unsuccessful, try again with the same request or ask differently. Code works correctly some of the times. To use voice input, click Settings.


Python

OpenAI charges 2¢ per 1000 tokens/words from our account. Heavy users please use your own account. See Settings.

Slava Ukraini!

Comments & questions

RTutor.ai 0.94



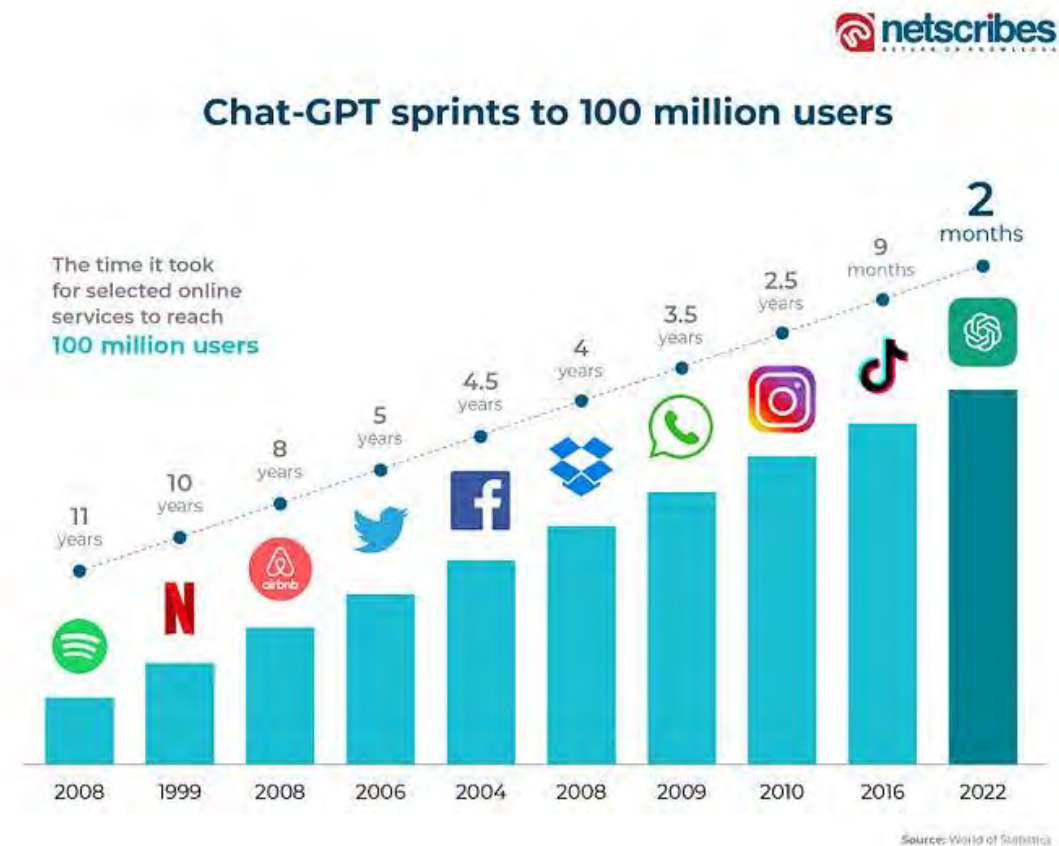
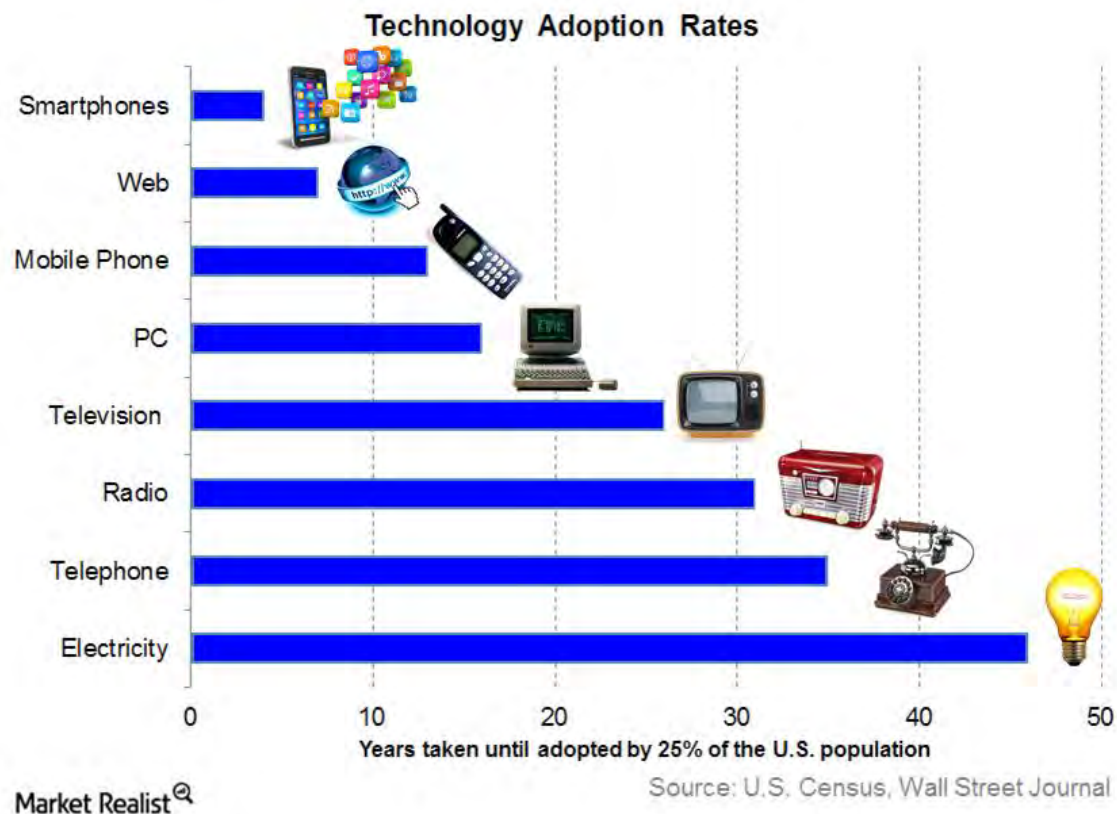
Chat with your data in dozens of human languages. I am still in college learning new things. But I try to be helpful. I did finish my required reading: thousands of books, millions of code repositories, and billions of web pages.

Instructions:

- Start small. Gradually add complexity. First, try simple requests such as distributions, basic plots, or simple models. Then customize it or add variables.
- Releases as a prototype, it is still being developed. Please send us your valuable feedback (lower left).
- It can take a few tries to get it correct. If it still does not work, rephrase your request. Also, increase the "Temperature" setting will make the AI more aggressive in seeking alternative solutions.
- Prepare and clean your data in Excel first! RTutor can only analyze traditional statistics data, where rows are observations and columns are variables.
- Once uploaded, your data is automatically loaded into RTutor as a data frame called df. Check if the data types of the columns are correct. Change if needed, especially when numbers are used to code for categories. Data types make a big difference in analysis and plots!
- Before sending your request to OpenAI, we add "Generate R code" before it, and append something like "Use the df data frame. Note that hwy is numeric" afterward. If you are not using any data (plot a function or simulations), choose "No data" from the Data dropdown.
- Your data is not sent to the AI! To ask generic questions without mentioning column names, briefly describe your data, especially the relevant columns, just like emailing a statistician who knows nothing about your data.
- Each chunk of code is run independently using your uploaded data. If you want to build upon the current code, select the "Continue from this chunk" checkbox. Your current R code will be inserted before your next chunk and get executed. This is especially important for data wrangling when you remove rows, add columns, or log-transform. You can go back to any previous chunks and continue from there.

Data Types	Description
<pre> 'data.frame': 153 obs. of 6 variables: \$ Ozone : int 41 36 12 18 NA 28 23 19 8 NA ... \$ Solar.R: int 150 118 149 313 NA NA 299 99 19 194 ... \$ Wind : num 7.4 8 12.6 11.5 14.3 14.9 8.8 15.8 20.1 8.6 ... \$ Temp : int 67 72 74 62 56 66 65 59 61 69 ... \$ Month : factor w/ 5 levels "5","6","7","8",...: 1 1 1 1 1 1 1 1 1 1 ... \$ Day : int 1 2 3 4 5 6 7 8 9 10 ... </pre>	

Rates of technology adoption



Benefits of AI in the workforce



- Increased Productivity and Efficiency
 - Automation of routine tasks, optimization of processes, and handling vast amounts of data, leading to enhanced productivity and efficiency



- Enhanced Decision-making
 - Analyze complex data, identify patterns, and generate insights, enabling better decision-making and strategic planning



- Automation of Repetitive Tasks
 - Automate mundane and repetitive tasks, freeing up human resources for more creative and strategic endeavors



AI is reshaping specific industries

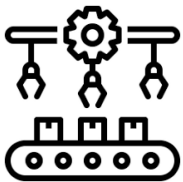
Not exhaustive



- Finance and Banking
 - Fraud detection, algorithmic trading, and personalized financial recommendations



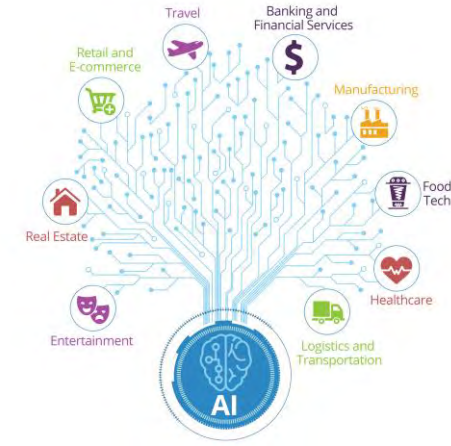
- Healthcare
 - Medical imaging analysis, drug discovery, and patient risk prediction for better healthcare outcomes



- Manufacturing
 - Predictive maintenance, quality control, and autonomous robotics to optimize production processes

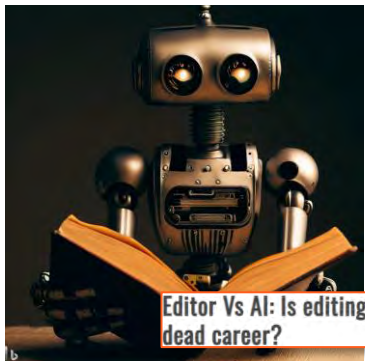


- Transportation
 - Autonomous vehicles, traffic management systems, and route optimization to improve safety and efficiency



Professions impacted by advances in generative AI

Automating processes and collaborating with humans to solve problems

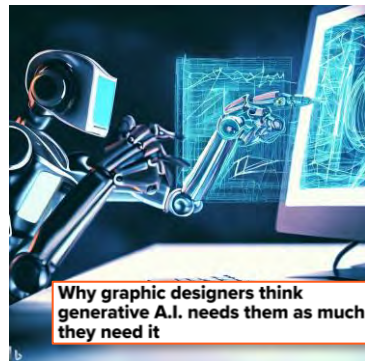


Editor Vs AI: Is editing a dead career?

