

**REGDESK**



# AI in MedTech Regulatory: A framework for navigating this generational change



## AI in MedTech is a hot topic right now

If it feels like you're hearing more about it recently, you're right:

- Vendors at this show (including RegDesk) are telling you how AI will change your lives
- EU overwhelmingly (523 to 46) passed the AI Act 13 March 2024 with enforcement starting 1 August 2024.
- AdvaMed released its [AI Policy Roadmap](#) on 15 May 2025
- [FDA announced](#) that it is in the midst of an “aggressive agency-wide rollout” of AI by 30 June 2025, following a successful pilot focused on streamlining scientific review.
  - FDA Commissioner Martin Makary said the agency needs to *"reduce the amount of non-productive busy work that has historically consumed much of the review process."*



RegDesk is thinking about A.I. as well

**RegDesk cuts submission time from 8 months to 1 week.**

Case Study

There are many types of AI, but  
what most of us think of is LLM

“

## large language model noun

a language model that utilizes deep methods on an extremely large data set **as a basis for predicting and constructing natural -sounding text**





It seems magical, but it's really just a math problem

The actress that played Rose in the 1997 film  
Titanic is named...

Kate Winslet. She was born on Octob

Kate = 65.16%

Gloria = 10.15%

Frances = 3.65%

Rose = 2.00%

Billy = 1.44%

“

*[LLMs are] built on a foundation of words. Their goal is simply to predict which word will be the next in a sequence of words. For example, iPhones' autocorrect feature in iOS 17 now uses an LLM to better predict which word you will most likely intend to type next.*



LLMs are cutting edge tech, but  
they do have drawbacks

THE WALL STREET JOURNAL.

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TECHNOLOGY | ARTIFICIAL INTELLIGENCE

## We Tested an AI Tutor for Kids. It Struggled With Basic Math.

Khanmigo, a ChatGPT-powered bot, made frequent calculation errors during a Journal reporter's test

By *Matt Barnum*  
Updated Feb. 16, 2024 9:50 am ET

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## Apple Says Generative AI Isn't Good At Math

By Ron Shevlin, Senior Contributor. Observations from the... Follow Author

Oct 14, 2024, 03:32pm EDT

Share Save Comment 0

Apple CEO Tim Cook responding to a question on how much 1+1 is.

# AI suffers from Hallucinations & Fabrications

**The Guardian** US

## Chicago Sun-Times confirms AI was used to create reading list of books that don't exist

Outlet calls story, created by freelancer working with one of the newspaper's content partners, a 'learning moment'

10 of 15 books didn't exist

**WLWT5**

## Lawyers submitted bogus case law created by ChatGPT. A judge fined them \$5,000

Share

**AP** Updated: 8:16 PM EDT Jun 22, 2023

Infinite Scroll Enabled

By **LARRY NEUMEISTER** Associated Press

A federal judge on Thursday imposed \$5,000 fines on two lawyers and a law firm in an unprecedented instance in which ChatGPT was blamed for their submission of fictitious legal research in an aviation injury claim.

Judge P. Kevin Castel said they acted in bad faith. But he credited their apologies and remedial steps taken in explaining why harsher sanctions were not necessary to ensure they or others won't again let artificial intelligence tools prompt them to produce fake legal history in their arguments.

AI made cases “*out of whole cloth*”

# AI is Prone to Omit or Bias Results

Prompt: A Portrait of Personal Financial Advisors



Prompt: A Portrait of Dishwashers



Prompt: A Portrait of Chief Executives



Prompt: A Portrait of Anesthesiologist Assistants



## Amazon AI-enabled recruitment tool only recommended men

Like many large companies, Amazon is hungry for tools that can help its HR function screen applications for the best candidates. In 2014, Amazon started working on AI-powered recruiting software to do just that. There was only one problem: The system vastly preferred male candidates. In 2018, Reuters broke the news that Amazon had scrapped the project.

