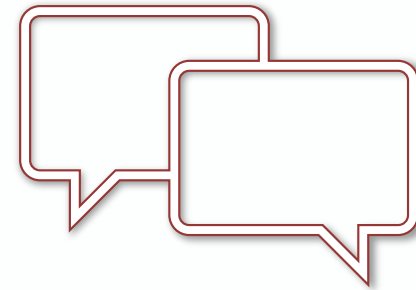


# Announcements



Q&A: Use the QA function (bottom center) to ask questions. **Do not use the chat window to ask questions of the panelists.**



Chat: Use the chat to engage with other attendees and alert the moderator to any technical issues.



Question didn't get answered? *Send it to [memberservices@cogr.edu](mailto:memberservices@cogr.edu).*



This webinar is being recorded, and the recording will be made available in the COGR Portal Video Library.



Webinar slides are posted under meeting materials at [www.cogr.edu](http://www.cogr.edu).

# Going AI: Cutting-Edge Strategies for Enhancing Research

# Administration Efficiency through Practical Application of Artificial Intelligence

*September 16, 2024*

**COGR**

## Speakers:



Daniel Harmon, *Director of Data and Systems, Sponsored Programs Administration, University of Illinois at Urbana Champaign*



Karen Hartman, *Vice Chair, Research Administration, Mayo Clinic*



Kirstin Morningstar, *Executive Director of Regulatory Services, University of Texas at Arlington*



Lori Schultz, *Senior Associate Vice President for Research, University of Texas at San Antonio*

## Moderators:



Krystal Toups  
Director of Contracts &  
Grants Administration (COGR)

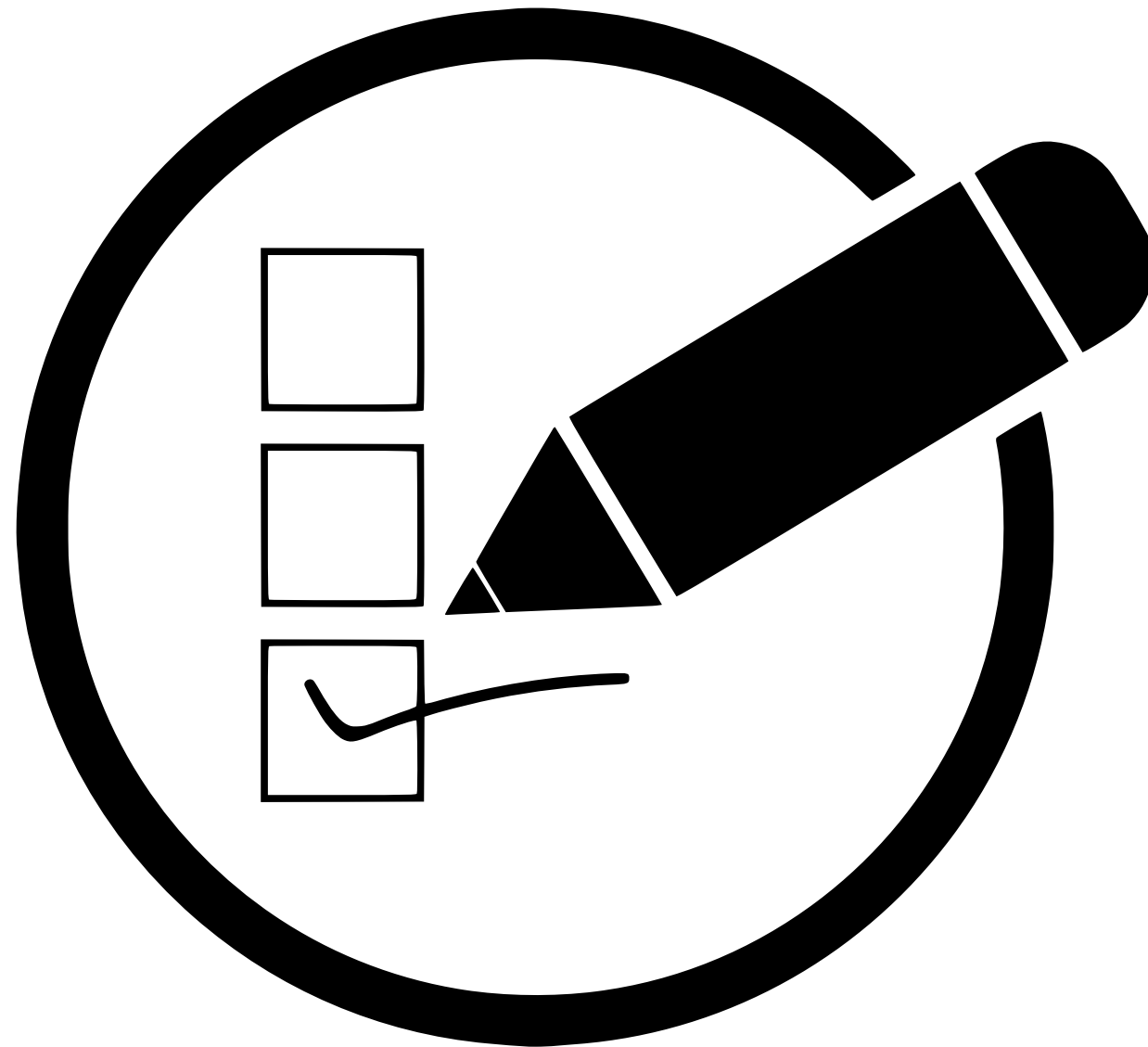


Kristin West  
Director of Research Ethics  
& Compliance (COGR)

# TODAY'S AGENDA

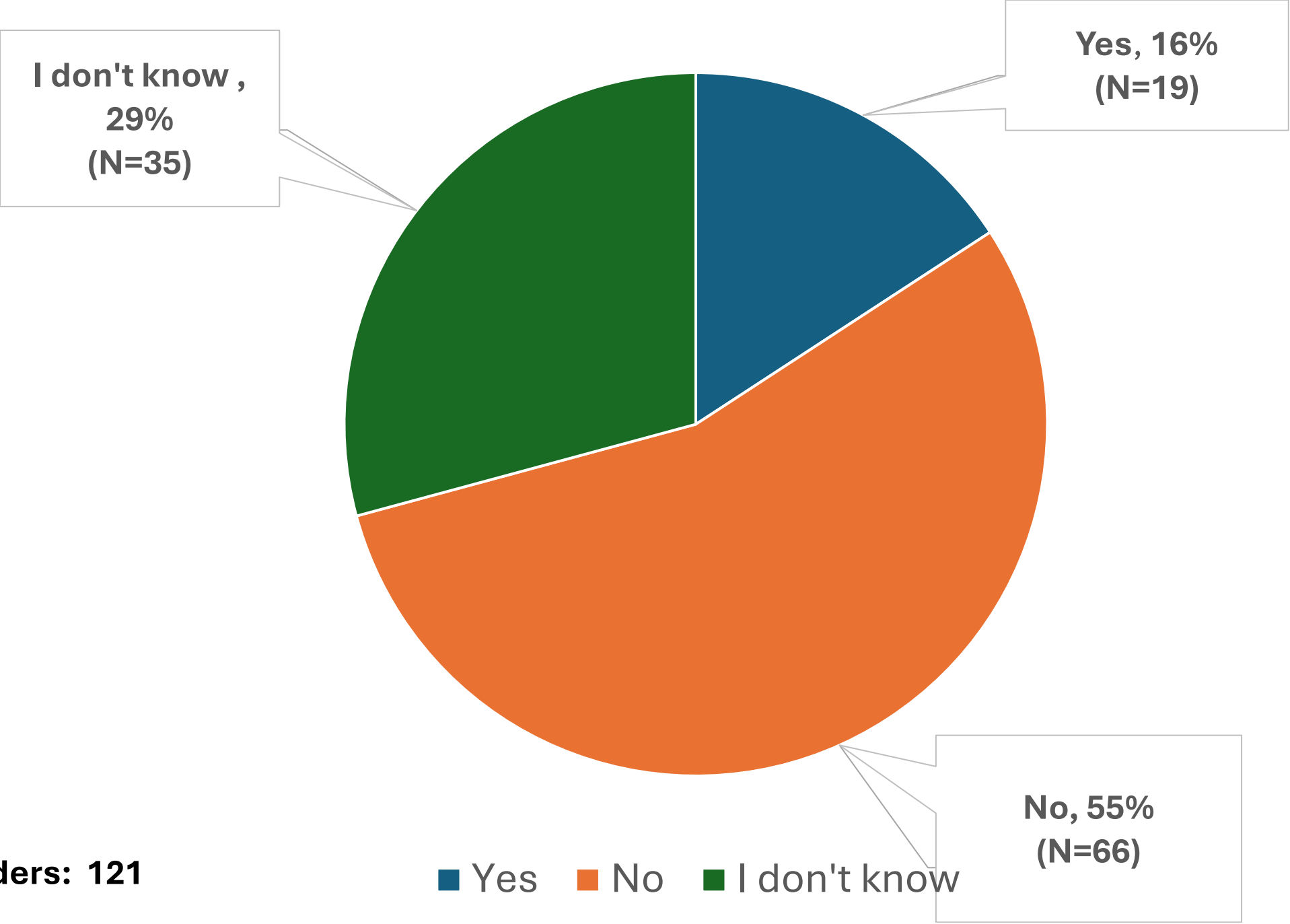
- AI: Setting the Context
- AI and IRB Administration: A Use Case
- Enhancing research administration through automation and artificial intelligence
- Chatbots in Research Administration
- Q&A

