

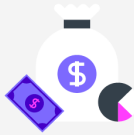


# Building the Foundation for QMS AI From Paper to AI

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## MYTH

As a life science company, you need a costly and complex quality management system (QMS) that cripples you financially, takes months to configure and implement, and continuously surprises you with hidden fees for updates, upgrades and validation.



## REALITY

Within weeks you can be up and running with a ready to use, cloud-based QMS that is preconfigured based on industry best practices to support the quality and compliance processes you need when you need them.



**What does it take to be a successful quality organization in today's business climate?**

# Agenda



TRANSITION FROM PAPER  
AND FILE-BASED SYSTEMS  
TO AUTOMATED QUALITY



ADVANTAGES OF A MODERN  
CLOUD QUALITY  
MANAGEMENT SYSTEM



LAYING THE FOUNDATION  
FOR AI



KNOWING BENEFITS &  
MITIGATING THE RISKS

# Transitioning from paper & file-based quality

Where are you now?



A recent survey indicated that of the surveyed businesses, only 22% use a cloud-based QMS and more than half use either Excel (27%) or paper-based systems (26%).



Survey by DOT Compliance



# Transitioning from paper & file-based quality

Where are you now?



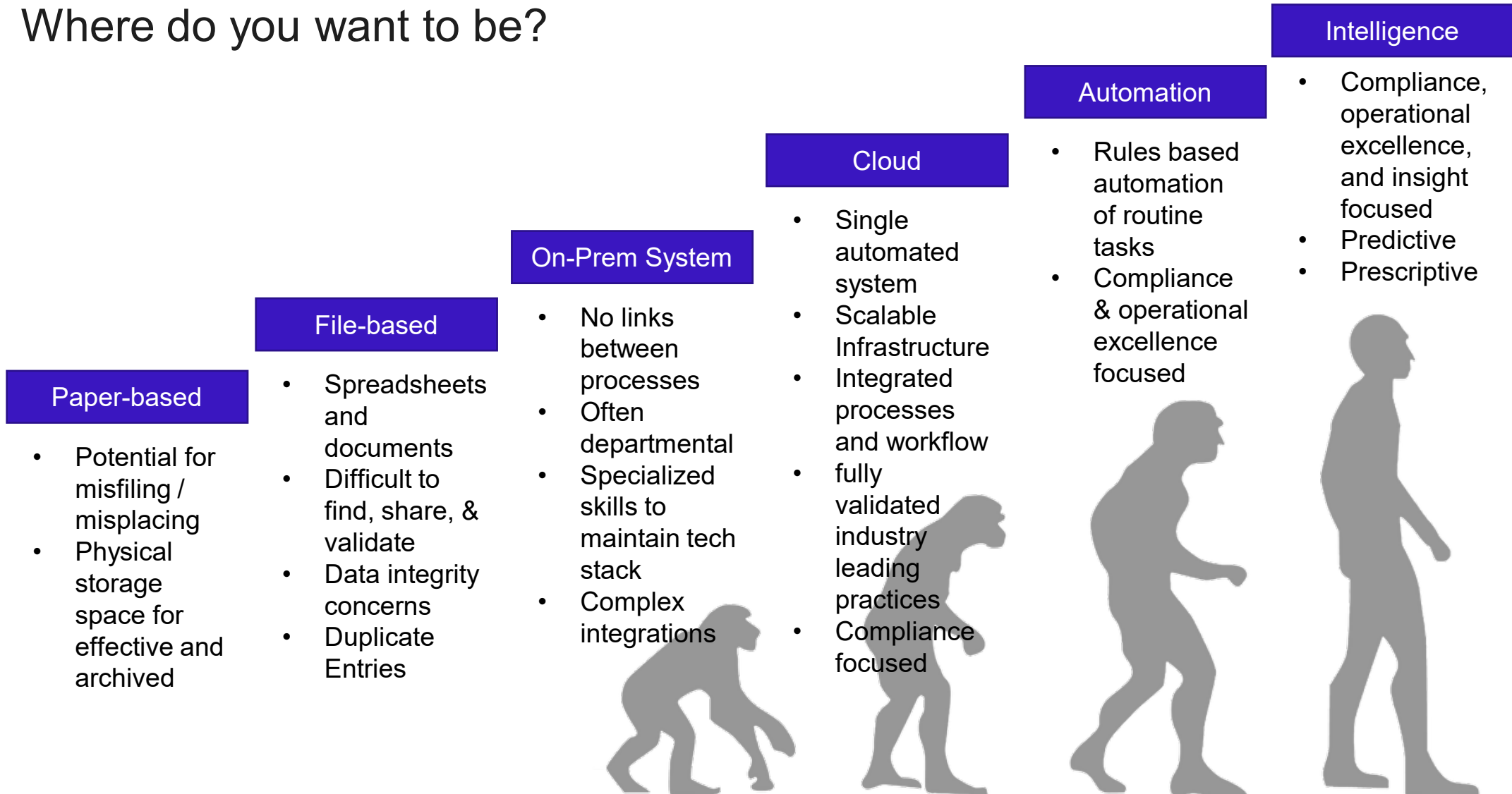
More than half of office professionals spend more time searching for information and documents than they do working.