Copy editing

Generate draft content, allowing copy editors to focus on polishing, fact-checking, and editing instead of writing from scratch

<https://scieditor.ca/2023/01/editor-vs-ai-is-editing-a-dead-career/>

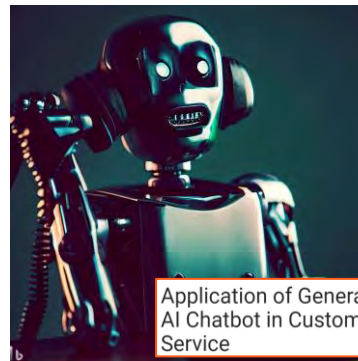


Why graphic designers think generative A.I. needs them as much as they need it

Graphic design

Design mockups, logos, and marketing materials, enhancing designers' workflows

<https://www.cnbc.com/2023/08/05/why-graphic-designers-think-gen-ai-needs-them-as-much-as-they-need-it.html>



Application of Generative AI Chatbot in Customer Service

Customer service

Chatbots for simple customer inquiries, allowing agents to handle more complex issues

<https://www.bcg.com/publications/2023/how-generative-ai-transforms-customer-service>

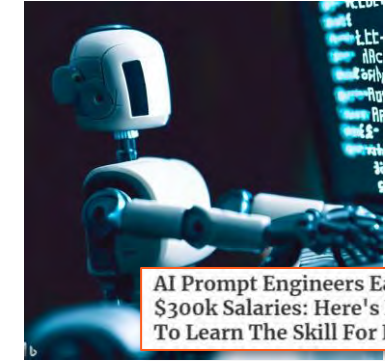


Researchers Leverage AI to Detect Causes of Alzheimer's Disease

Medical imaging

Automate annotation of scans to spot anomalies, acting as a diagnostic aid for radiologists

<https://healthitanalytics.com/news/researchers-leverage-ai-to-detect-causes-of-alzheimers-disease#:~:text=September%2021%2C%202022%20%2D%20Published%20in,early%20indicators%20of%20Alzheimer's%20Disease.>



AI Prompt Engineers Earn \$300k Salaries: Here's How To Learn The Skill For Free

Software engineer

Prompting to accelerate coding, allowing engineers to focus on more complex problems

<https://www.forbes.com/sites/jodiecook/2023/07/12/ai-prompt-engineers-earn-300k-salaries-heres-how-to-learn-the-skill-for-free/?sh=65b40129d4a1>

The promise of AI in drug discovery

1 Speed and efficiency

Accelerate with more efficient ways of identifying the right targets.

2 Improved decision making

Enabling researchers to make better and more informed decisions at every stage of the process.

3 Cost savings

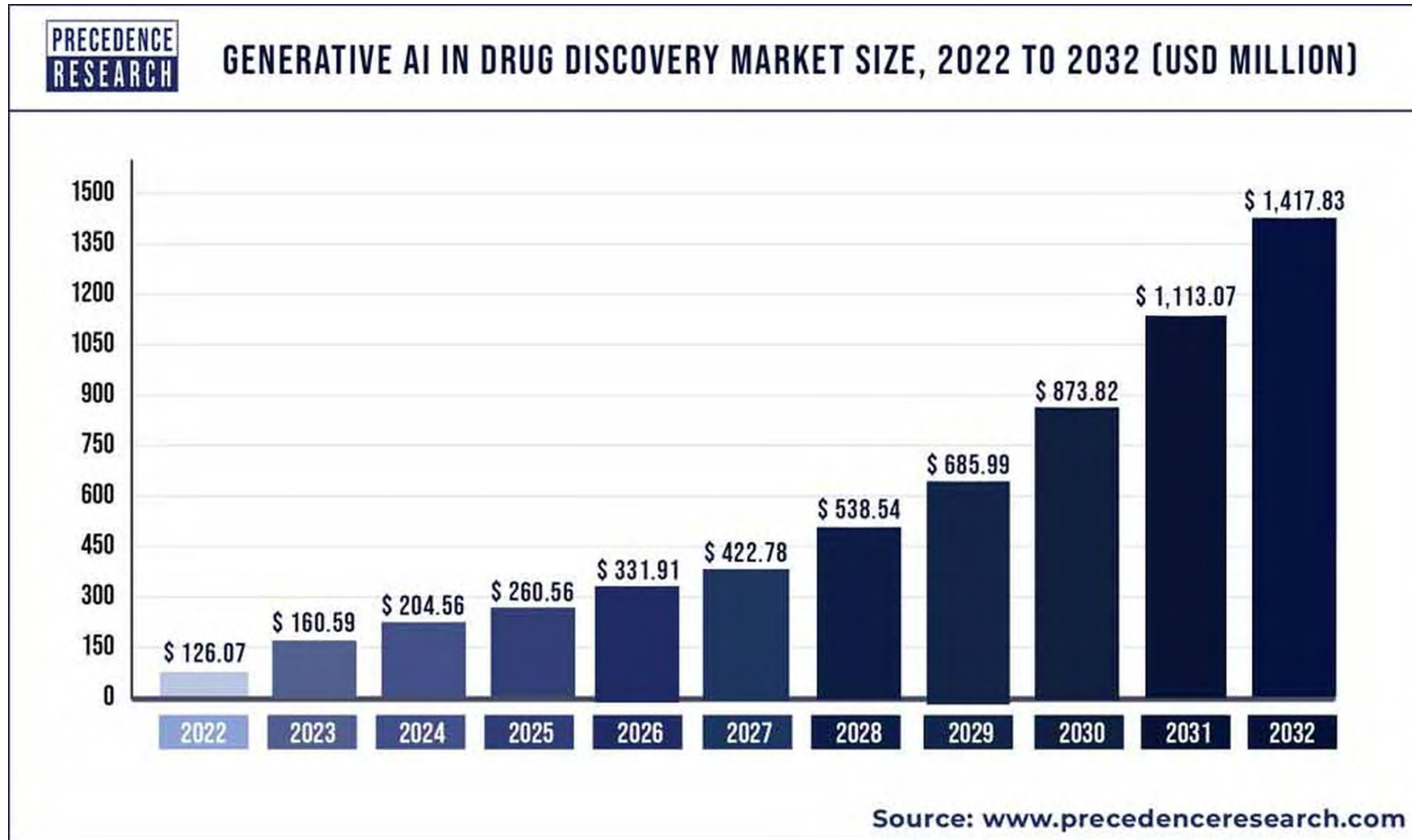
Reduce time-consuming experiments and high failure rates and increase the likelihood of success

4 Transformative potential

Investors, scientists, and regulators are interested in AI, as it is poised to revolutionize the future of drug development



AI in drug discovery has enormous profit potential



Some key components of drug discovery



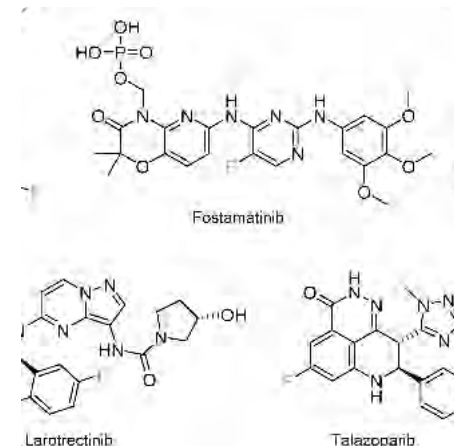
Understanding Diseases and Selecting Therapies

AI is helping scientists analyze vast amounts of data to better understand diseases and the best therapies for them.



Identifying and Validating Targets

ML methods can learn from existing data and predict which protein targets might be most effective in treating a given condition.



Designing Therapeutic Modalities

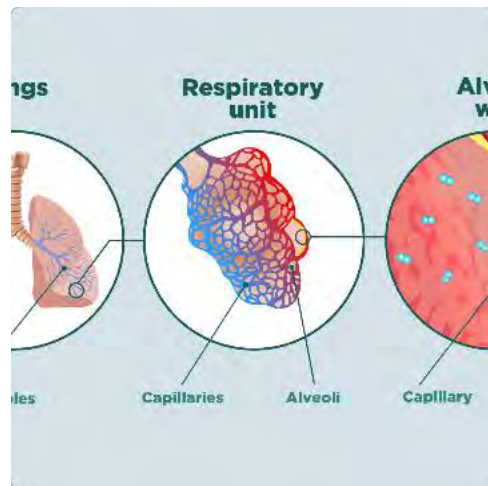
AI algorithms can help in designing therapeutic modalities, such as small molecules and biologics, that have the desired biological properties.

AI-designed compounds in clinical trials



Exscientia

The first AI-designed drug for the treatment of obsessive-compulsive disorder (OCD); currently in Phase I clinical trials.



Insilico Medicine

AI-designed drug for idiopathic pulmonary fibrosis (IPF), in Phase II clinical trials.



Relay Therapeutics

Drug candidates for the treatment of cancer and other diseases, including inhibitors for SHP2 and FGFR protein; advancing in clinical trials.

HR: Unlocking the potential of AI



Recruitment

Job descriptions (JDs):
Provide a previous JD or a set of requirements and let generative AI compose the rest

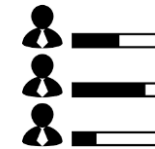
Resumes: Summarize qualifications in few words, prioritize with weighting metrics for experience and skillsets across candidates



Onboarding

Chatbots can provide 24/7 support, answering common questions and guiding employees through the onboarding process

AI-based recommendation systems can offer personalized training programs based on an employee's role, skills, and career goals



Performance

AI-driven performance metrics, feedback, and employee data to identify patterns and trends

AI mapping tools to identify skill gaps and recommend targeted training programs to enhance employee performance



Engagement & Retention

AI-powered sentiment analysis can analyze employee feedback, surveys, and social media data to measure employee satisfaction

What are some of the ways we are leveraging AI at Genmab?