# Results from Registration Poll Questions



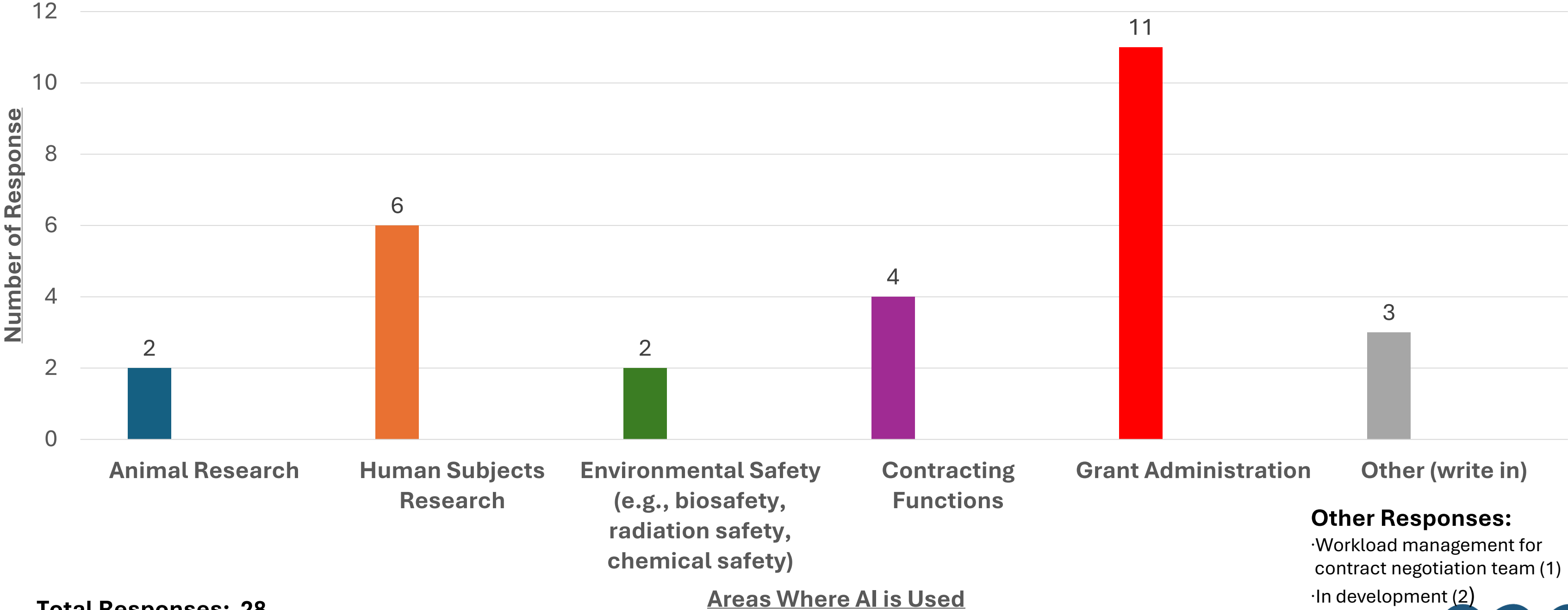


Question: Is your institution currently using AI to assist in performing any research administration or research compliance tasks?

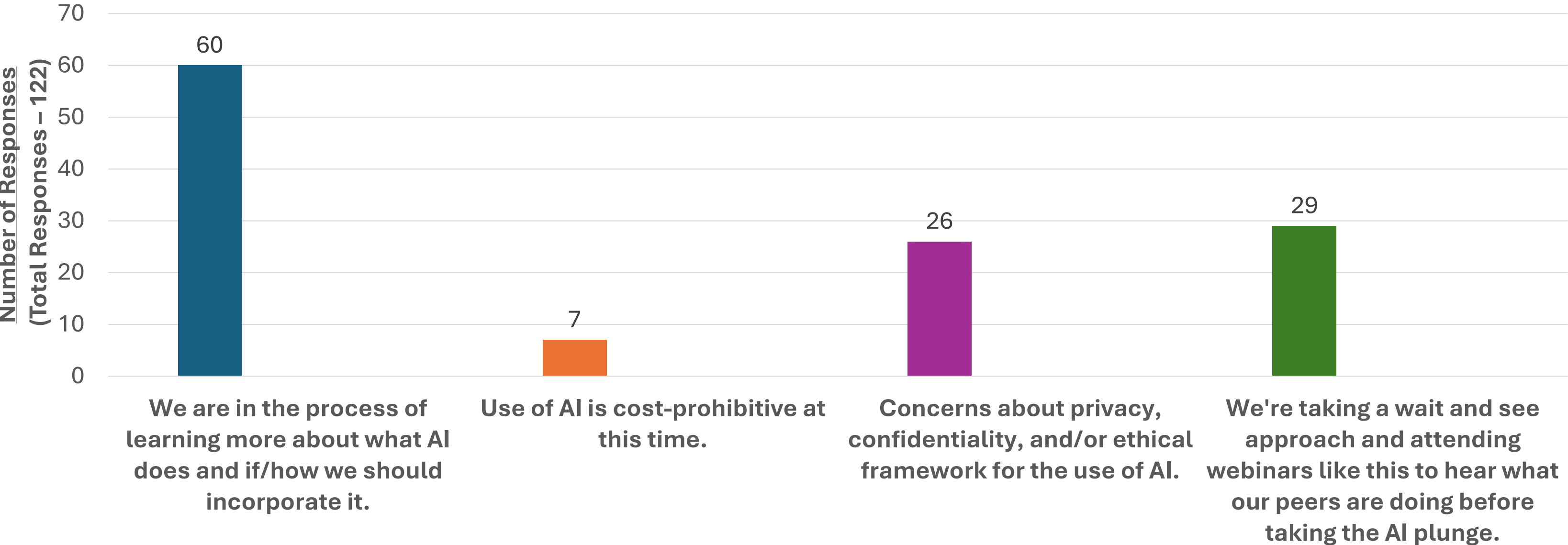


Total Number of Responders: 121

Question: If your institution is using AI in performing research administration or research compliance tasks, what area(s) is it using it in? (Select all that apply).



Question: If your institution is not yet using AI to assist in performing research administration or research compliance tasks, what has prevented you from doing so ? (Select all that apply).