Wakefield Research & Elastic

# Transitioning from paper & file-based quality

Where do you want to be?



# Poll #1

- Where are you in your journey today?
  - Paper-based
  - File-based
  - Legacy On-Prem
  - Cloud
  - Cloud + Automation
  - Cloud + Automation + Intelligence



# Poll #2

- Where in the maturity matrix would you like to be within a year?
  - Paper-based
  - File-based
  - Legacy On-Prem
  - Cloud
  - Cloud + Automation
  - Cloud + Automation + Intelligence





# The “Airbnb” eQMS Adoption Model



Fully furnished, ready to use, validated yet flexible (furniture is not “cemented to the ground”)

# Transitioning from paper & file-based quality

How do you get there?

## INITIATION

Engage aligning and leveraging leadership to support change: Assign stakeholders & project team.

## DESIGN

Prepare environment strategy, migration plan, interface requirements

## SYSTEM REVIEW & ADOPTION

System walkthrough: layouts, lifecycle, permissions, reports and dashboards.  
Practice sessions.

## LEADER & END USER ENGAGEMENT



## BUSINESS & OPERATIONAL READINESS

What's changing and impact analysis

Readiness Action Plan & Tracking

Validation Package Acceptance

Operating Procedure Updates

Admin & End User Training

Proficiency and practice sessions

Readiness Assessment

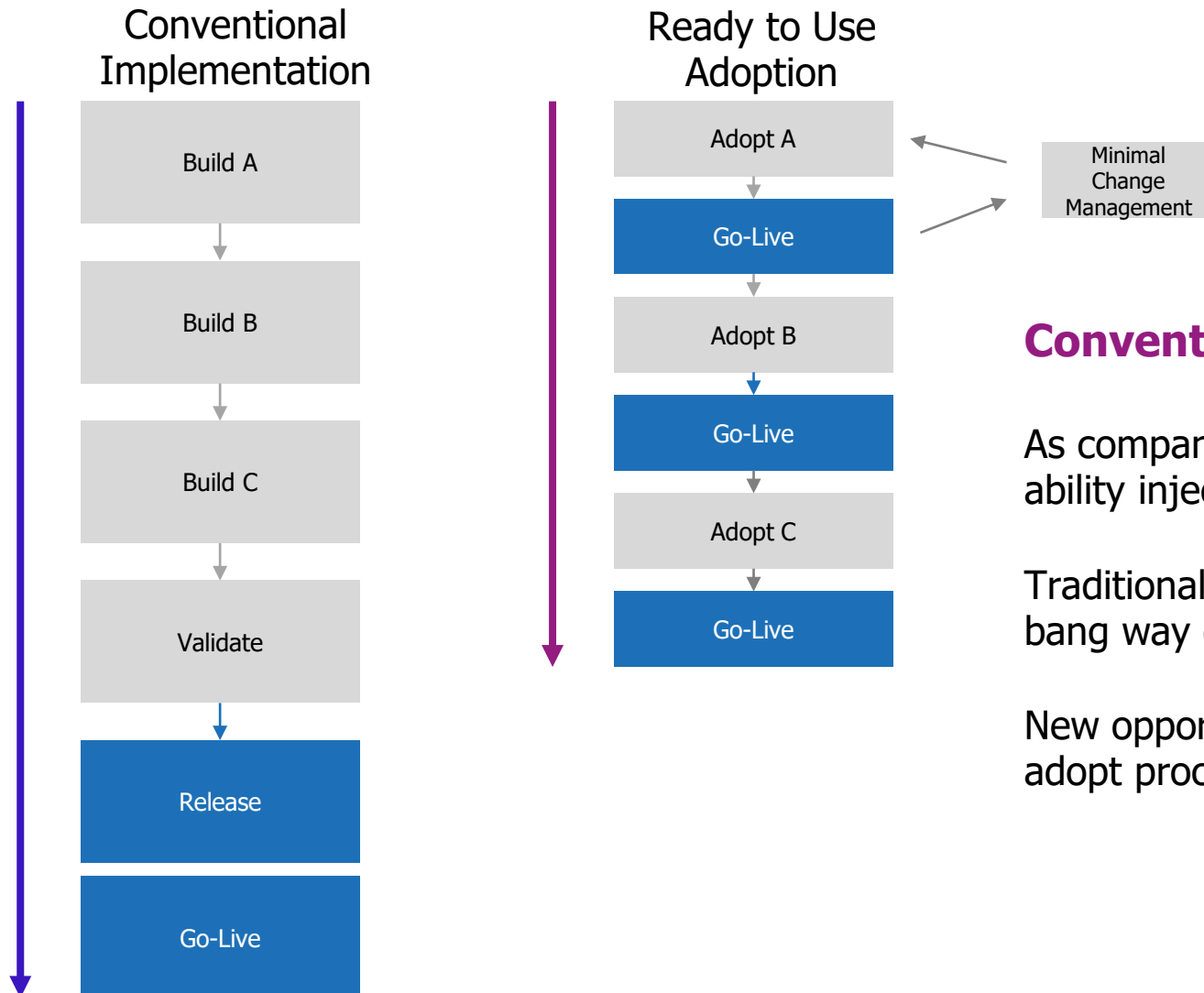
Go-Live & Hypercare

Post go-live Optimization

ADOPTION  
&  
OWNERSHIP



# Adoption versus Implementation



## Conventional vs Ready To Use

As companies adopt ready to use solutions, they gain the ability injecting agility into the process.

Traditionally, companies would release solutions in a big bang way due to dependencies between builds.