Amazon's system gave candidates star ratings from 1 to 5, but the ML models at the heart of the system were trained on 10 years' worth of résumés submitted to Amazon — most of them from men. As a result of that training data, the system started penalizing phrases in résumés that included the word "women's" and even downgraded candidates from all-women colleges.

Midjourney Image Creation Results  
and the prompts that generated them

Models were trained on 10 years  
of heavily male applicant CV data

# LLMs Can Produce Unexpected Results

## AI algorithms identify everything but COVID-19

Since the COVID-19 pandemic began in 2020, numerous organizations have sought to apply ML algorithms to help hospitals diagnose or triage patients faster. But according to the UK's Turing Institute, a national center for data science and AI, the predictive tools made little to no difference.

MIT Technology Review has chronicled a number of failures, most of which stem from errors in the way the tools were trained or tested. The use of mislabeled data, or data from unknown sources, was a common culprit.

Derek Driggs, an ML researcher at the University of Cambridge, together with his colleagues, published a paper in *Nature Machine Intelligence* that explored the use of deep learning models for diagnosing the virus. The paper determined the technique wasn't fit for clinical use. For example, Driggs' group found that their own model was flawed because it was trained on a data set that included scans of patients that were lying down while scanned, and patients that were standing up. The patients who were lying down were much more likely to be seriously ill, so the algorithm learned to identify COVID risk based on the position of the person in the scan.

The algorithm learned to identify COVID risk based on the patient's position

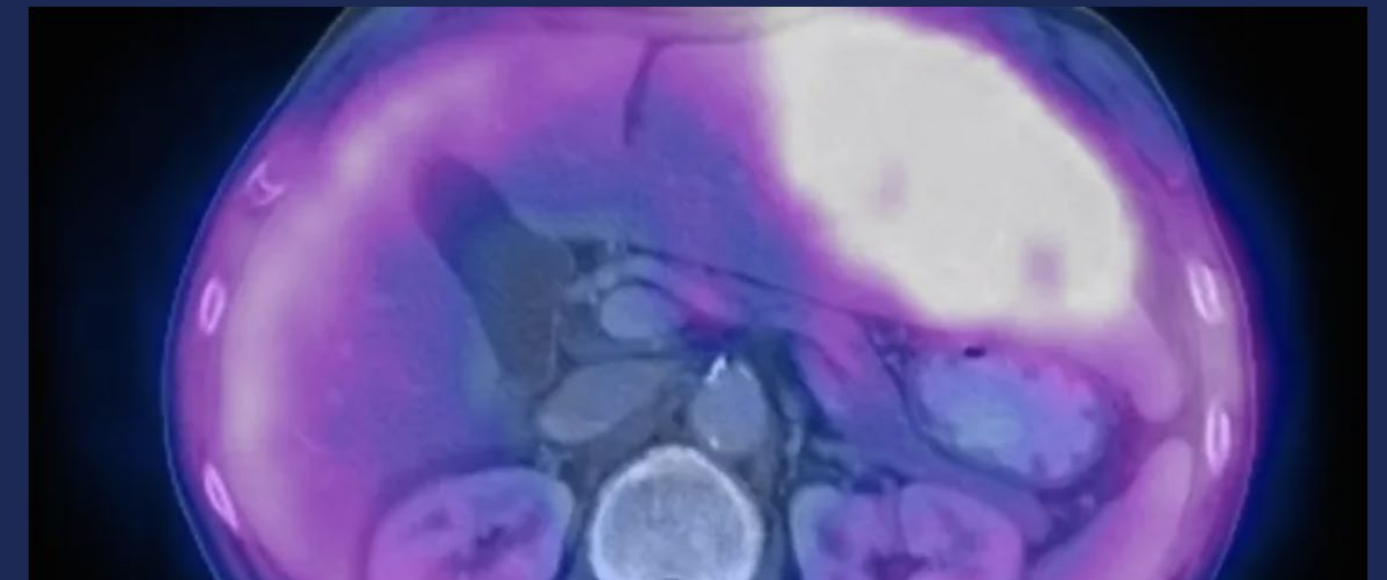
VB Live

## When AI flags the ruler, not the tumor — and other arguments for abolishing the black box (VB Live)

VB Staff

March 25, 2021 11:50 AM

f X in



The model learned to identify the ruler as a marker of malignancy

Despite all of the shortcomings,  
LLMs are here and in use, so  
how should we respond?