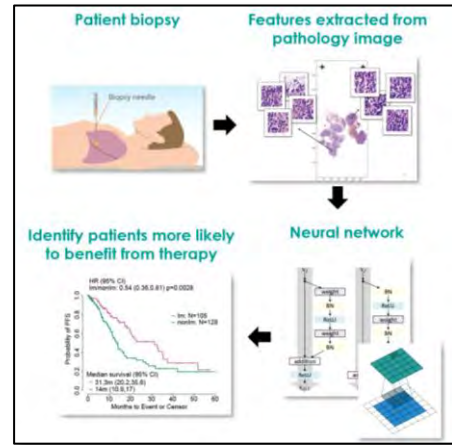


AI applications at Genmab



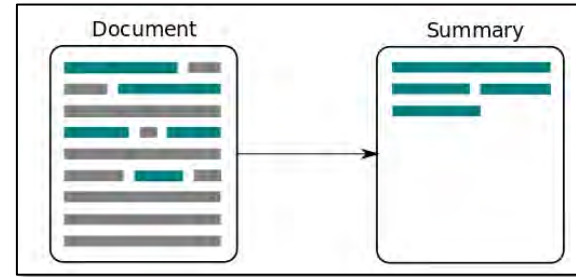
Virtual control arms

Use real-world data (RWD) to simulate clinical outcomes in comparator arm; ultimately de-risking pivotal clinical trials



Digital pathology

From patient biopsy to histology slide, to predicting likelihood of responding to a therapy



Summarization

Automated summarization and simplification of scientific conference content



Prompt-driven analysis

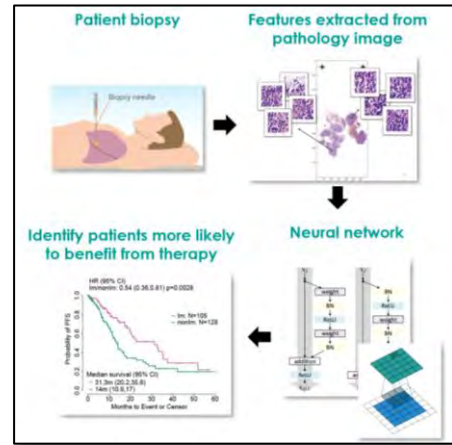
Biomarker and clinical correlative analysis using generative AI to derive code and graphics

AI applications at Genmab



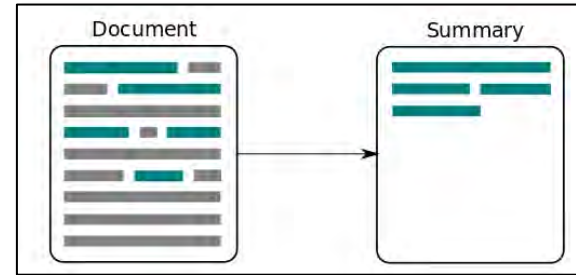
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The balance of virtual control arms



Advantages

- Large real-world data sets provide broader, more generalizable patient populations
 - Eliminates cost of patient recruitment
 - Reduces duration of trial
- Contemporary data reflects current standards of care
- Matching methods balance baseline characteristics and reduce bias
- Can answer research questions not feasible in RCTs

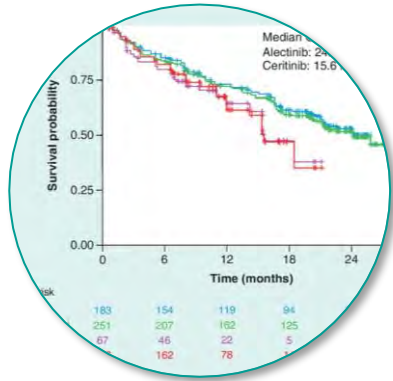


Challenges

- Residual confounding from unmeasured factors
- Data quality limitations (e.g. missing data, variability in collection methods)
- Endpoint differences (RECIST vs clinical documentation of progression)
- Generalizability to clinical trial population
- Acceptance of methodology by stakeholders

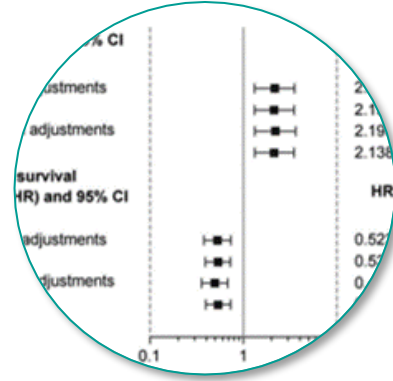
Examples in oncology trials

Demonstrate improved efficacy or noninferiority over standard of care



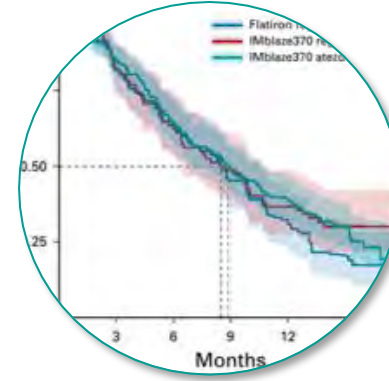
- Alectinib in ALK+ NSCLC (n=138) vs RWD control (n=306): OS HR 0.65

Davies et al., 2018



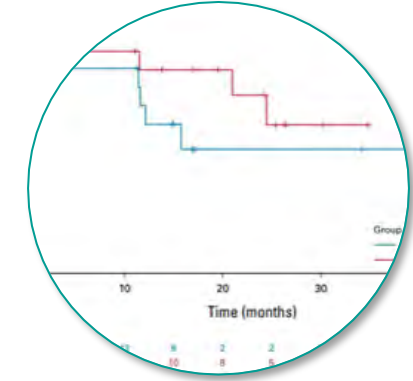
- Blinatumomab (CD19xCD3) in relapsed/refractory ALL (n=134) vs RWD control (n=478): CR 40% vs 25%

Gökbüget et al., Blood Cancer Journal, 2016



- Atezolizumab + Cobimetinib (MEKi) in mCRC (n=183) vs RWD controls (n=173-179): OS HR 0.67-0.86

Schroder et al., JCO Clinical Cancer Informatics, 2021



- GEN-1 (IL-12) + chemo in ovarian cancer (n=18/15) vs RWD control (n=41/15): PFS HR 0.53

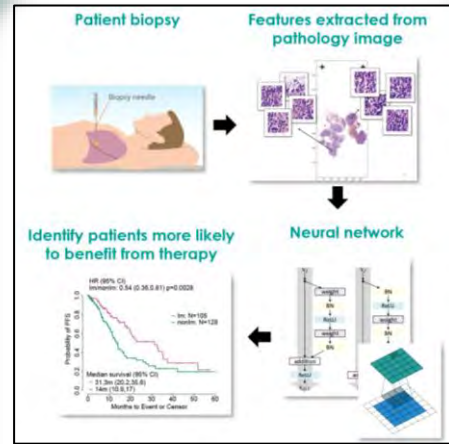
Yin et al., JCO Clinical Cancer Informatics, 2023

AI applications at Genmab



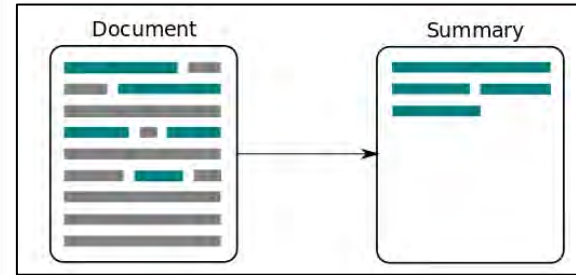
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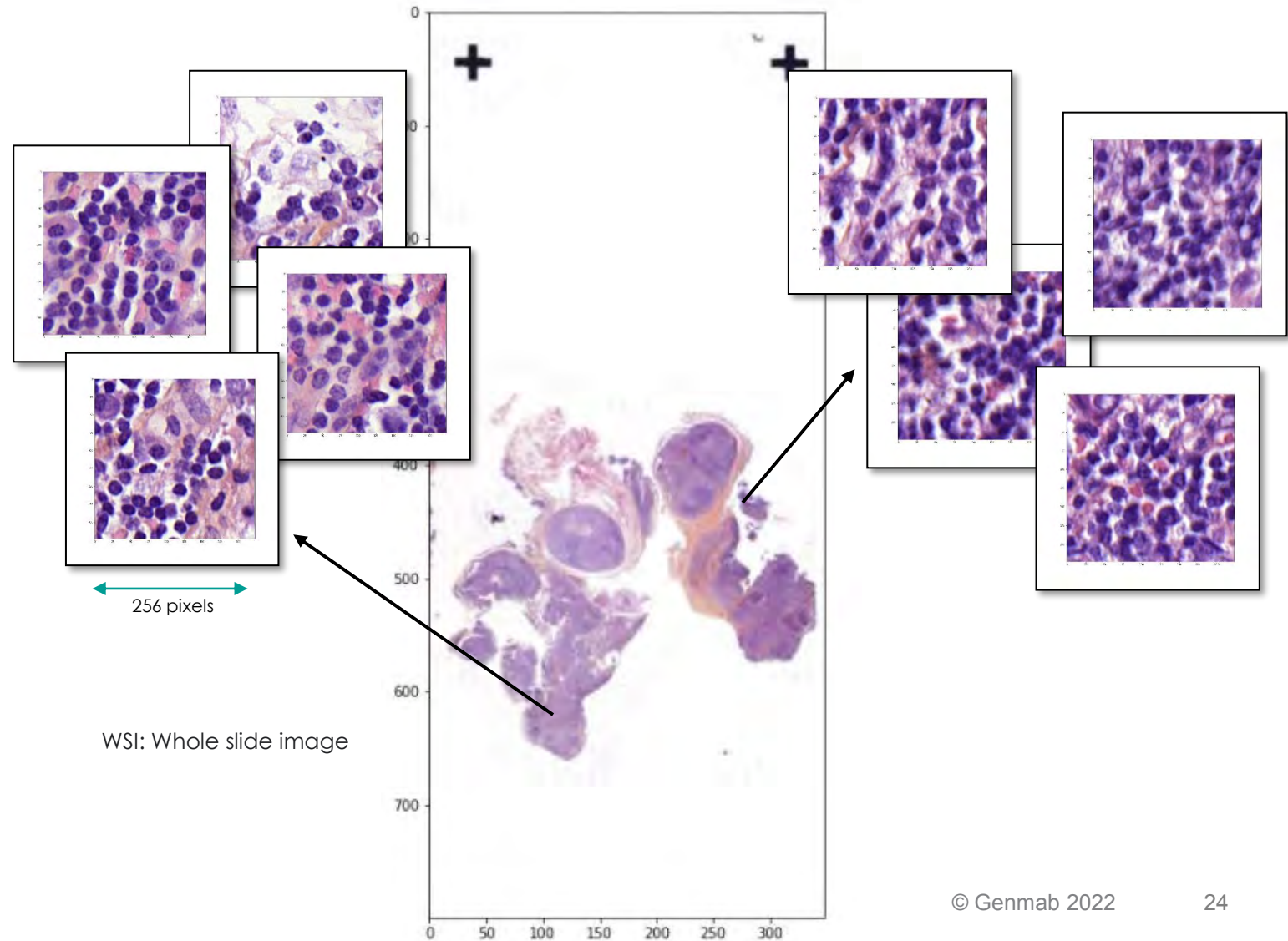