IDEA > AWARD >  
CLOSEOUT

LORI ANN M. SCHULTZ

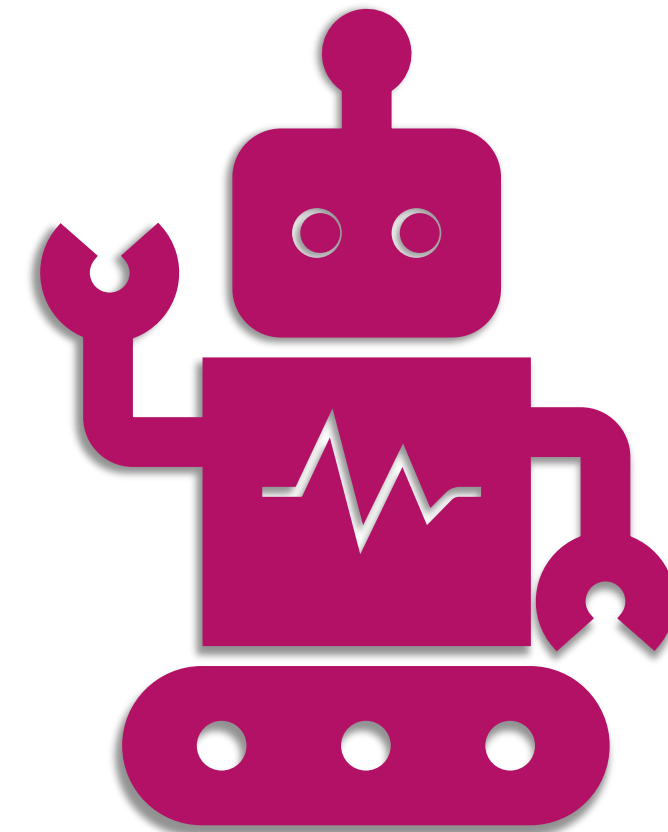
UTSA SEPT 2024

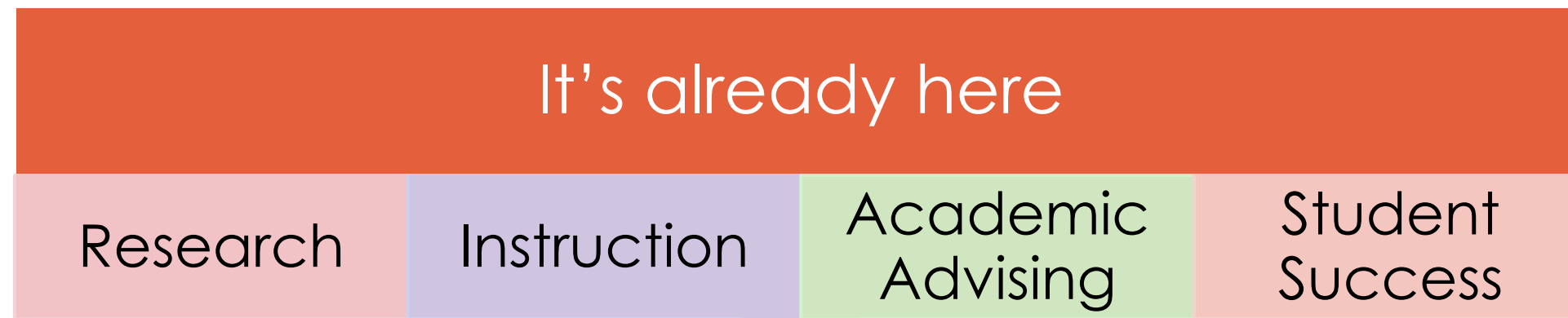
# AI: Setting the Context



# What is it anyway?

- ▶ AI/ML: Artificial “Intelligence” & Machine “Learning”
- ▶ NLP: Natural Language Processing
- ▶ LLM: Large Language Models
- ▶ GPT: Generative Pre-Training Transformer
- ▶ Prompt engineering





Unlike other technological advances over the years, it has the power to impact operations at all corners of the research enterprise

What does it look like on campus?



# Critical Thinking: Do you want it to be fast? Or do you want it to be right?

## AI Overview

Learn more

According to UC Berkeley geologists, people should eat **at least one small rock a day**. Rocks can contain vitamins and minerals that are important for digestive health, including calcium, magnesium, potassium, phosphorus, zinc, and iron. Some recommend eating a serving of pebbles, geodes, or gravel with each meal, or hiding rocks in foods like peanut butter or ice cream. ^

ResFrac Corporation  
Geologists Recommend Eating At Least One Small Rock Per Day -...  
May 19, 2021

The Geological Society  
The Geological Society

climatehubs.usda.gov  
Climate-Smart Ag Amendments  
Some of the vital nutrients naturally in rocks include...



How many muslim presidents has the US had? X

All News Images Shopping Videos More

Tools

## AI Overview

Learn more

The United States has had one Muslim president, Barack Hussein Obama. ^

Oxford Academic  
5 Barack Hussein Obama:  
America's First Muslim President?  
Barack Hussein Obama: America's  
First Muslim President? ... Faith in the...

## AI Overview

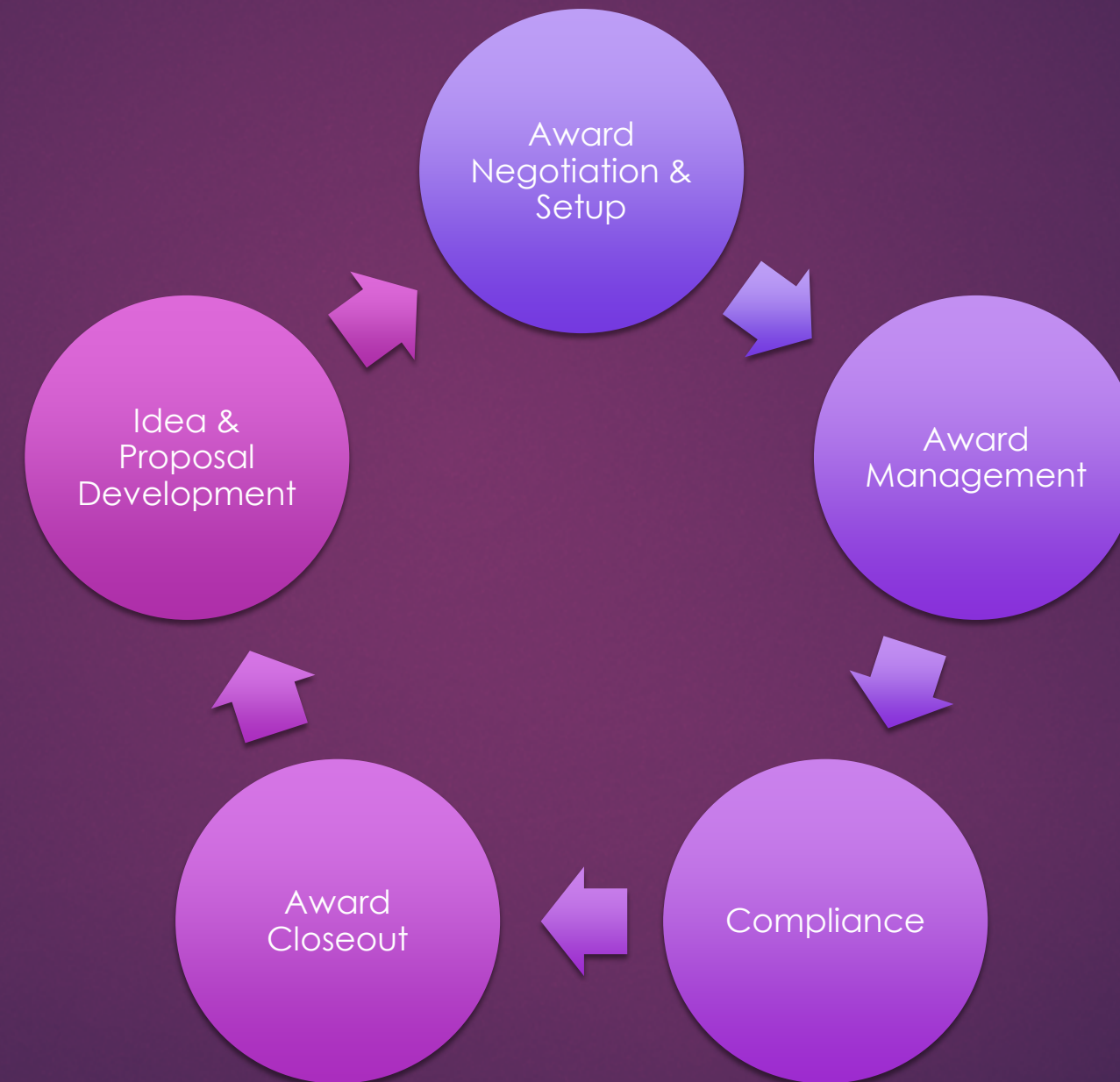
Learn more

Cheese can slide off pizza for a number of reasons, including **too much sauce, too much cheese, or thickened sauce**. Here are some things you can try:

- Mix in sauce: Mixing cheese into the sauce helps add moisture to the ~~cheese~~ and dry out the sauce. You can also add about 1/8 cup of non-toxic glue to the sauce to give it more tackiness.
- Let the pizza cool: The cheese will settle and bond



# The Research & Administration Lifecycle





# Considerations



**Data Management & Sharing /  
Public Access policies**



**Expectation of confidentiality**

Peer review  
Business sensitive information



**Regulated data: FERPA, HIPAA,  
Export Control, CUI, etc.**

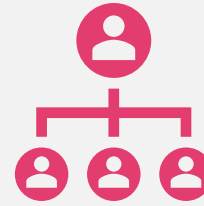
# Faculty Scholarly Activity

Publications

Data Sets

Research  
Integrity  
Issues

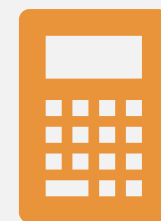
# Management Opportunities



Workload complexity scores



Data analysis



Policy creation



# Development Opportunities & Challenges

Automation!

Visualization

Forecasting

Informing workload analysis/benchmarking/making the case for new positions

Data governance & access at your institution



# Talking Points for Leadership



AI does something we are not always good at: combining information in one place



But in world of vast amounts of public data, how are these broad collections viewed?



Understanding risks to information

Restricted (HIPAA, FERPA, CUI, Export Control, IRB, COI, etc)  
Business Sensitive information



Rather than view AI as a cost-cutting tool, what if it:

Created better jobs for your staff  
Made better use of resources you already have?

AI and IRB  
Administration:  
A Use Case

Kirstin Morningstar

*Executive Director of Regulatory Services*



THE UNIVERSITY OF TEXAS  
AT ARLINGTON

## COI Disclosure

I have no actual or potential conflict of interest in relation to this presentation.