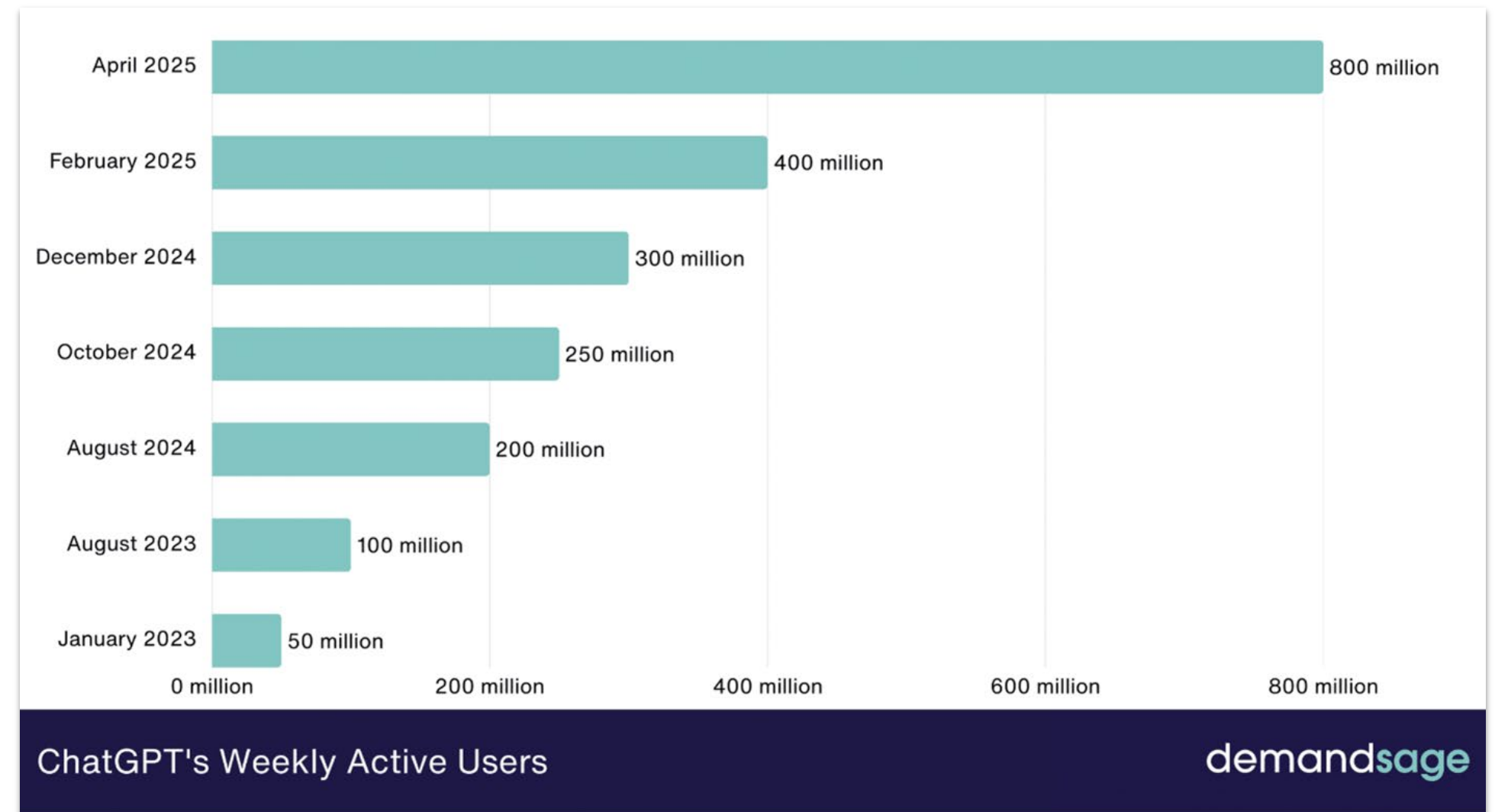
# 1. Acknowledge it's happening



# Consider the growth of OpenAI as a Proxy

## OpenAI hit 1M users in 5 days

- Instagram took 2.5 months and Netflix took 3.5 years
- In April 2025, OpenAI surpassed 800M weekly users
- Even if it's not officially sanctioned by your organization, it's likely that a percentage of your staff is using it personally (and professionally?)



“

This is a time where it's really important for us to pay attention because the