Prompt-driven analysis

Biomarker and clinical correlative analysis using generative AI to derive code and graphics

Tile/Patch extraction from whole slide image

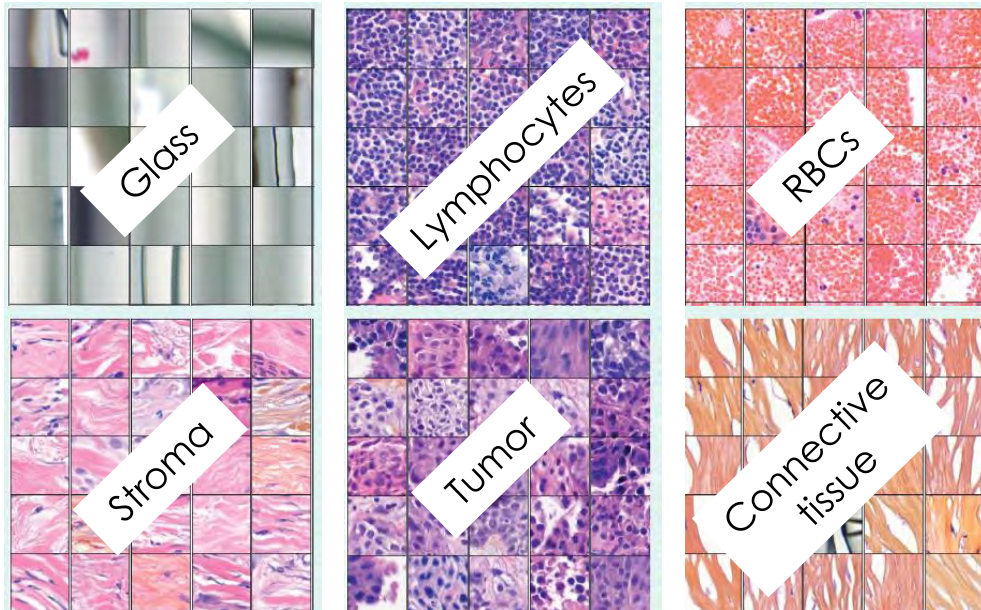
- Tissue contexture is heterogeneous and varies by region
 - WSI is prohibitively large search space
- Can divide the WSI into thousands of small image tile representations
- Use these tiles as micro-representations of the tissue
- Size of WSI versus tile
 - Single WSI: 1-3 GB
 - Tile size:
[(256x256 pixels) x 24 bits]/8 = 197KB



Automated histologic, morphologic, and artifact detection

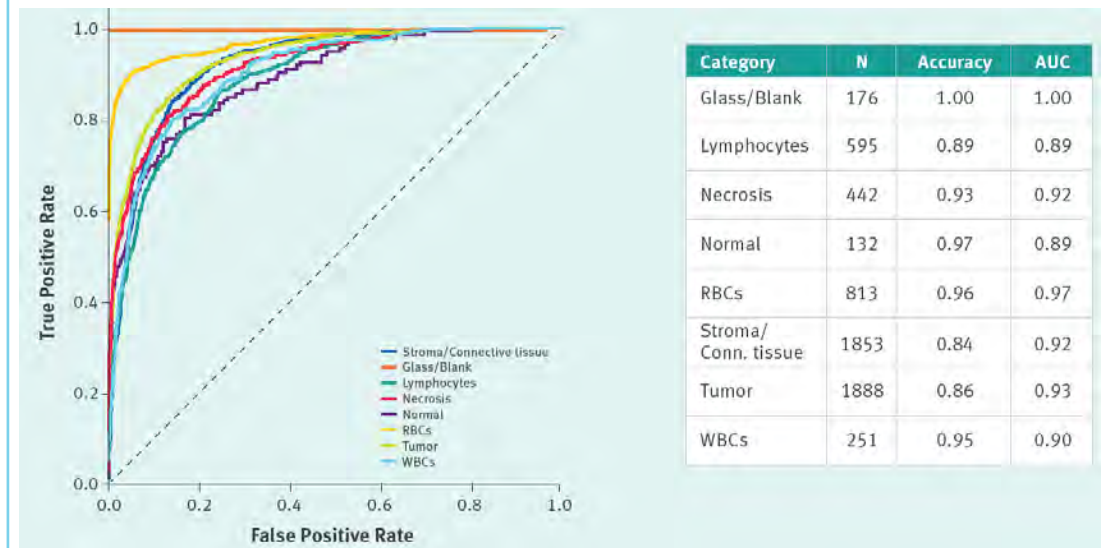
- ResNet-50 CNN used to learn pathologists' annotations

Example image tiles with different morphologic features



Soong et al, SITC 2021

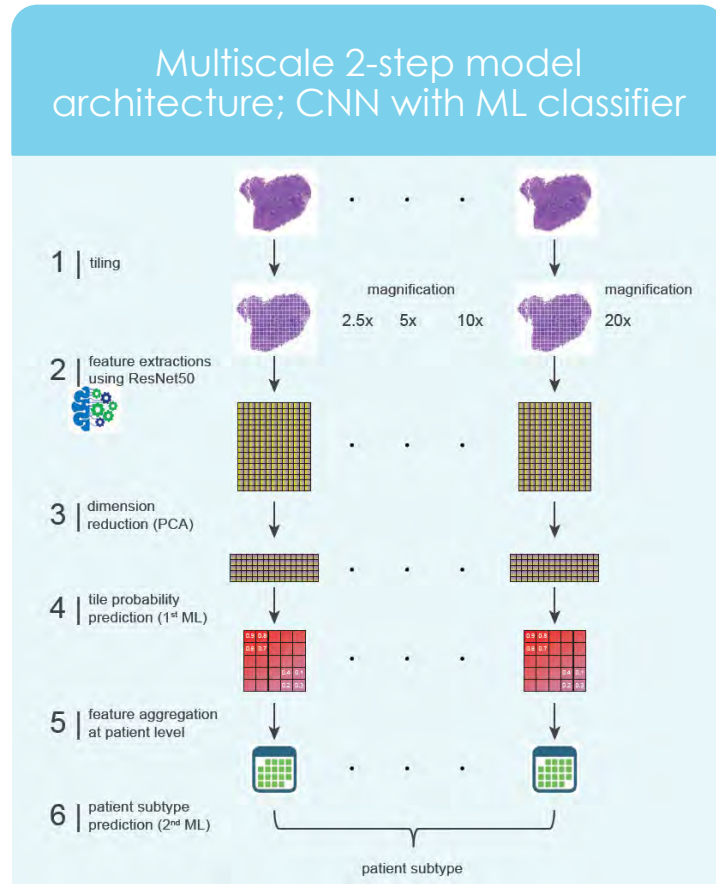
Deep neural network classifier performance (five-fold cross validation)



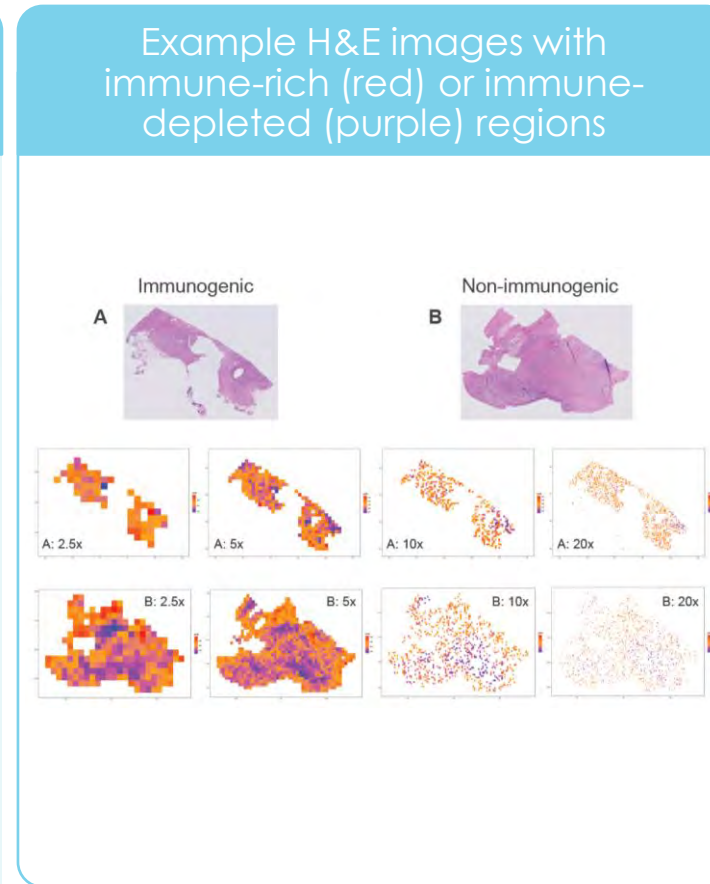
H&E: Hematoxylin-and-Eosin (stain)