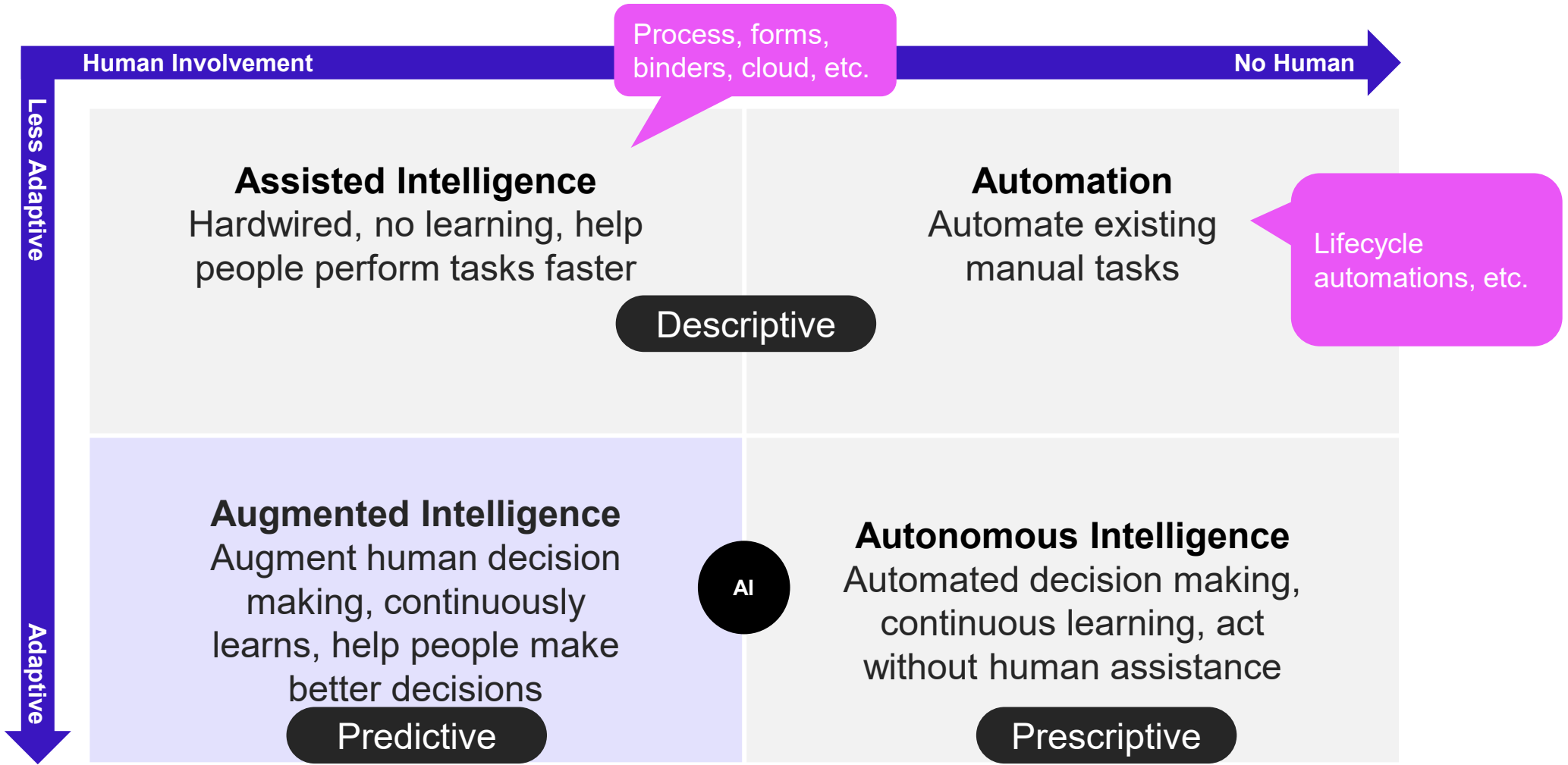
New opportunities exist with ready to use solutions to adopt processes on-the-go.



# Laying the Foundation for AI



# Is digitization enough?



# Laying the foundation for AI

In the past we said...

Implementing AI  
won't be  
immediate

It requires lots  
of data to start

It requires clean  
data

The more data  
validations there  
are in the QMS  
the better

Stop entering  
data into large  
text fields

Define  
reference and  
master data



# Laying the foundation for AI

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# Why the sudden change in thinking?

- Generational change in AI has brought machines closer to exhibiting human behavior
- With advances in **Generative AI**, machines can now generate original content and engage in sophisticated conversations.
- Unsupervised, Massive Deep Learning, Large Language Models (LLM)