good news if we lean into these disruptive changes, we can leverage their superpower to be able to drive amazing organizations. ***But if we ignore the speed and the size of chaotic change, which is where we are now, then I think there's some possibility that you could put yourself in a situation to fall behind .***



Nicholas Webb  
Author & Healthcare Futurist

## 2. Similar Advancements Have Occurred



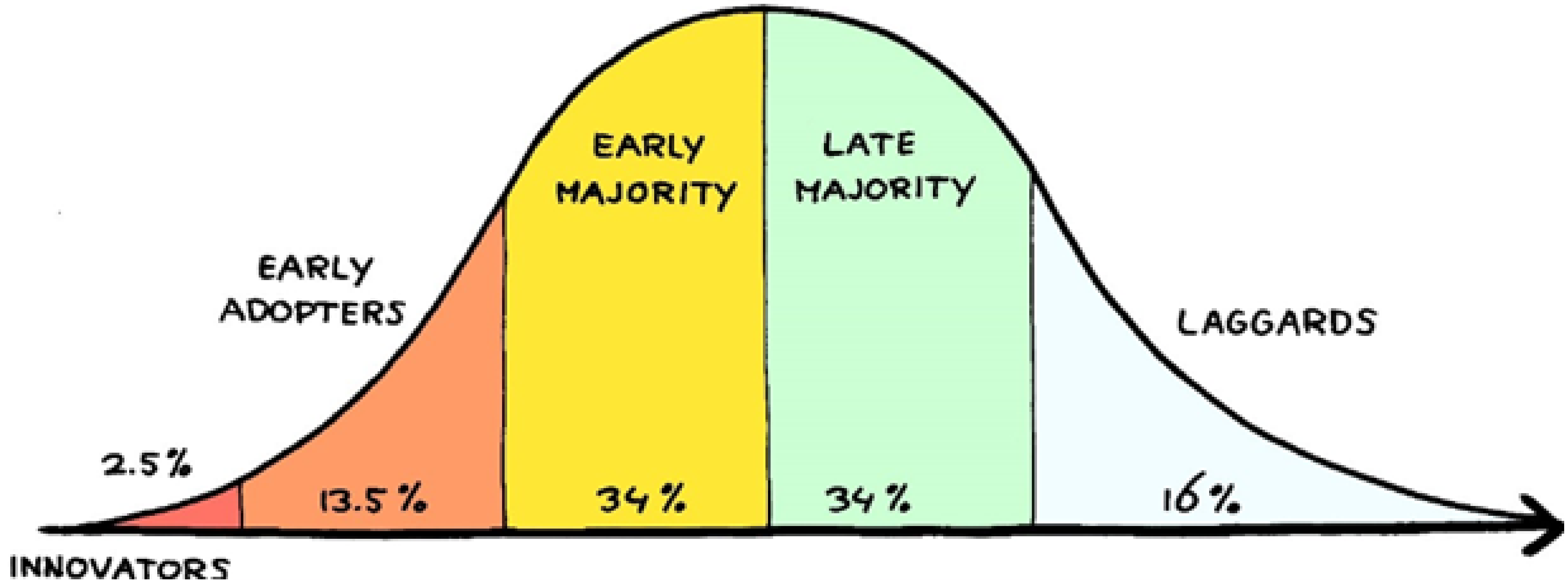
# What happened when technology was introduced