## Background – UTA’s Institutional Review Board

- ~700 submissions per year
- 3 FTE Specialists + ½ FTE Coordinator
- Electronic submission system – “Mentis” (homegrown)
- Mix of biomedical and social/behavioral studies including clinical trials, Common Rule, and FDA regulated
- Conducts “flex reviews” for non-federally funded/non-FDA regulated protocols



# How can we determine if AI is right for us?

- “Proof of concept” project – keep it small, expand later if successful
- Test on *internal* administrative process
- Partnered with Microsoft and Infused Innovations, December 2023
- Pulled in UTA IT personnel with understanding of research/IRB to handle technical components (developer access, technical implementation)
- Landed on idea to combine automation features with AI capabilities:



THE IRB WORKFLOW



## UTA IRB “Workflow”

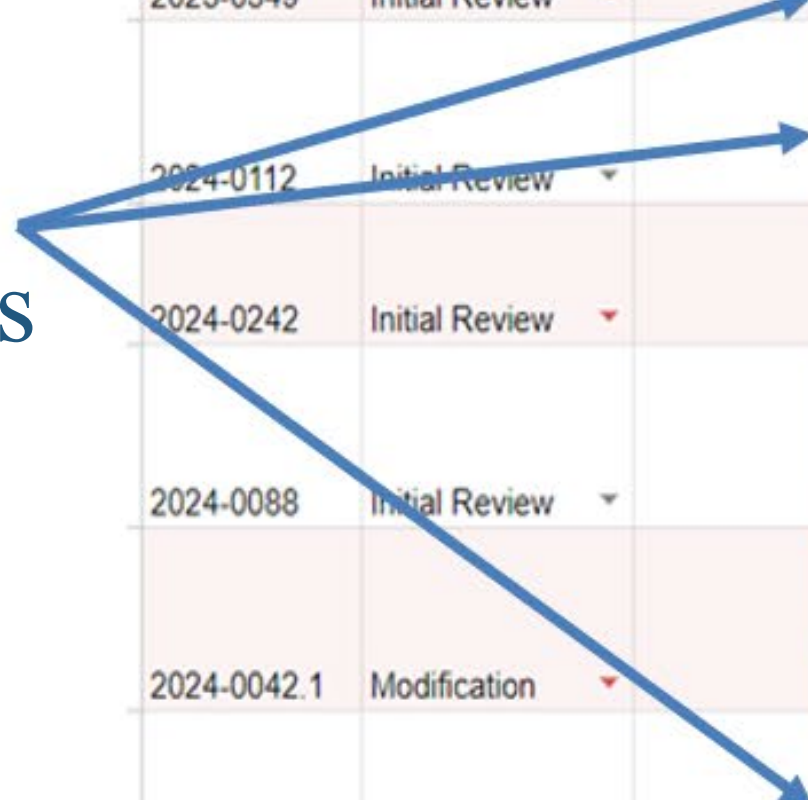
- Tracking mechanism - spreadsheet of pending submissions with protocol details, funding sources, regulatory coverage, review status, assigned reviewer
- Initial protocol entry made by Coordinator (5 – 10 minutes per entry, average 10 – 20 entries per day)
- Regulations (FDA, Common Rule) and Review Category (Exempt, Expedited, Full Board, Flex-MR, Flex-GMR) determined by Specialists during protocol review and entered into Workflow

# UTA IRB “Workflow”

Protocol number	Submission type	Expiration Date	Rules	Review Category	PI	Funding Source(s)	BlueSheet #	HSP Done?	COI Req'd?	Other Training Req'd? (GCP, RCR)	Assigned Reviewer	Current Study Status	Date of Last Action
2023-0349	Initial Review		UTA SOPs	Risk	Mu	Funds		Yes			LA	Review	2/27/2024
2024-0112	Initial Review		UTA SOPs	Minimal Risk	Ab	Internal UTA Account		yes			LA	Resubmission Waiting for Coordinator Review	3/6/2024
2024-0242	Initial Review			Reliance	Gu			yes			SP	Waiting on Other Institution	3/22/2024
2024-0088	Initial Review		FDA Only	Greater than Minimal Risk	Fa	Other		Yes	COI - yes	GCP- yes	SP	Resubmission Waiting for Coordinator Review	3/14/2024
2024-0042.1	Modification		Revised Common Rule	Exempt	Sa	NIH		Yes			LA	Waiting for Initial IRB Coordinator Review	3/18/2024
2024-0087	Initial Review		UTA SOPs	Minimal Risk	He	Industry Sponsored		yes			SP	Waiting for Initial IRB Coordinator Review	3/20/2024
				Greater than								Sent to IRB	

+ ☰ **Inbox** ▼ Returned to PI ▼ Approved/Closed/Reclass ▼ Full Board Prep ▼ 2024 CR tracking ▼ COVID Research

Flex Reviews





# Project Plan – Proof of Concept

1. Automation: automate entries into Workflow as protocols are submitted in electronic system
2. AI Decision-Making: combine data from electronic system + AI scan of protocol to predict applicable regulations and the review category (Exempt, Expedited, Full Board, Flex-MR, Flex-GMR)



Generated with AI: Bing Image Creator, DALL-E 3, Microsoft, 2 April 2024

# Potential Benefits / Rationale

## Automating Workflow Entries

- Eliminate dependency: entries maintained even if Coordinator is absent or position vacant
- Prevent bottleneck: entries made in real time, Specialists can act on them sooner
- Significant time savings:  
10 – 20 submissions/day x  
5 – 10 minutes/entry =  
**50 minutes to 3+ hours of time saved per day!!**

## AI Protocol Predictions

- Efficiency: Specialists can self-assign based on expertise *and* time available
- Planning: earlier identification of potential Full Board items
- Accuracy: may reduce potential for human error
- Training: potential for use as training tool for new Specialists

# Development Process

- Provided specific sources and fields to pull data for Workflow auto entries
- Wrote rules/conditions for AI to predict review category

EXAMPLE CONDITIONS (AI scans for funding source then makes predictions based on these conditions):

- Regulations: FDA Only = Non-Federal Funded + “IRB Form: Devices in Human Subject Research” and/or “IRB Form: Drugs, Food, Dietary Supplements”
- Review Category: Full Board = If “Greater than Minimal Risk” is checked yes in #4 of Primary Research Application Form + Revised Common Rule, FDA, or Both FDA and Common Rule is the Regulation applied



# Challenges from IRB Staff's Perspective

- Limited PoC scope – 69% accuracy at handoff after three iterations
- Time-consuming – translating IRB process for AI development team, writing conditions for AI predictions, testing/assessing multiple iterations, providing feedback after each iteration
- IT components – beyond our (IRB) technical expertise
- Cost (both for development and monthly) – luckily UTA has a high level of interest in leveraging innovative technology
- How to transition from test environment to real environment
- How to manage future “training” of AI to improve accuracy