OpenAI

ChatGPT



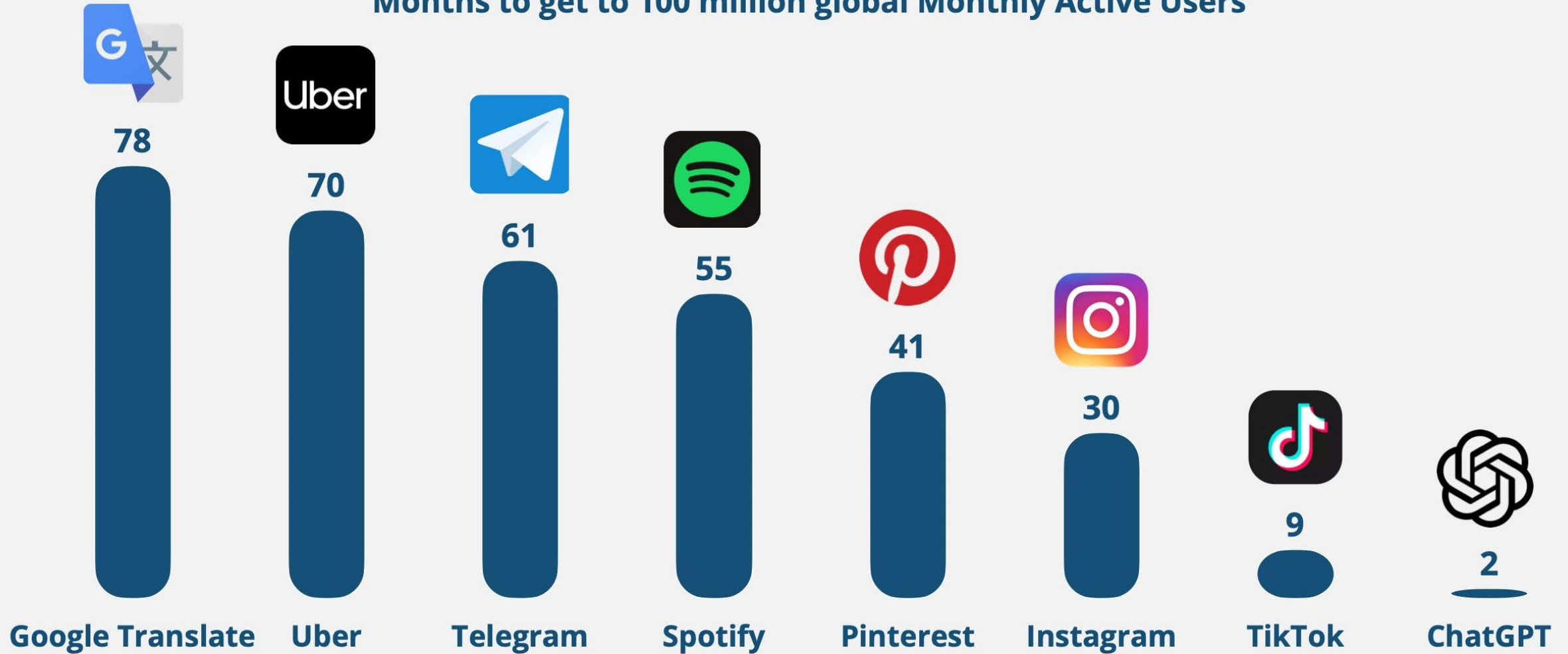
Google AI

BARD



# Time to Reach 100M Users

Months to get to 100 million global Monthly Active Users



Source: UBS / Yahoo Finance

 @EconomyApp

 APP ECONOMY INSIGHTS

# ChatGPT versus Bard

	ChatGPT	Google Bard
<b>Type of Platform</b>	Conversational AI Tool	AI-Powered Conversational Internet Search
<b>Powered By</b>	OpenAI's GPT-3.5 Language Model	Google's LaMDA
<b>Data Source</b>	570 GB of textual data from websites, books, and other sources.	Websites & Sources on Google Search Index
<b>Knowledgebase</b>	Limited up to 2021	Aware of all present & past events
<b>Availability</b>	Generally Available (Free + Paid)	Currently Available in the United States

- **ChatGPT Adoption:** 1M users in less than a week! 100M users in less than 2 months!
- **ChatGPT Total Website Visits:** 619 million in January. Jumped to 1 Billion in February 2023, 1.6 Billion in March 2023  
(Source: Similarweb)



# The Generative AI Tools Ecosystem is Exploding

## AI CHAT AND SEARCH

- **ChatGPT:** Conversational AI trained on a large set of text from 2021 and earlier. Free, but costs \$20 per month to speed up responses and use during peak demand.
- **The new Bing:** ChatGPT-based conversations and search results inside Bing. Limited beta requires joining a waitlist.
- **Perplexity.ai:** Ask questions and follow-ups, get direct responses with citations. Free to use with no limitations.
- **YouChat:** Ask questions and follow-ups, and engage in ChatGPT-style conversations. Free; sign-in required.
- **NeevaAI:** Get direct, AI-generated responses with citations, followed by standard search results. Free; sign-in required.
- **Poe:** Conversational AI from Quora that includes multiple assistants with differing strengths. Free; currently iPhone only.