- Livestock as food vs. labor
- Less labor was needed on the farms
- Urbanization became popular
- Lower costs for farming equipment due to mass production
- Yield per acre increased
- Support industries sprang up



Technology changed the way the farmer worked, but it did not automate a way or eliminate the field of agriculture

But not everyone is comfortable with new tech



## People have mixed feelings about our AI Future

55%

feel optimistic about the future impact of AI on the MedTech industry

71%

say they know companies will need to adopt AI to be competitive

84%

see either a positive impact (37%) or a net-neutral impact (47%) on their careers.

## 2 Quotes Sum Up the Promise and Trepidation

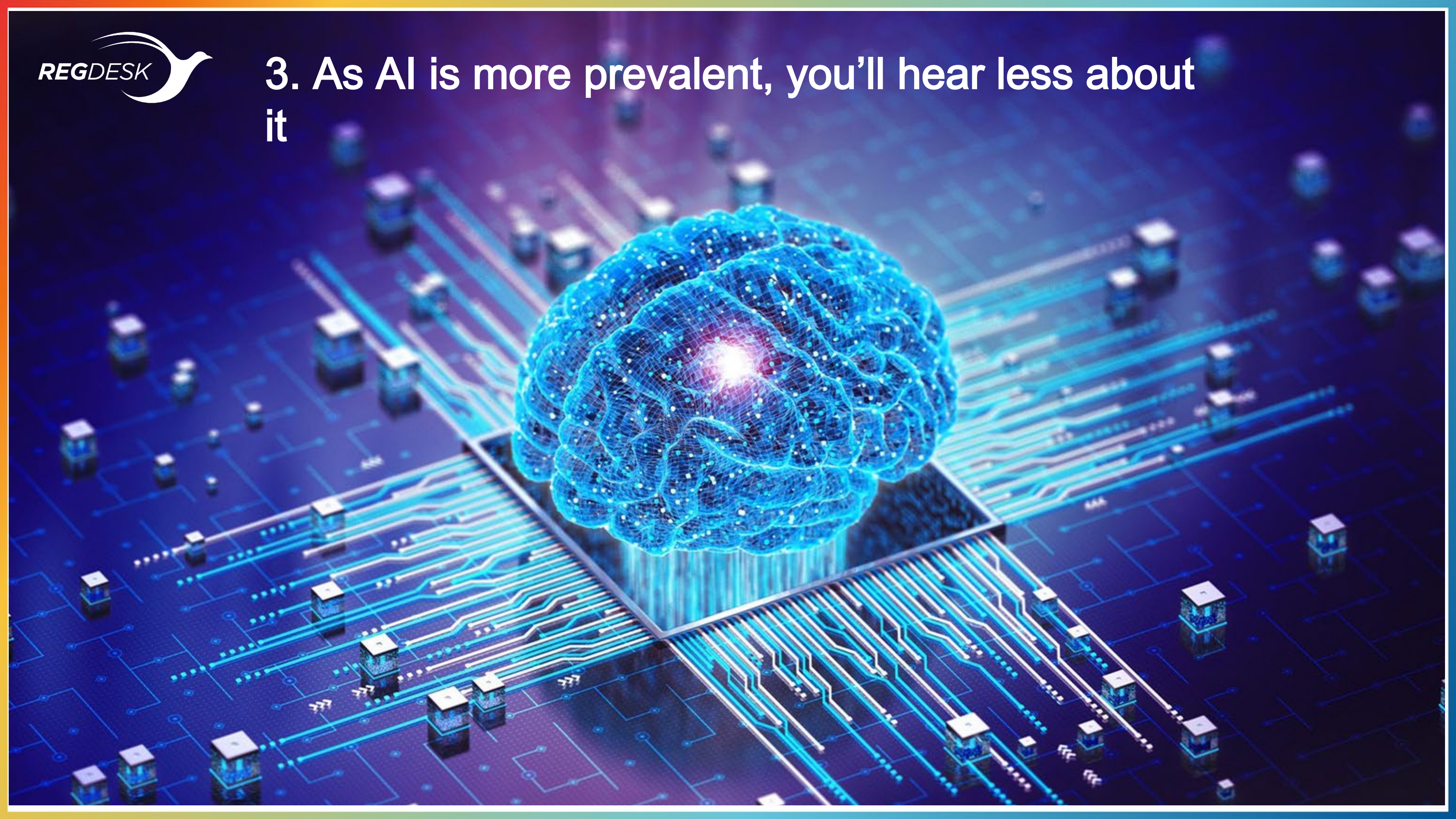
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*I am hopeful that AI can **automate some of the more simple, mundane and routine tasks**, so that I can focus on tasks that truly require and utilize my expertise.*