Image-based prediction of immunogenic subtype in pancreatic cancer

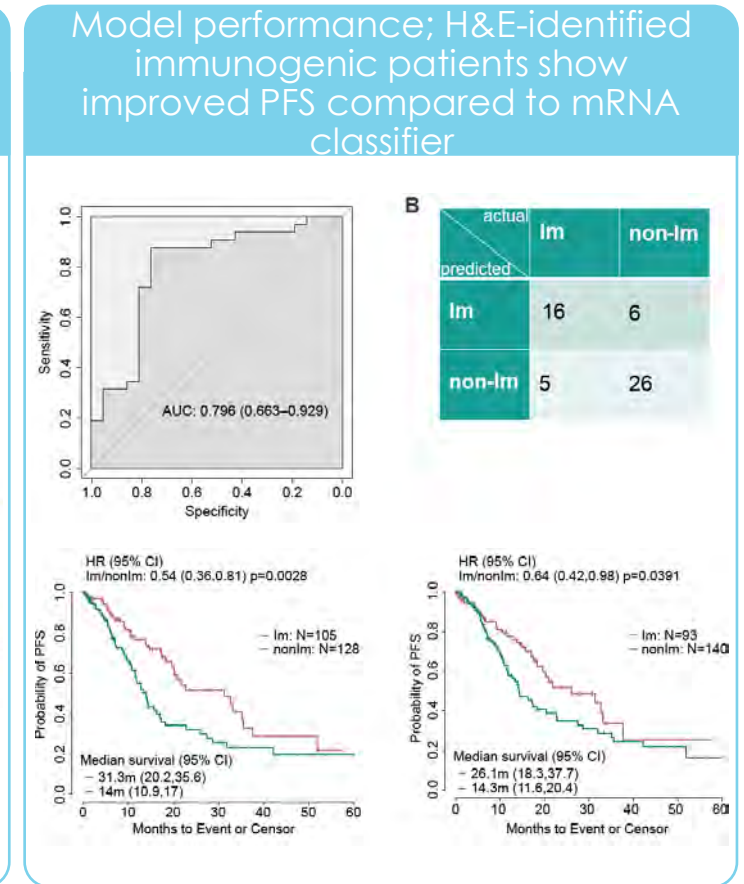
- Identifying patients with immunogenic phenotype using whole slide H&E images
- ResNet-50 CNN architecture implemented



Si et al, AACR 2022



H&E: Hematoxylin-and-Eosin (stain)

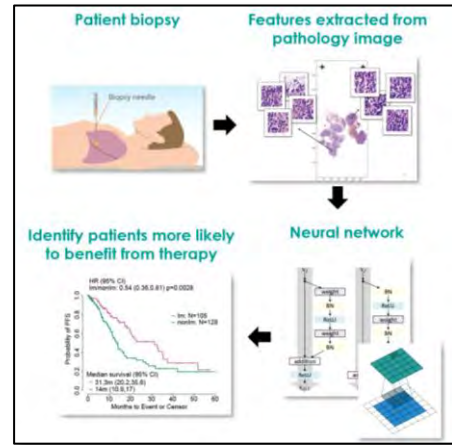


AI applications at Genmab



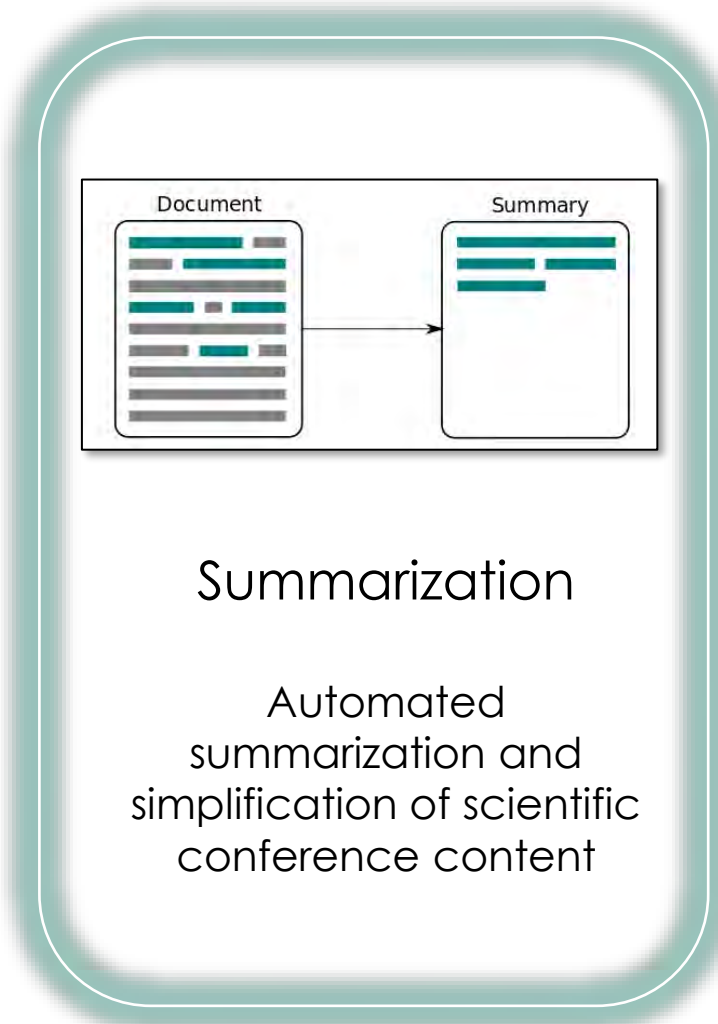
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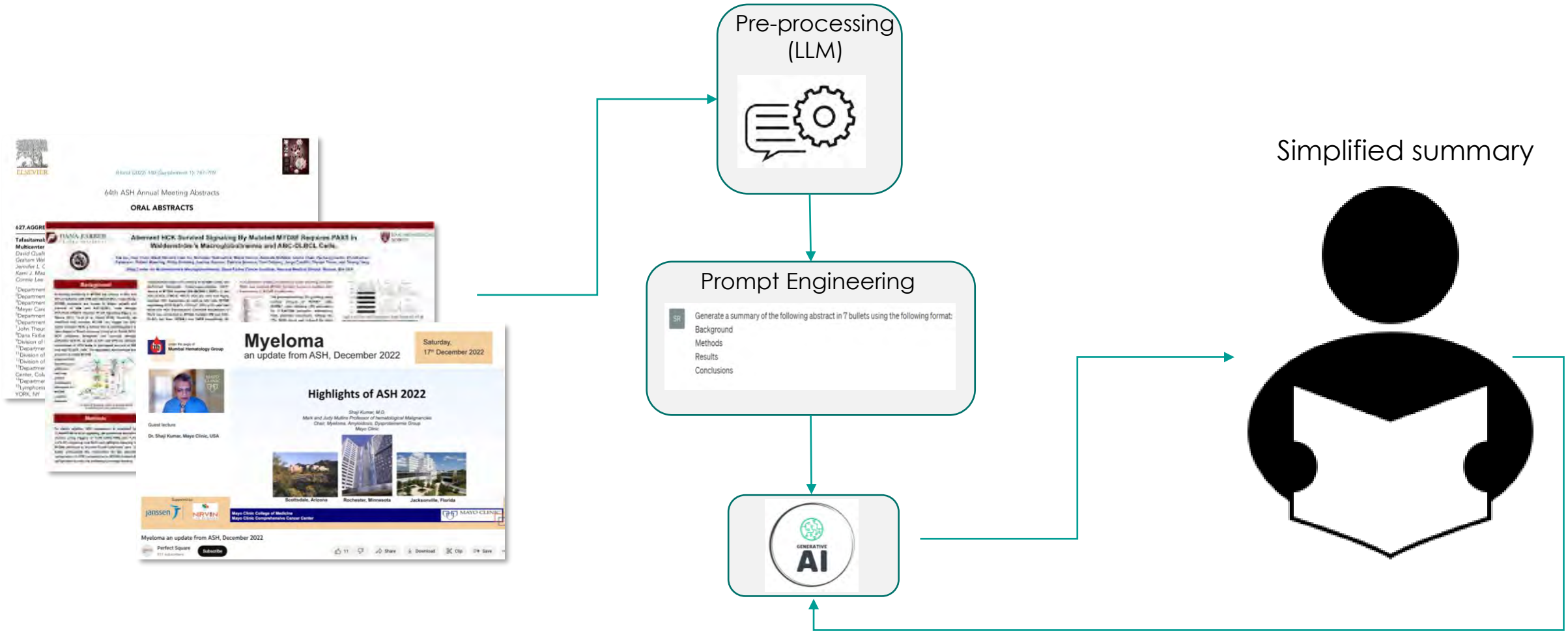
Automated summarization and simplification of scientific conference content



Prompt-driven analysis

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AI-generated conference content summaries



Technical challenges of AI summarization

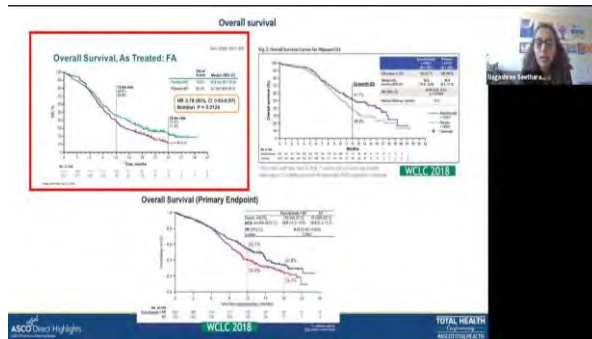
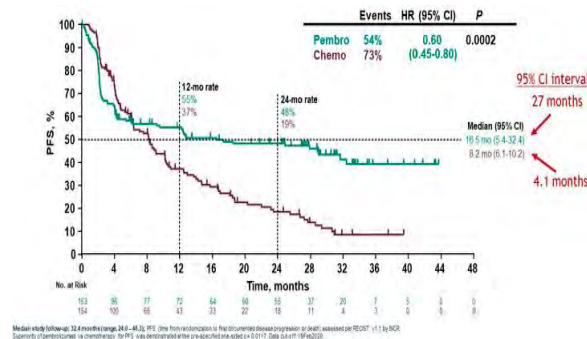


Image quality & resolution

OCR may struggle with low resolution, poor image quality, or too many small images on a slide, making it difficult to recognize characters and numbers

accurately



Graph interpretation

Interpreting and extracting statistics or graphical elements from KM graphs, bar graphs, or pie charts can require more advanced capabilities

Table 1: Baseline

	N	A N = 81	B N = 169	P-value
age	250	60 65 70	61 67 73	0.104 ¹
Sex	250			0.453 ²
male		78% (63)	73% (124)	
Race	250			0.189 ²
Black		0% (0)	3% (5)	
Caucasian		98% (79)	96% (163)	
Oriental		1% (1)	0% (0)	
Other		1% (1)	1% (1)	
height	250	164 169 175	164 168 173	0.185 ¹
weight	250	65 75 89	63 74 85	0.516 ¹
bmi	250	23.3 25.4 29.6	22.6 25.8 29.4	0.996 ¹
smoking	250	37% (30)	35% (59)	0.743 ²
pack_yrs	250	30 48 60	30 42 60	0.862 ¹