## AI ARTWORK GENERATORS

- **Stable Diffusion Online:** Free Stable Diffusion artwork generator; no login required.
- **El Pintador:** Free Stable Diffusion artwork generator for iOS with a “Learn” section that provides prompt crafting advice.
- **DiffusionBee:** Stable Diffusion artwork generator for MacOS, works offline with no usage limits.
- **Craiyon:** Online artwork generator that uses the Dall-E Mini model. Removing watermarks requires a \$5-per-month subscription.
- **Dall-E:** Create up to 15 free images per month with OpenAI’s image-generation tool.
- **Nvidia Canvas:** Windows software that turns brushstrokes into artwork. Requires an Nvidia RTX graphics card.
- **Playform:** Online app that turns sketches into artwork. Free to try, but requires paid credits to download watermark-free images.

## AI VISUAL EDITORS

- **Runway:** Photo and video editor with an array of AI tools, including green screen, image expansion, and 3D texture creation. Free with limitations on export resolution and AI tool use, then \$15 per month.
- **Genmo:** Turn still images into animations using text prompts. Free with usage limits.

## AI AUDIO TOOLS

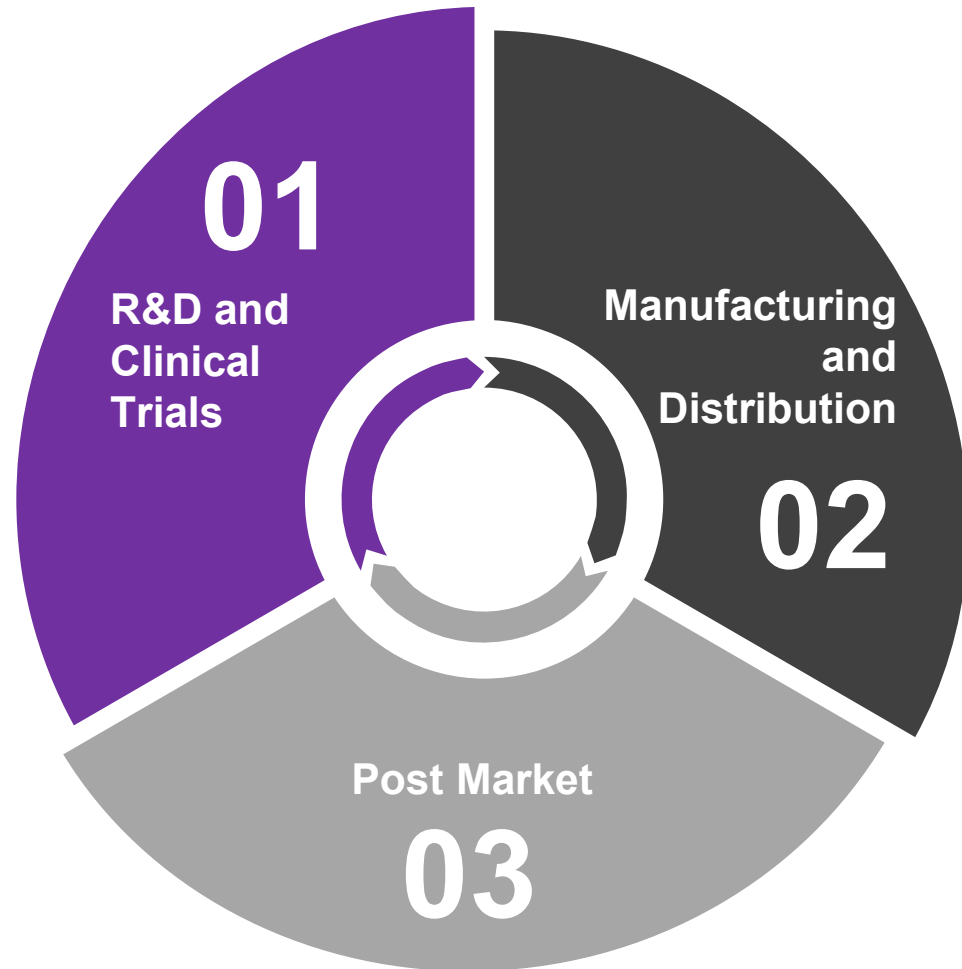
- **Eleven Labs:** Generate speech from text, free for up to 10,000 characters of text per month. A \$5-per-month subscription lets users clone an existing voice.
- **Riffusion:** Generate music from text descriptions using Stable Diffusion. Free.
- **Boomy:** Generate music tracks by specifying the genre, instruments, and production values. Free.
- **Beatoven:** Create music by specifying the genre and mood. Free to use with up to 15 minutes of monthly downloads, then \$20 per month.