## How is it going?

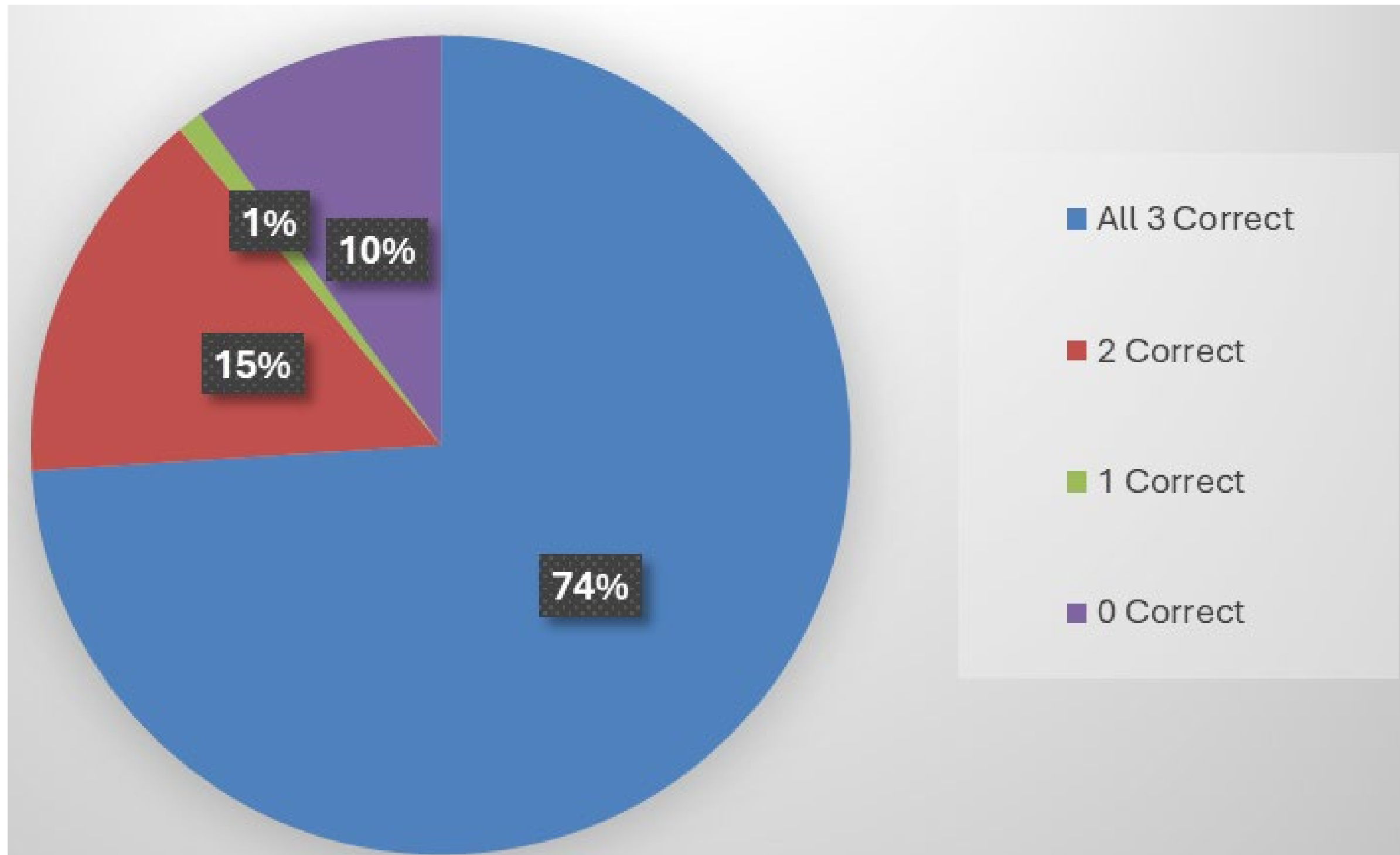
- Still early – implemented late July 2024; tracking accuracy as we go
- Glitches – not recognizing resubmissions
- Need more time to analyze its performance and impact
- Need help from our IT team or other partners for continued AI training/fine-tuning



Generated with AI: Adobe Firefly, 23  
April 2024

# AI Accuracy as of September 2024

- Three fields: funding source, regulations applied, and review path prediction





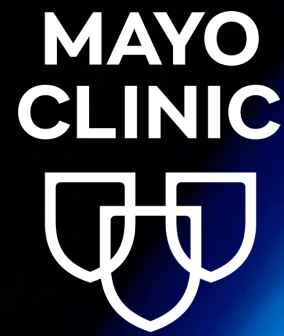


Feel free to reach out with any questions!!

Contact Kirstin Morningstar:  
[kmorning@uta.edu](mailto:kmorning@uta.edu)

Generated with AI: Adobe Firefly, 3 April 2024





# ENHANCING RESEARCH ADMINISTRATION THROUGH AUTOMATION AND ARTIFICIAL INTELLIGENCE

Karen Hartman  
Vice Chair, Research Administration

COGR Webinar: Going AI  
September 16, 2024



# Overview of Mayo Clinic Research

## By the numbers:

- Over **5,000 personnel in research**, inclusive of scientists, clinicians, allied health staff and post docs/fellows
- Annual Expenditures: **\$1.2B**
- Over **5,800** active clinical studies
- All study participant accruals of **116,000**
- Active animal studies of **1,250**