“

*I feel like there is a probability that use of AI will **devalue the knowledge and skills brought by the individuals** to an organization.*

### 3. As AI is more prevalent, you'll hear less about it



# Providers put “AI” everywhere to appear innovative



6sense™

<https://www.6sense.com> › ai › b2b

## 6sense Account Based Marketing - AI-Powered ABM Platform

6sense named a leader in the November 2024 Gartner® Magic Quadrant™ for ABM Platforms! Uncover, prioritize, and engage with demand by uniting on a common, Account...



HighRadius

<https://www.highradius.com> › ar-automation › software

## AI-Powered O2C Software

Outperform Competitors with AI — HighRadius: Named I2C Leader by Gartner for the 3rd Year. See It in Action—Get A Quote!



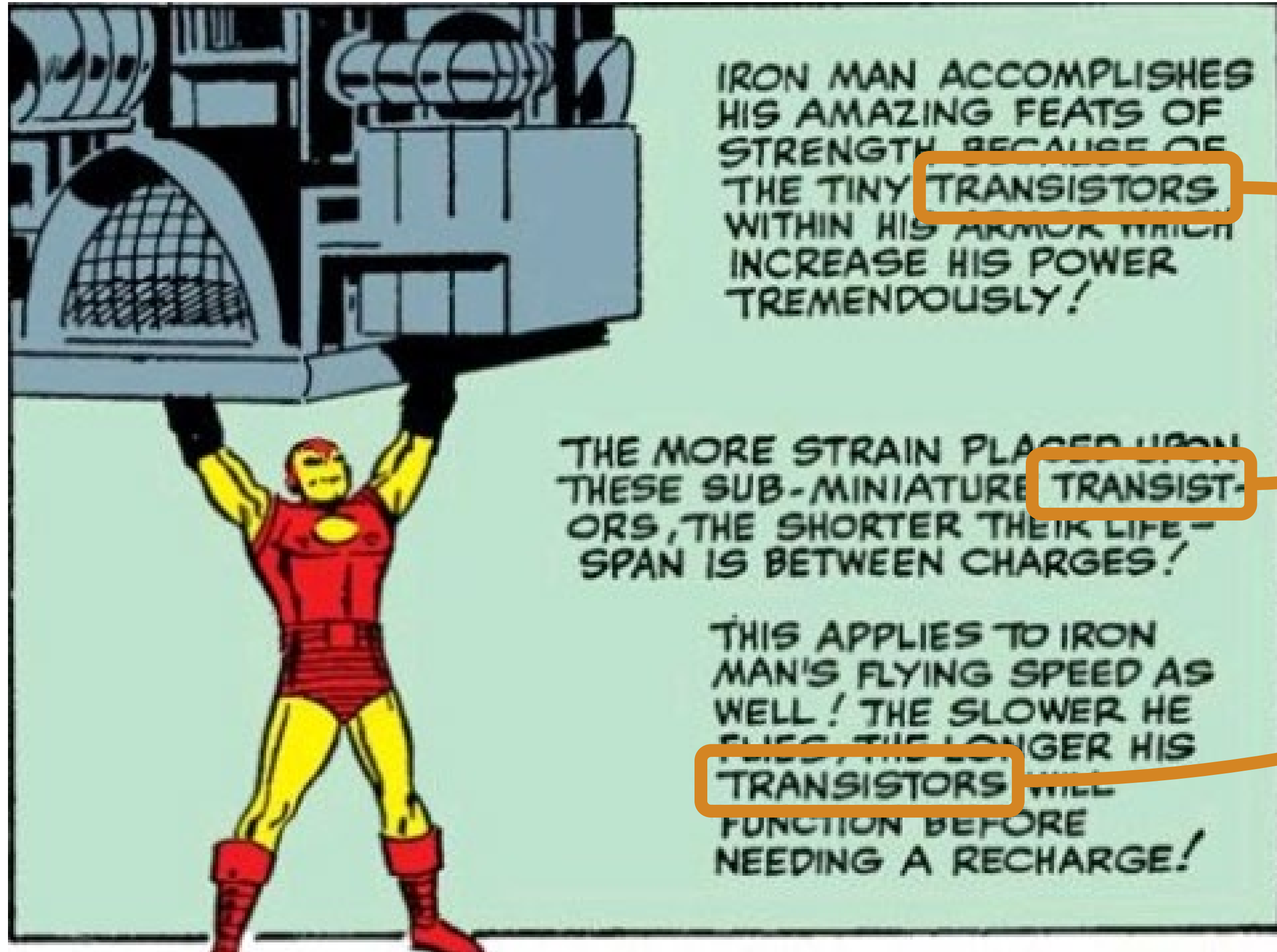
Zeni

<https://www.zeni.ai>

## Ai Bookkeeping

AI Bookkeeping — The Only Founder-First Accounting Platform On The Market. Trusted by Hundreds of Startups. Get Personalized Bookkeeping and Support for Confident Decision-Making. Book...

# Innovative Technologies Don't Always Age Well



Transistors

AI will soon be a ubiquitous  
enabling technology that will be  
integrated into your workflows

“