## AI SPEECH-TO-TEXT TRANSCRIPTIONS

- **Whisper:** Online transcription of audio files using language models from OpenAI. Free.
- **Buzz:** Offline version of Whisper for Windows, free unlimited use.
- **MacWhisper:** Offline version of Whisper for Mac. Pay what you want, or \$14 for larger language models and translation.



# Enhance quality in every area of business with AI



## 01 Optimize Quality Processes

Achieve faster product development, approval, and market launch.

## 02 Uncover Hidden Insights

Detect, predict, and report deviations in materials, processes, etc.

## 03 Reduce Costs

Proactively minimize the risks associated with costly regulatory penalties, recalls, and reputational damage.

# Application of AI in Life Sciences Quality Management



# But how does it make your life better?

## Improve Data Quality

Contextually organize & visualize quality records and documents

Standardize quality professional language

Data entry validation recommendations when filling forms

Identify duplicate and conflicting quality documents and recommend changes

Summarize cases, complaints, investigations

## Make Better Decisions

Detect impactful data changes and launch tasks for review & decision making

Detect Deviations/OOS and recommend immediate actions

- Predict record state transition timing
- Determine timeline risk
- Recommend route changes

- Route Cause Analysis
- Return Product Analysis
- Regulatory Reportability Analysis

Product Troubleshooting

## Improve Productivity

Identify and leverage similar and related quality records  
\* Deviations, CAPAs, Change Controls, Complaints

Suggest and launch processes  
\* Risk Assessments, Regulatory, Audits, etc.

Generate communication / correspondence letters and emails

- Production Optimization
- Predictive Maintenance

Predictive Shelf-Life and Survivorship



# Poll #3

- Do you see yourself/your department/company using an AI-driven QMS in the future?
  - Yes
  - No



# What have we heard about ChatGPT?

## ⊗ Risk

- ⊗ **Opaque Models**– We don't know how generative AI is trained, what data was used, where the data comes from, etc.

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- ⊗ **Hallucination** – A confident response by an AI that does not seem to be justified by its training data can lead to poor choices with consequences.

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- ⊗ **Exposure of sensitive data** – Inappropriate use of technology can inadvertently put sensitive information at risk.

## ✓ Mitigation

- ✓ Embed AI solutions with explainable AI principles to provide evidence-based support and reasoning for results.

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- ✓ Embed AI solutions with built-in contextual prompts can help avoid hallucination. Also, keep a human in the loop and give them the opportunity to offer feedback that can be used to fine tune the model.

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- ✓ Embed AI solutions with guardrails that constrain user input and limit output tokens. Look for solutions that enforce application security on both going and incoming data.



# Key Take Aways

- Know where you are in your journey today
- Jumping to the end is now possible
- Generative & predictive AI empowers decision making
- Continue to use the 4 eyes principle
- Low-skill, routine tasks will be automated
- Jobs will become more analytical in nature
- Plan to upskill your workforce, so they can focus on the things that matter
- Choose fit-for-purpose solutions with built-in guardrails to mitigate risk
- Ready-to-Use AI-base eQMS is real!



# Thank You!

Contact Us: [hello@dotcompliance.com](mailto:hello@dotcompliance.com)  
[www.dotcompliance.com](http://www.dotcompliance.com)



Industry-first, **ready-to-use AI-Based electronic Quality Management System** for Life sciences, powered by an **embedded generative and predictive artificial intelligence**.

## Good to Know

We are designed for fast deployment, flexibility and minimal implementation effort.

- ✓ Includes all core quality assurance processes, training, regulatory compliance, and document control
- ✓ Dot Compliance ready to use solutions helps you mitigate manufacturing risks, while ensuring compliance with regulations such as 21 CFR Part 11, 21 CFR Part 820, GMP, ISO13485, ISO9001, ISO14971 and others
- ✓ Ensures your organization and outsourced suppliers get the required visibility in real-time from early product development through manufacturing – to commercialization and post-market surveillance.