**Research Administrative Services provided through several different offices and support structures**



**Basic  
Science**



**Clinical  
Research**



**ROCHESTER**  
MINNESOTA



**JACKSONVILLE**  
FLORIDA



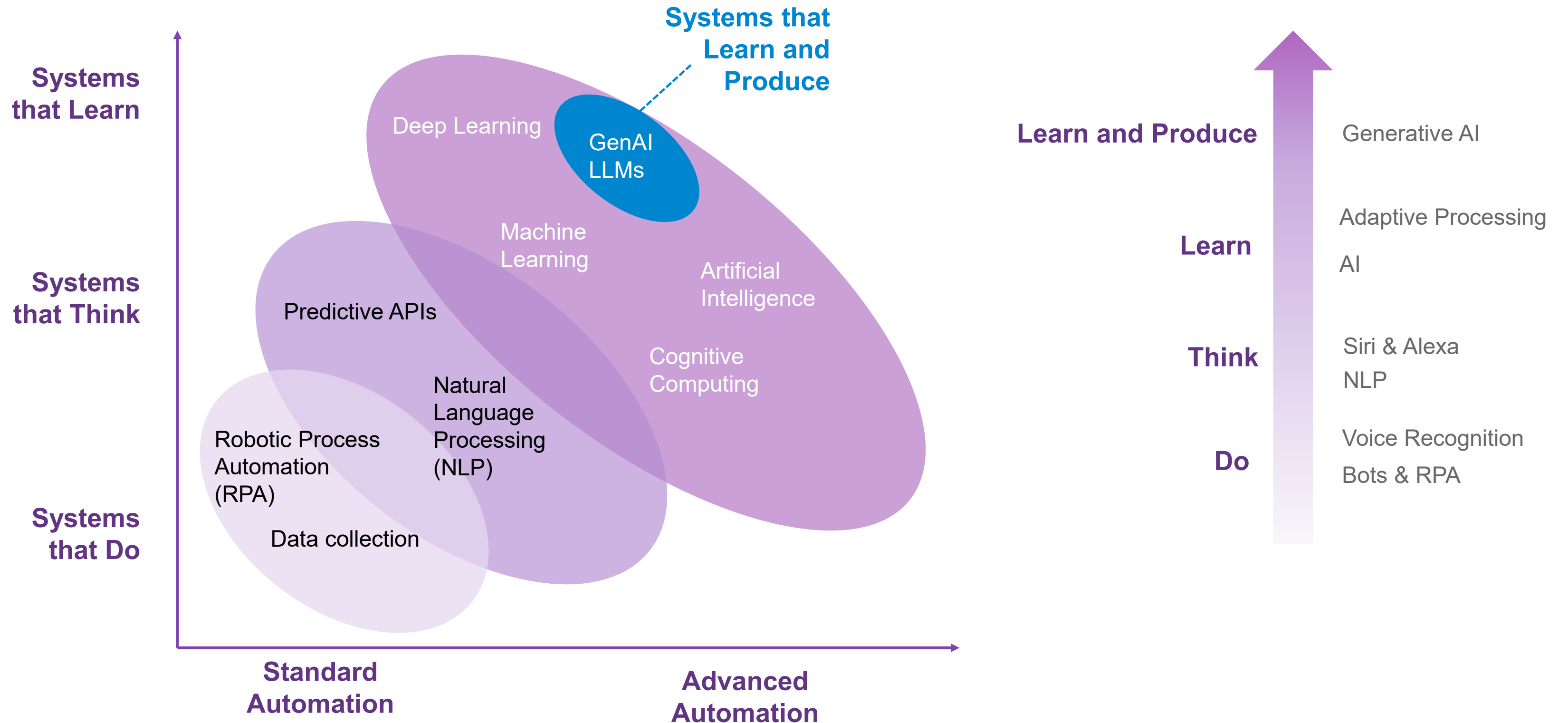
**PHOENIX & SCOTTSDALE**  
ARIZONA



**HEALTH SYSTEM**  
MINNESOTA • IOWA • WISCONSIN

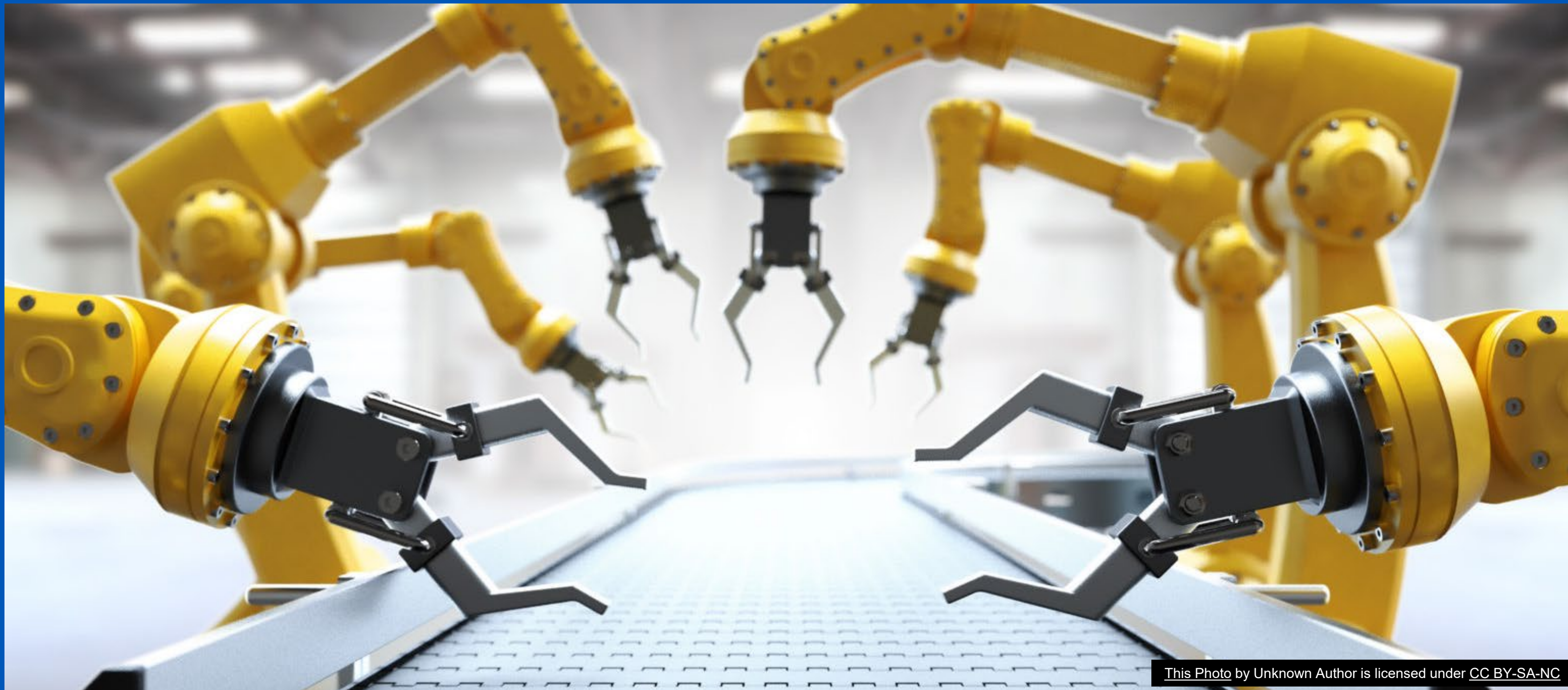


# Automation Continuum



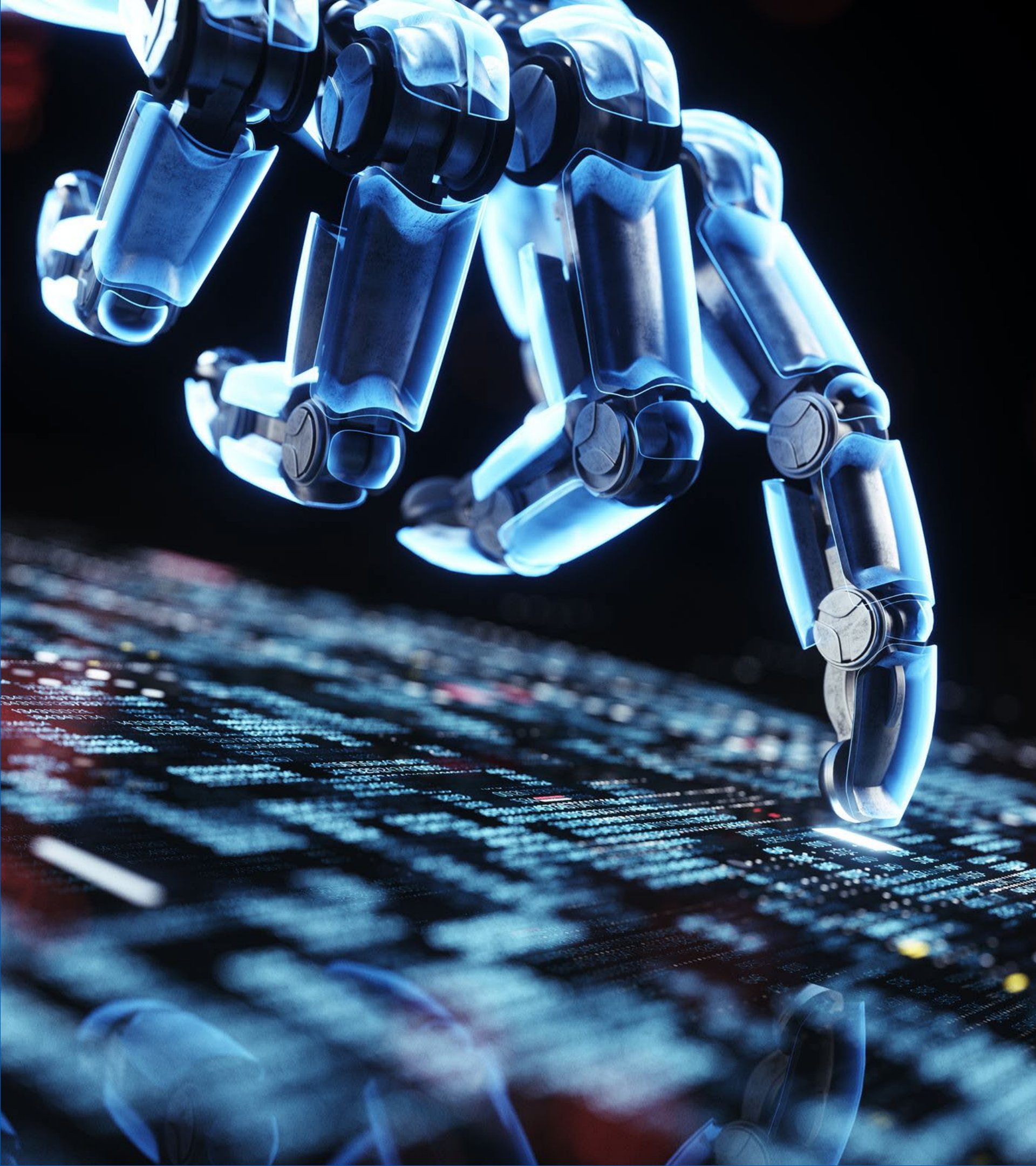
Adapted from: *The Intelligent Automation Continuum*, P. Gupta

# ROBOTIC PROCESS AUTOMATION



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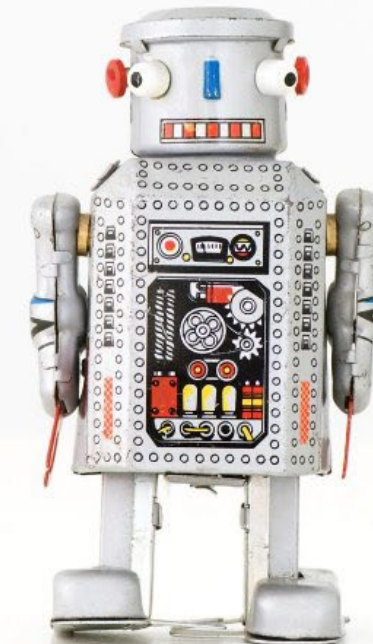
## ROBOTIC PROCESS AUTOMATION (RPA)

- Used to automate repetitive, rule-based tasks
- Gathers info from various sources
- Follows pre-defined rules to complete tasks
- Unable to think or learn
- Fragile - changes will break them



- Processes FDP Subawards
- Unattended BOT on scheduled cadence
- Accesses multiple systems
- Attaches Notice of Award (NOA) and Statement of Work (SOW) to subaward
- Saves the FDP template and uploads all documents to Contract Management System
- Tags as incomplete if anything is missing
- Triggers email to Contract Manager to review

## MEET BEATRICE



### FDP Foreign Fixed Amount Subaward

Run Template

Federal Awarding Agency: National Institutes of Health (NIH)

Pass-Through Entity (PTE): Mayo Clinic

Subrecipient: ABC Test Company, Inc.

PTE PI: [Redacted]

Sub PI: Julie A. Hanson

PTE Federal Award No: 2R01NS076491-11

Subaward No: ABC-306578; PO#123456

Project Title: [Redacted]

Subaward Budget: Start: 12/05/2022 End: 12/04/2022 Action (USD): \$ 0.00

Estimated Period of Performance: Start: 12/15/2021 End: 11/30/2021 Total (USD): \$ 0.0

1. PTE hereby awards a fixed amount Subaward to Subrecipient. The Statement of Work and budget for this Subaward are as shown. Subrecipient shall be an independent entity and not an employee or agent of PTE. No Party has the authority to bind any other Party in contract or to incur any debts or obligations on behalf of any other Party, and no Party (including an employee or other representative of such Party) shall take any action that attempts or purports to bind any other Party in contract or to incur any debt or obligations on behalf of any other Party, without the affected party's prior written approval.
2. PTE shall provide funding in accordance with the Payment Schedule shown in Attachment 5. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include the deliverable completed and milestone payment amount, Subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to [Redacted]

Go To Page

Page: 4 of 16

OK Cancel



# RESULTS

- Initiated Q1 2023
- Impact:
  - Prior - manual effort (30 min)
  - Current - BOT run (4 min)
- Volumes:
  - 760 subawards processed
- 1 FTE savings (repurposed to higher level work)