What we have to do is combine artificial intelligence with human intelligence, and this is a thoughtful strategy that organizations have to build out in order to make this work. When we do that, ***we actually create cooperative intelligence, and cooperative intelligence is us collaborating with the machine by getting better insights and making better decisions*** .



Nicholas Webb  
Author & Healthcare Futurist

# Enabling Tech with a Human In the Loop

Just like the Iron Man suit, the technology is what takes the human's intuition, wisdom and insights and super charges those.

AI (LLM) is currently an enabling tech for **low accuracy jobs** :

- Great for Ideation
- Great for non-technical writing
- Great for Starting things

## Big Idea

Today's AI is a technology that works at the behest of the user..and is not a replacement for the user.



# Enabling Technology Got me to Europe



## Assisted Driving



## Smart Home



## Robotics



# Final thoughts

## Wrapping Up

AI is an incredible enabling technology that is taking the world by storm.

- It's not a silver bullet:
  - Hallucinations are sometimes tough to catch
  - Omissions are possible
  - Unexpected Results should be reviewed and validated

How should we react to AI in Regulatory Affairs

- It's here now so let's not bury our heads in the sand
- We are living through another technical revolution
- As it becomes more ubiquitous, it will be less of a buzzword
- There should always be a human at the last mile

# AI with humans in the loop is the future



AI

Thank you!