¹ a b c represent the lower quartile a, the median b, and the upper quartile c for continuous variables. N is the number of non-missing values. Numbers after percent are frequencies. Tests used: ¹Wilcoxon test; ²Pearson test

Complex table structures

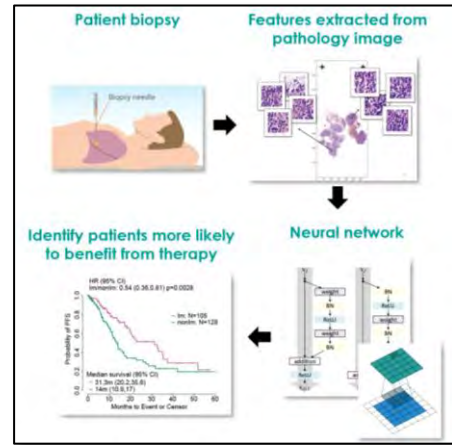
Merged cells, missing values, indentation, footnotes, nested sub-tables, or varying row or column sizes, make the OCR extraction process more difficult

AI applications at Genmab



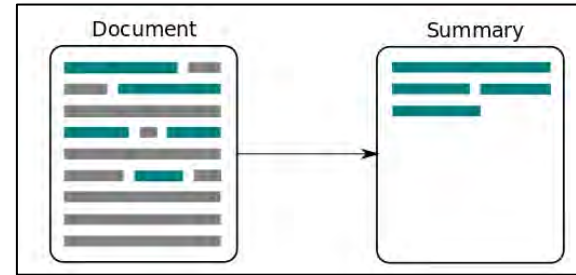
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A screenshot of a software interface for prompt-driven analysis. It features a text input field with a prompt: 'Provide the R code to calculate a t-test between two groups for all genes and plot a heatmap of the results where each row is a gene and each sample is a column.' Below the input is a code editor showing R code:

```
design <- model.matrix(~group)
# Assuming your data is stored in a variable called
# and your grouping variable is stored in a variable
design)
t.test(coef = "group", number = n)
```

 Below the code is a heatmap visualization with a dendrogram on the left side, showing gene expression data across samples.

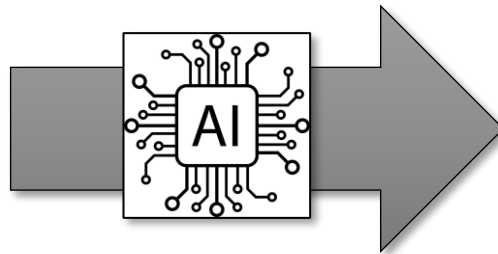
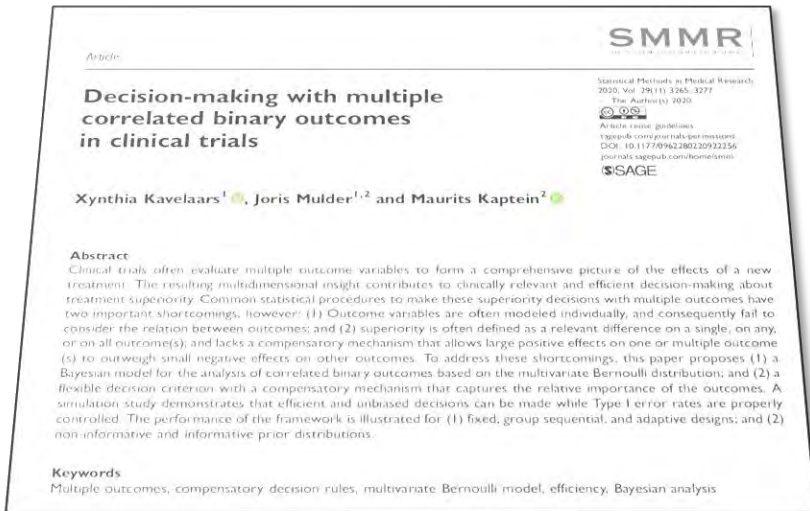
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Writing prompts to create programming code and graphics

can you provide R code to calculate this using the method in the uploaded paper? BH

Sure, here is some R code to calculate the sample size for the example I walked through, using the approach from the paper you provided:



```
r Copy code
# Required packages
library(stats)

# Fatigue effect size
p_fatigue = 0.6 # Proportion

# Pain effect size
percent_pain = 0.1 # 10% dec
p0_pain = 0.5
p1_pain = p0_pain * (1 - per

# Null probabilities
p0_fatigue = 0.5
p0_pain = 0.5

# Alternative probabilities
p1_fatigue = p_fatigue
p1_pain = p0_pain * (1 - percent_pain)

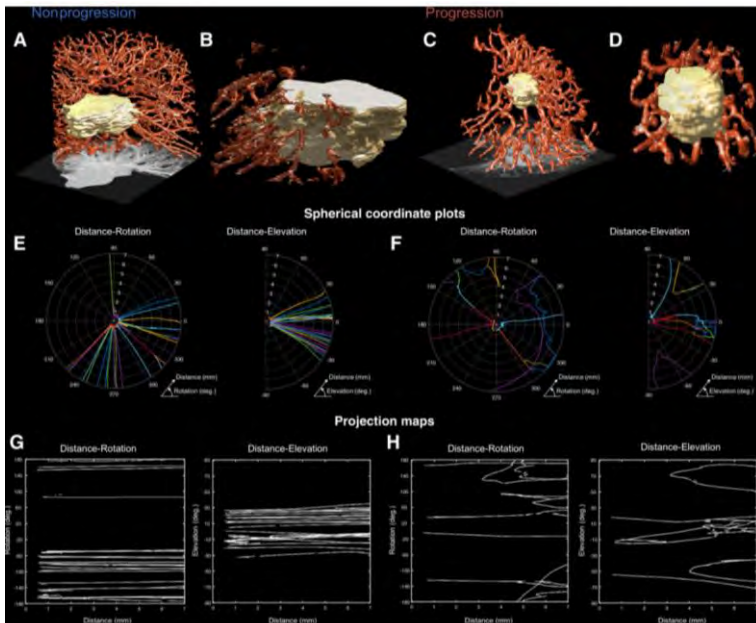
# Effect sizes
delta_fatigue = p1_fatigue - p0_fatigue
delta_pain = p1_pain - p0_pain
```

Power vs. Intervention Sample Size for Control Sample Size = 100 (Odds Ratios: 1.5, 2, 2.5, 3, 3.5)

Intervention Sample Size	Control N=100, Odds Ratio=1.5, Int. Prop=0.1	Control N=100, Odds Ratio=1.5, Int. Prop=0.4	Control N=100, Odds Ratio=1.5, Int. Prop=0.6	Control N=100, Odds Ratio=2, Int. Prop=0.1	Control N=100, Odds Ratio=2, Int. Prop=0.4	Control N=100, Odds Ratio=2, Int. Prop=0.6	Control N=100, Odds Ratio=2, Int. Prop=0.8	Control N=100, Odds Ratio=2.5, Int. Prop=0.1	Control N=100, Odds Ratio=2.5, Int. Prop=0.4	Control N=100, Odds Ratio=2.5, Int. Prop=0.6	Control N=100, Odds Ratio=2.5, Int. Prop=0.8	Control N=100, Odds Ratio=3, Int. Prop=0.1	Control N=100, Odds Ratio=3, Int. Prop=0.4	Control N=100, Odds Ratio=3, Int. Prop=0.6	Control N=100, Odds Ratio=3, Int. Prop=0.7
5	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90
10	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
15	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	0.98
20	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	0.98	0.99
25	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	0.98	0.99	1.00
30	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	0.98	0.99	1.00	1.00
35	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	0.98	0.99	1.00	1.00	1.00
40	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	0.98	0.99	1.00	1.00	1.00	1.00

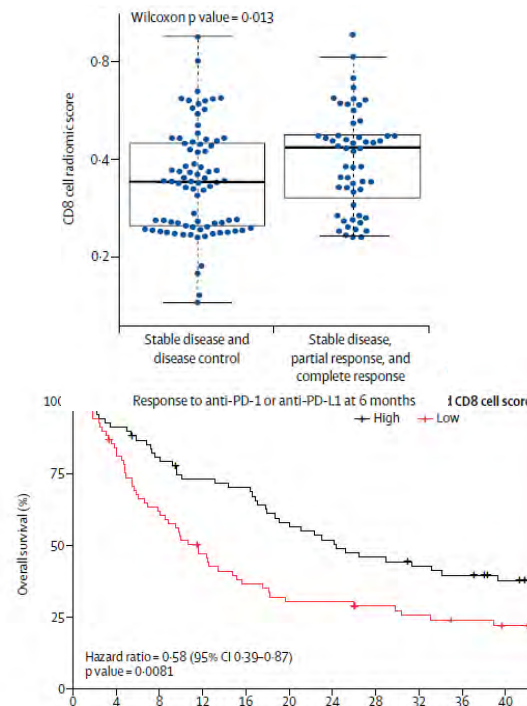
Radiomics as a noninvasive biomarker of target expression, safety, and clinical outcome