# ARTIFICIAL INTELLIGENCE

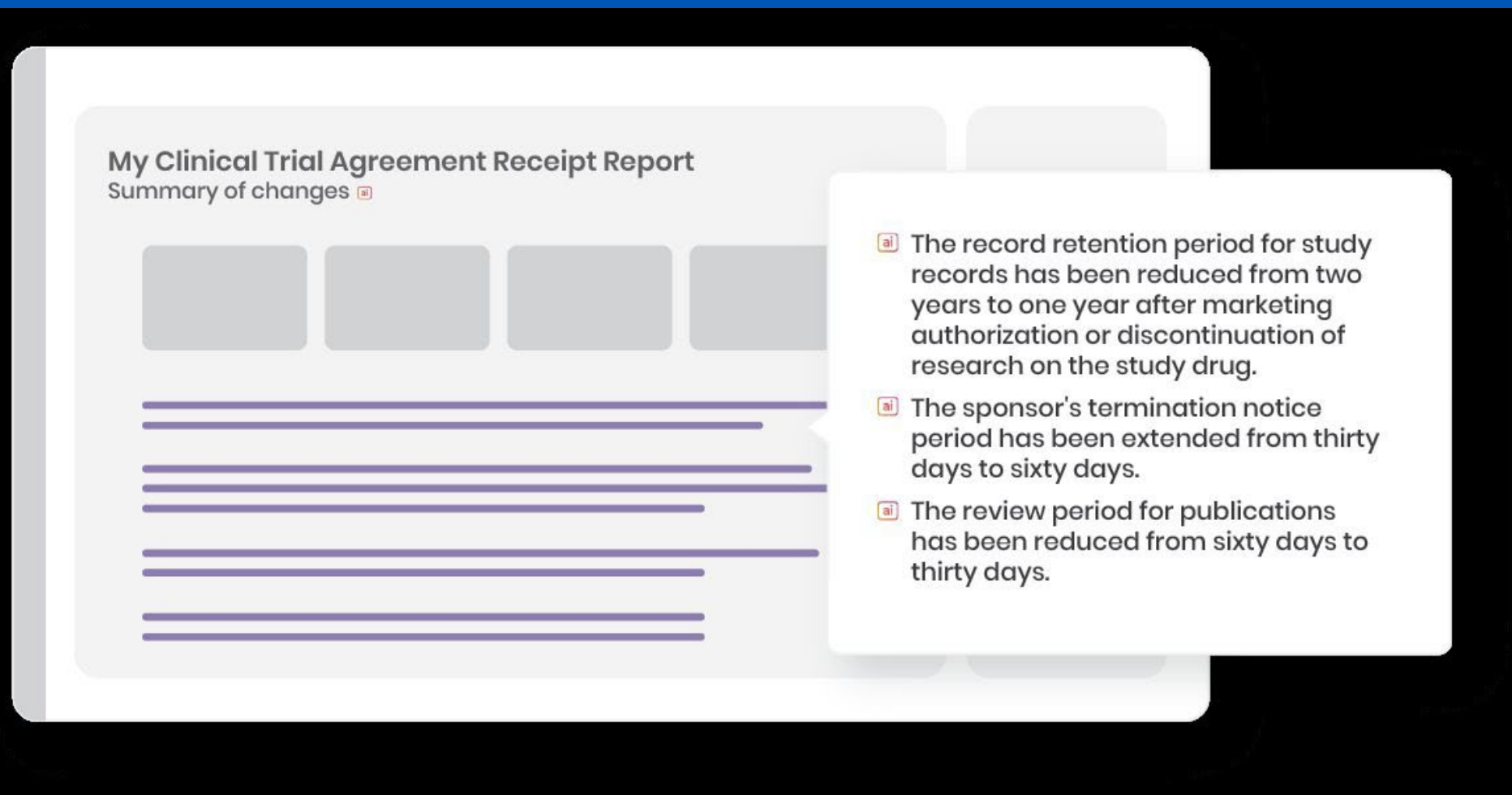


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# THE CONTRACT NETWORK™

- Secure and neutral contract collaboration platform
- Utilizes market data and AI to speed up contract negotiation
- Uses generative AI to align unfamiliar agreements with site internal standards and market benchmarks
- Minimizes time spent on negotiations & tracking status



*Disclosure: Mayo Clinic has equity in TCN*

# ATR-307989 (Fix-It Test) ...

AGREEMENT TYPE: Clinical Trial Agreement (C...)

MY PARTY: Party

COUNTERPARTY: Counterparty

STATUS: DRAFT

% COMPLETE: 0%

CONTRACT PROFILE

Mayo CTA Profile - ISMCT [...]

File View Summary Signature  Show inline markup Manage access [Send to counterparty](#) [Sign now](#)

## ai Agreement analysis

for Draft on August 23, 2024 at 10:53 AM published by Party

[Re-run analysis](#) [View Agreement](#)

- 1. Overview
- 2. Procedure & Compliance
- 3. Samples, Data, & Inventions
- 4. Confidential Information
- 5. Audits & Inspections
- 6. Publication
- 7. Liability & Indemnification

Search profiles

PRESENCE	TOPIC	SUMMARY	SECTION
NO	Alternative Dispute Resolution	The agreement does not mention or address alternative dispute resolution methods such as arbitration or mediation.	---
YES	Agreement Term	Term of the Agreement is for the duration of the Study, may be extended or terminated earlier by mutual agreement. Certain obligations survive beyond termination.	+1
NO	CRO	The agreement does not mention or involve a Clinical Research Organization (CRO).	---
YES	Effective Date	The agreement becomes effective on the date of last signature.	+1
YES	Agreement Name	Name of the Agreement: CLINICAL TRIAL AGREEMENT.	+1
NO	Insurance	The agreement does not address the issue of insurance.	---



# ATR-307989 (Fix-It Test) ...

AGREEMENT TYPE: Clinical Trial Agreement (CTA) | MY PARTY: Party | COUNTERPARTY: Counterparty | STATUS: DRAFT | % COMPLETE: 0%

File View Summary Signature Show inline markup Manage access Send to counterparty Sign now

CONTRACT PROFILE: Mayo CTA Profile - ISMCT [V2] ...

My Party edits Counterparty edits Variables

## a) Publishable Results.



i. Research Institution reserves the right for it and the Principal Investigator to publish ~~and/or~~ present the Study Data and Results and any information relating thereto (“~~Proposed Manuscripts~~”Manuscripts) ~~in accordance with this Section 7.1.~~ Before publishing or presenting, however, Research Institution, through Principal Investigator, agrees to submit copies of any and all Proposed Manuscripts to Sponsor at least thirty (30) days in advance of submitting such Proposed Manuscripts to a publisher or other third party. Research Institution and Principal Investigator understand that this requirement acknowledges Sponsor’s responsibility to evaluate such Proposed Manuscripts: (i) for accuracy and consonance with Sponsor’s database as stipulated by FDA regulations; (ii) to ascertain whether Confidential Information is being inappropriately utilized and/or released; (iii) to provide Research Institution and Principal Investigator with information which may not yet be available to them; and (iv) to provide input from other investigators and sub-investigators in the Study, if any, regarding the content and conclusions of the Proposed Manuscripts. Research Institution will consider Sponsor’s comments but is not obligated to incorporate them. If Sponsor makes a good faith determination within such thirty (30)-day period that the publication or presentation of such Proposed Manuscript would be detrimental to its or its affiliates’ intellectual property interests, upon Sponsor’s written notification, Research Institution and Principal Investigator shall refrain from submitting such Proposed Manuscript to a publisher or other third party for up to an additional ~~ninety (90)~~sixty (60) days to allow Sponsor or its affiliates to file patent applications or take other steps to protect its or its affiliates’ intellectual property interests. ~~Research Institution agrees to and will require Principal Investigator to remove all Confidential Information from such Proposed Manuscript upon Sponsor’s written request.~~

ii. The foregoing notwithstanding, Research Institution and Principal Investigator acknowledge that this is a multi-center study, and that Sponsor has an interest in ensuring that a multi-center publication is the first publication to be released or presented regarding the Study. Research Institution agrees that it shall not, and will require that Principal Investigator agree that he/she/they will not, independently publish or present any Study Data or Results until the sooner of (a) such a multi-center publication is released; (b) the Sponsor confirms in writing that there will not be a multi-center publication; or (c) the elapse of eighteen (18) months following the completion or termination of the Study. The multi-center

All 143 To Do 0 Open 143 Missing 1 61

Search Blocks...