Vasculature morphology from imaging as a biomarker of 1L chemo response



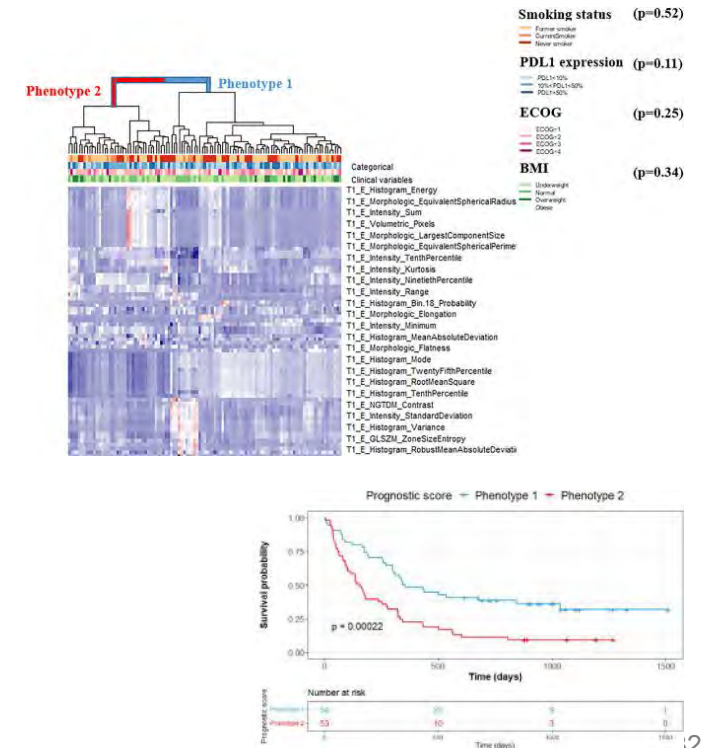
Braman et al, 2022

Radiomic signature correlates with CD8 infiltrate and response to aPD(L)1



Sun et al, 2018

Integrated molecular data with radiomic features predicts survival in NSCLC



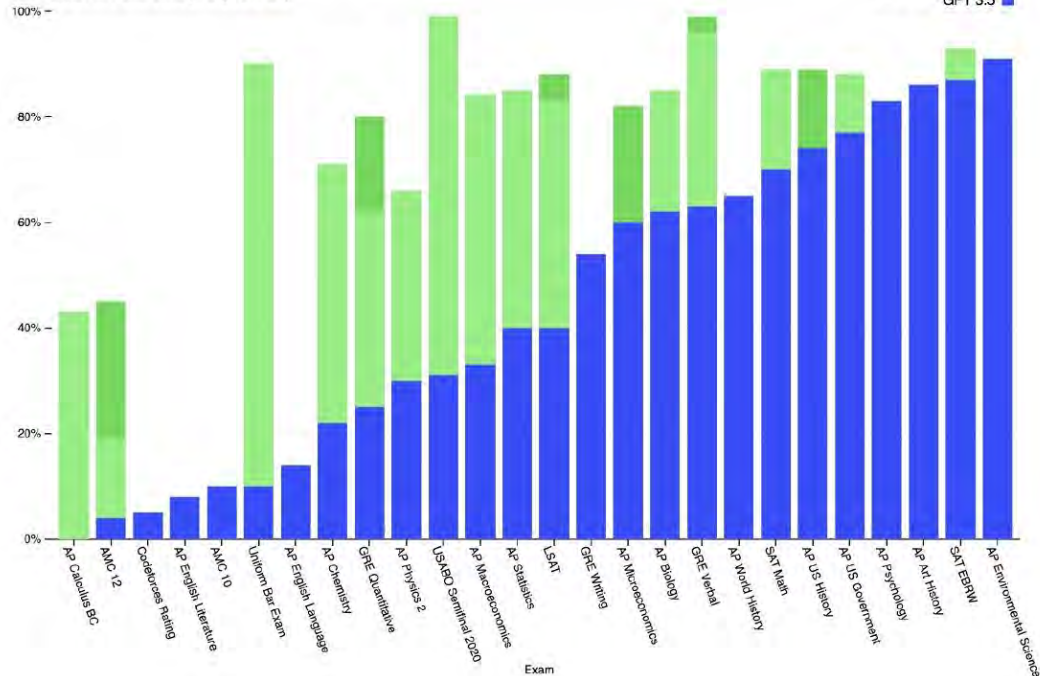
Singh et al, 2022

What skills are most affected or unaffected by generative AI

Exam performances by GPT3.5/4

Exam results (ordered by GPT 3.5 performance)

Estimated percentile lower bound (among test takers)



Skills importance for GPT

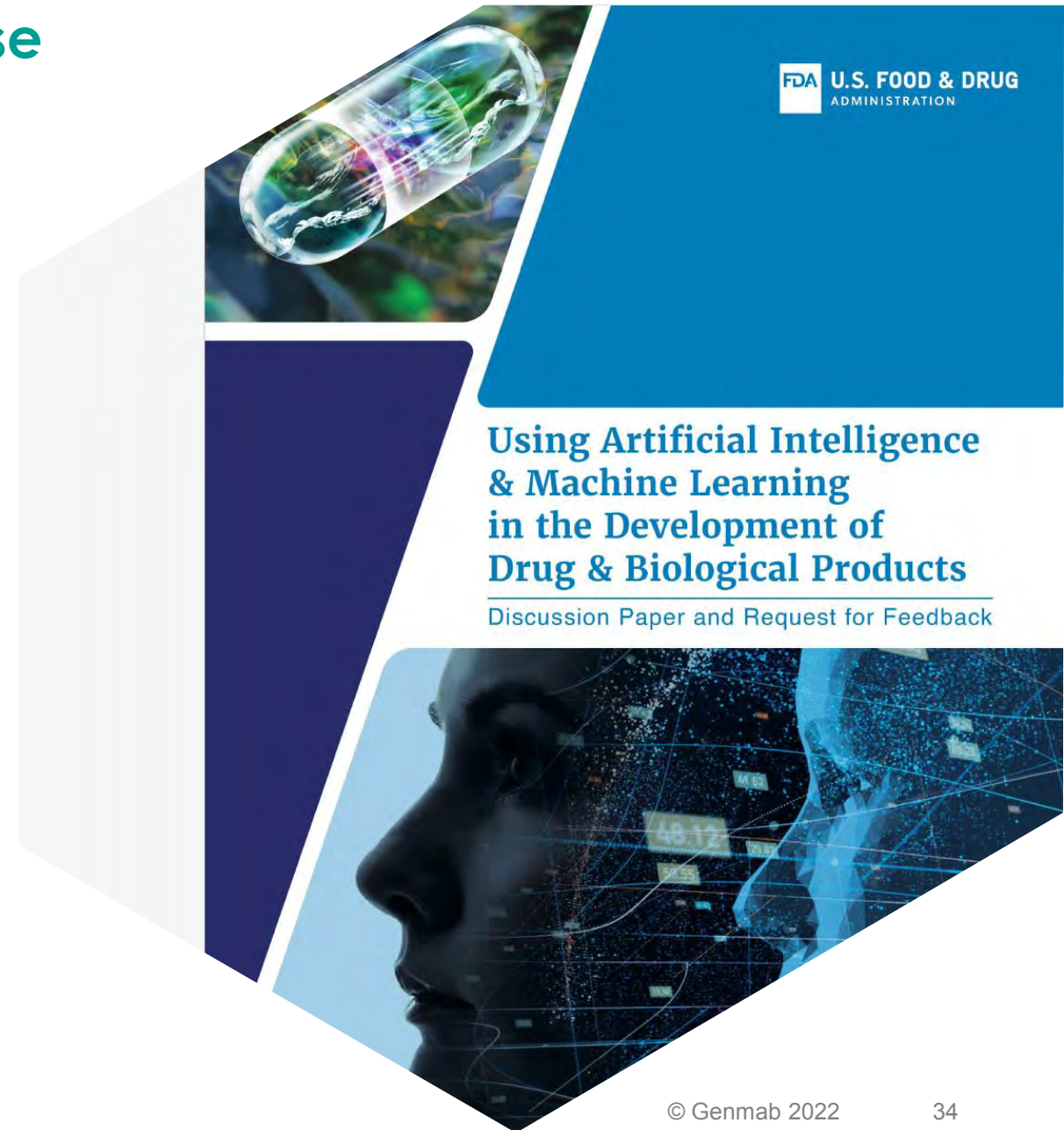
Basic Skill	α (std err)	β (std err)	ζ (std err)
<i>All skill importance scores are normalized to be between 0 and 1.</i>			
Constant	0.082*** (0.011)	-0.112*** (0.011)	0.300*** (0.057)
Active Listening	0.128** (0.047)	0.214*** (0.043)	0.449*** (0.027)
Mathematics	-0.127*** (0.026)	0.161*** (0.021)	0.787*** (0.049)
Reading Comprehension	0.153*** (0.041)	0.470*** (0.037)	-0.346*** (0.017)
Science	-0.114*** (0.014)	-0.230*** (0.012)	-0.346*** (0.017)
Speaking	-0.028 (0.039)	0.133*** (0.033)	0.294*** (0.042)
Writing	0.368*** (0.042)	0.467*** (0.037)	0.566*** (0.047)
Active Learning	-0.157*** (0.027)	-0.065** (0.024)	0.028 (0.032)
Critical Thinking	-0.264*** (0.036)	-0.196*** (0.033)	-0.129** (0.042)
Learning Strategies	-0.072* (0.028)	-0.209*** (0.025)	-0.346*** (0.034)
Monitoring	-0.067** (0.023)	-0.149*** (0.020)	-0.232*** (0.026)
Programming	0.637*** (0.030)	0.623*** (0.022)	0.609*** (0.024)

GPT lags

GPT excels

FDA guidance regarding appropriate use of AI/ML in drug development

- Efforts by FDA, NIST, ISO, and others to develop principles and standards for trustworthy and ethical AI use to inform drug development
- Transparency, human oversight, and model validation in the drug development context
- Engage stakeholders on considerations for AI/ML in drug development through a public workshop and other collaborative opportunities



General AI considerations in the popular press

Ensure responsible AI deployment

Accuracy

THE WALL STREET JOURNAL
LIFE & WORK | IDEAS | WORD ON THE STREET
'Hallucination': When Chatbots (and People) See What Isn't There
A Latin term for mental wandering was applied to the disorienting effects of psychological disorders and drug use—and then to the misfires of AI programs

When A.I. Chatbots Hallucinate

Give this article



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Bias

60 MINUTES OVERTIME
ChatGPT and large language model bias
MARCH 5, 2023 / 7:00 PM / CBS NEWS

Bloomberg

Live Now Markets Economics Industries Technology Politics Wealth Pursuits Opinion Businessweek

Newsletter

OpenAI Chatbot Spits Out Biased Musings, Despite Guardrails

Privacy

CW BUSINESS Markets Tech Media Calculators Videos

Don't tell anything to a chatbot you want to keep private

INFORMATION SECURITY

6 Tips to ensure that your chatbots are GDPR compliant

Job Displacement & Reskilling

What To Do About AI-Driven Job Displacement



Accountability & Responsibility

NEWS | 18 January 2023

ChatGPT listed as author on research papers: many scientists disapprove

At least four articles credit the AI tool as a co-author, as publishers scramble to regulate its use.

Technology

4 minute read - April 5, 2023 8:22 AM EDT - Last Updated a month ago

Elon Musk and others urge AI pause, citing 'risks to society'

Transparency & Explainability

Technology And Analytics

We Need AI That Is Explainable, Auditable, and Transparent

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Transparency & Explainability

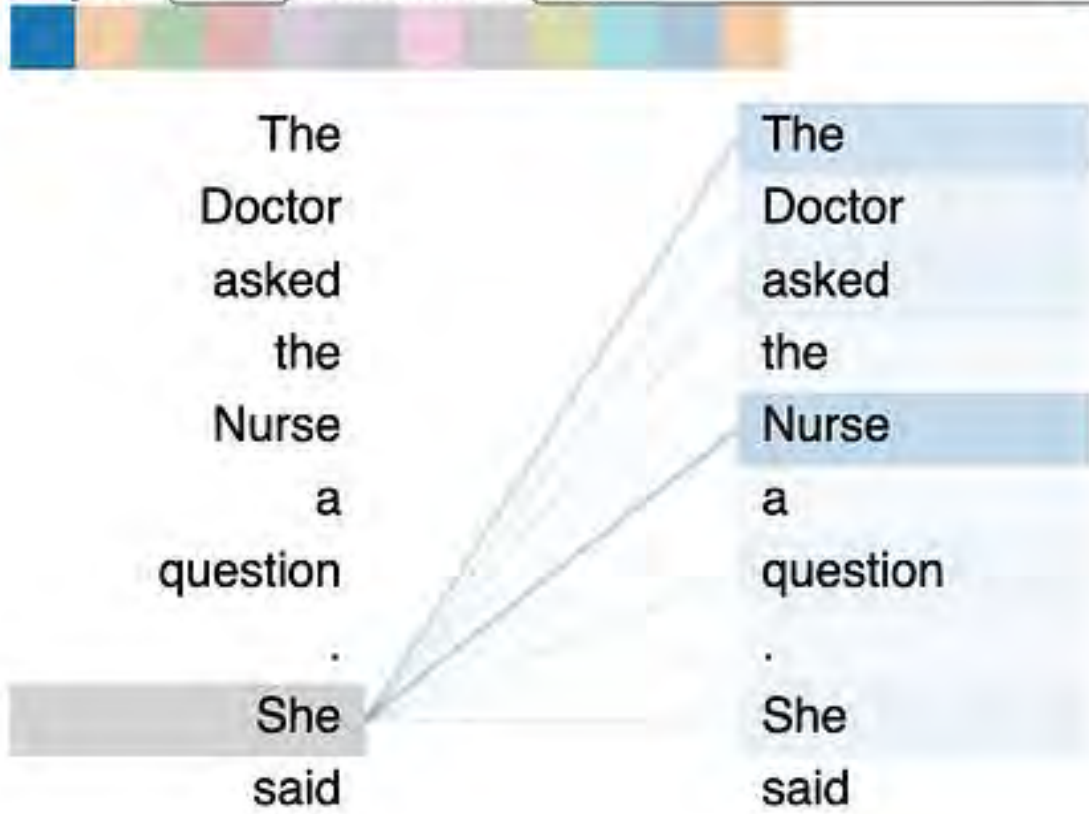
Technology And Analytics

We Need AI That Is Explainable, Auditable, and Transparent

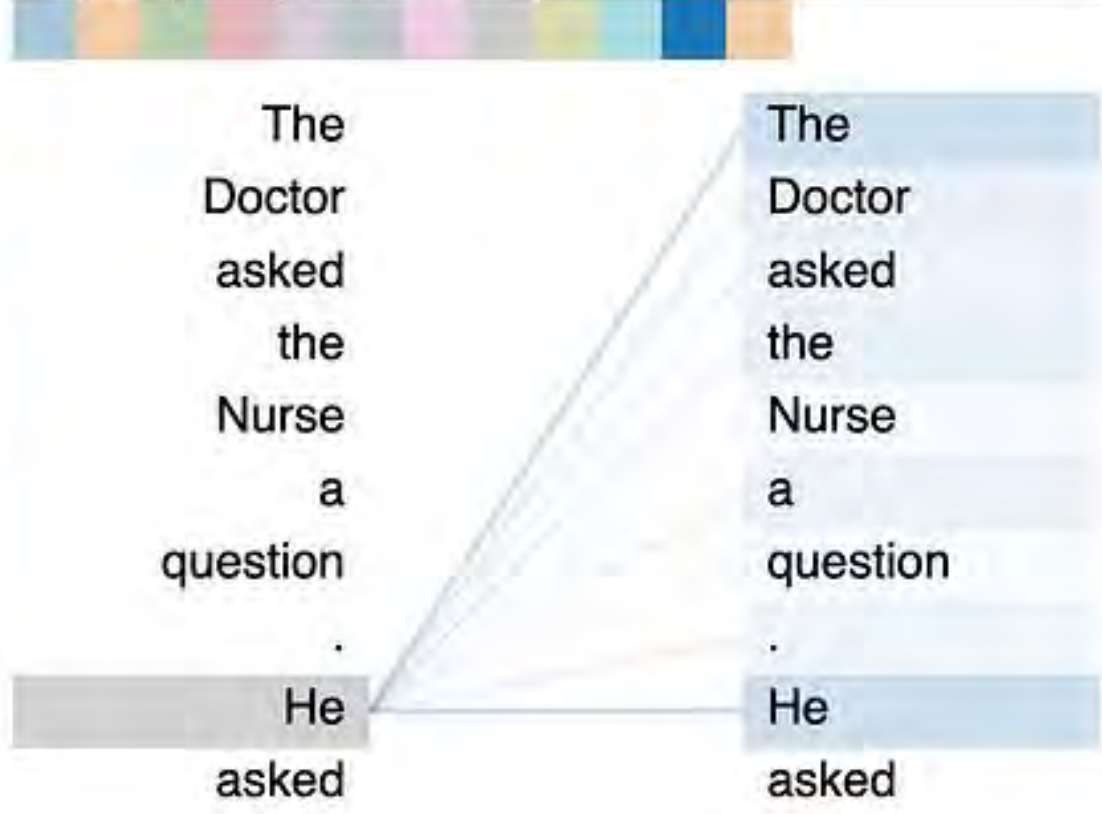
Example of gender bias in LLMs

Inherent weighting given to specific genders for certain professions

Layer: 0 ▾ Attention: All ▾



Layer: 0 ▾ Attention: All ▾



Concluding remarks

Balanced Approach: Integration with a balanced perspective, considering both potential and limitations

Ethical Considerations: Must be proactively addressed to maintain public trust and ensure equitable outcomes in drug development

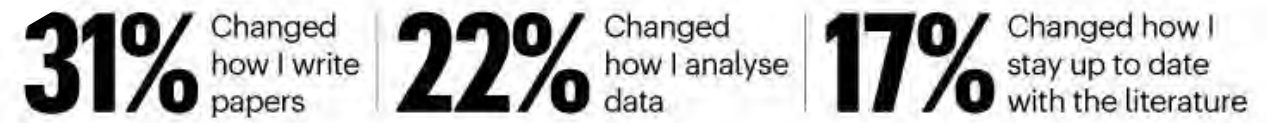
Workforce Adaptability: Pharma's workforce needs to be agile and adaptable, acquiring new skill sets to work alongside AI technologies effectively

Regulatory Framework: A growing need for robust regulatory frameworks to ensure that AI applications in drug development meet safety and efficacy standards

Future Preparedness: Improved collaboration to prepare the next generation of scientists, researchers, and professionals for a future where AI will be an integral part of drug development

CHATBOTS
postdoctoral researchers polled said that
AI chatbots, such as ChatGPT, for everything
fixing code and overcoming writer's block.

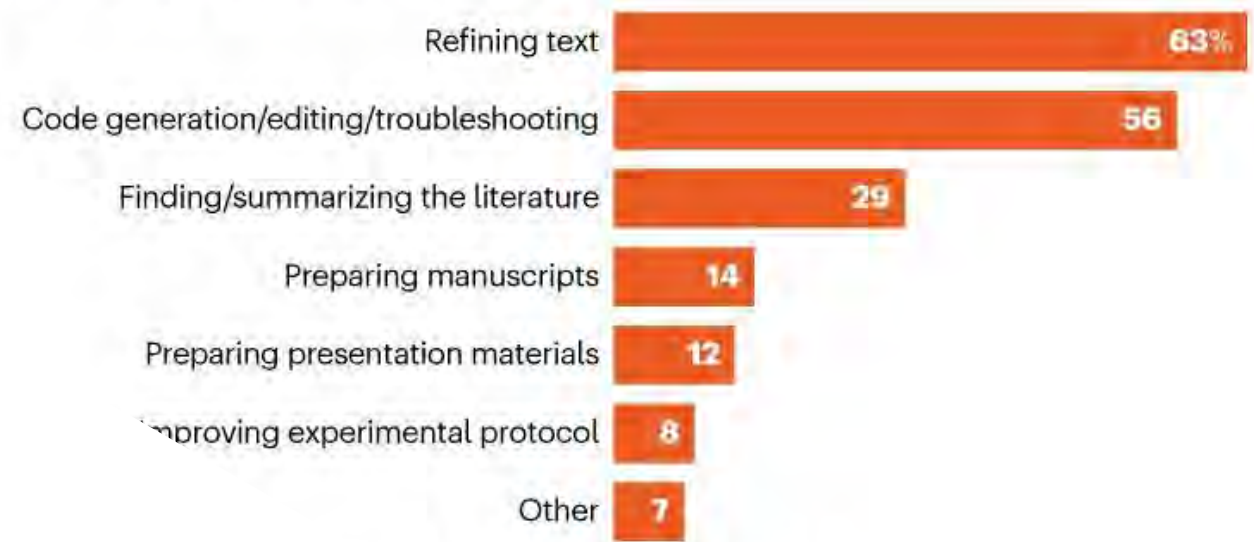
evolution and rapid adoption of AI chatbots changed your day-to-day work or career plans, if at all?



Do you use AI chatbots, such as ChatGPT, in your work?



What do you use AI chatbots for?



AI chatbots in your work

Acknowledgments

It takes a village...

- Genmab Translational & Quantitative Sciences
 - Han Si
 - David Soong
 - Sri Sridhar
 - Anantharaman Muthuswamy
 - Clifton Drew
 - Mohammed Qutaish
 - Mark Fereshteh
 - Manish Gupta
- Genmab Data Sciences & AI
 - Hisham Hamadeh
 - Sam Wagner
 - Scott Ogden
 - Kevin Tsai
 - Elmutaz Shaikho
 - Hareesh Chandrupatla
 - Sanyam Kumar
- Genmab Discovery Data Science
 - Chris Klijn
 - Roberto Spreafico
- Rutgers University
 - Janet Alder
- Neomorph
 - Suzana Couto