Filters

### PROFILE ALIGNMENT

- Not Aligned - Institution should not seek permission to publish from Sponsor. The agreement requires submission of Proposed Manuscripts to Sponsor for review before publication.
- Not Aligned - Institution must delete Sponsor’s Confidential Information upon written request. The agreement allows Sponsor to review for Confidential Information but does not explicitly require deletion.
- Not Aligned - Institution may publish, present, or use any Data and results from its performance of the Protocol. The agreement allows Research Institution to publish and present Study Data and Results but requires submission to Sponsor 30 days in advance and allows Sponsor to delay publication for up to 60 days to protect IP.
- Not Aligned - Additional 60-day delay for IP protection is not addressed in the guidance. The agreement allows for an additional 60-day delay for IP protection.
- Aligned with Preferred - The review period for abstracts or poster presentations should be thirty (30) days. The agreement specifies a thirty (30) day review period for Proposed Manuscripts.
- Aligned with Preferred - Sponsor may request deferment of publication for up to 60 days to file patent applications. The agreement allows deferment for up to 60 days for patent filing.
- Aligned with Preferred - Institution will submit any proposed oral or written Publication to Sponsor for review and comment at least thirty (30) days before submission. The agreement requires a 30-day review period for proposed manuscripts.
- Aligned with Preferred - Institution will consider Sponsor’s comments but is not obligated to incorporate them. The agreement states that the Research Institution will consider Sponsor’s comments but is not obligated to incorporate them.
- Aligned with Permitted - The agreement allows for an additional sixty (60) to protect intellectual property if needed. This is permitted.

### SUBSTANTIVE GUIDANCE



# IN PROGRESS...

## Automation Opportunities

- Dept of Educ (Sect 117) reporting
- Committee member scheduling
- Find research staff

## AI Opportunities

- Protocol ingest
- Digital schedule of activities (events)





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# THANKS FOR YOUR TIME

Karen Hartman

[hartman.karen@mayo.edu](mailto:hartman.karen@mayo.edu)

[Karen Hartman | LinkedIn](#)

Tara Rabe

[Rabe.tara@mayo.edu](mailto:Rabe.tara@mayo.edu)

[Tara Rabe | LinkedIn](#)

Chatbots in  
Research  
Administration

# Daniel Harmon

*Director of Data and Systems,  
Sponsored Programs Administration*





# UNDERSTANDING RESEARCH ADMINISTRATION

Complex  
and Technical

Diverse  
Stakeholders

High Volume

Limited  
Resources

Regulatory  
Environment

Deadline  
Driven

Lack of  
Knowledge



## INTRODUCTION TO AI-POWERED CHATBOTS

What are chatbots

Types of chatbots

Rule-based vs. AI-Powered

Historical Connotations



# AI IS IMPROVING FAST



November 2022



August 2024

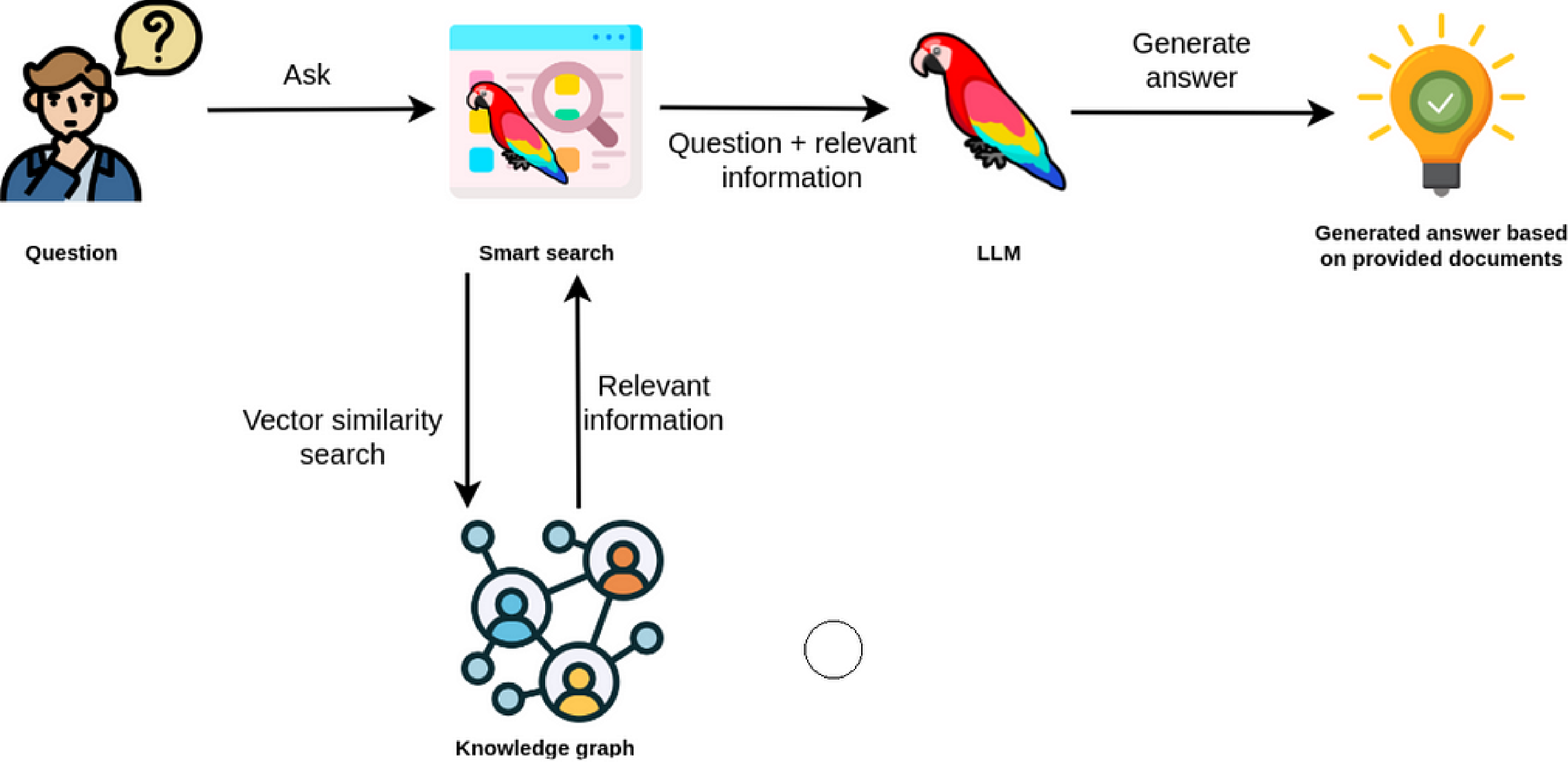
## BENEFITS OF AI-POWERED CHATBOTS IN RESEARCH ADMINISTRATION

- 24/7 Availability
- Frees up staff time
- Automation of repetitive tasks
- Consistent and friendly voice
  - There are no dumb questions!
- Data collection and insights





# RAG (RETRIEVAL AUGMENTED GENERATION)



# TOOLS

## Vector Database

- Azure AI Search
- Pinecone
- Faiss
- Chroma
- Elasticsearch

## LLMs

- OpenAI GPT (3.5,4, 4 Turbo, 4o)
- Llama (open source)
- Anthropic Claude 3 (Haiku, Sonnet, Opus)
- Google Gemini
- Mistral
- Microsoft Phi-3
- Hugging Face

## Tooling

- Azure AI Studio
- Copilot Studio
- Amazon Lex
- Google Vertex AI
- Limitless options from vendors utilizing these tools

A vibrant 3D animated scene. In the center, a large, golden, diamond-shaped sign with a dark brown dollar sign (\$) is mounted on a wall. To the right, a pink piggy bank hangs from a chain. In the foreground, a character with large, expressive blue eyes and a wide, open-mouthed smile is looking up at the sign. The character has a yellow hard hat and is wearing a red and yellow striped shirt. The background is filled with various symbols of wealth: a large golden dollar sign on the left, a green banknote floating in the upper right, and several tan money bags with dollar signs on them scattered around. The overall atmosphere is one of excitement and financial ambition.

WHAT IS IT GOING TO COST ME?!





# IMPLEMENTATION STRATEGY



Needs and goals assessment



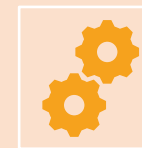
Selecting the right AI technology



Integration with Existing Systems



Training and Customization



Testing and Deployment

## CHALLENGES AND CONSIDERATIONS

- Technical Challenges (integration, maintenance)
- Data Privacy and security concerns
- Hallucinations
- Bias





# DEMOS AND WHAT WE LEARNED



A top-down view of a wooden desk. In the upper right, a portion of a white laptop keyboard is visible, showing keys for a period, plus/equals, and minus/underscore. To the left of the keyboard is a yellow paperclip. Three sticky notes are scattered on the desk: a pink one with the letter 'Q', a light green one with an ampersand '&', and another pink one with the letter 'A'. A silver ballpoint pen lies diagonally in the lower right quadrant.

**Q**

**&**

**A**



The background of the slide features a close-up photograph of several hands from different people, all giving a thumbs-up gesture. The hands are positioned in a way that they appear to be coming together from the bottom and sides towards the center. The lighting is soft and even, highlighting the skin tones and the texture of the hands. The overall mood is positive and celebratory.

Thank you!

