



AI Governance:

Three Real-World Implementations in Health Care

Presented by: Cora Han, JD; Lucia Savage, JD; Alya Sulaiman, JD.

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Good AI Governance: “keeping robots from
prescribing pizza for headaches.”

ChatGPT 4.0 (4-8-25)

2

Your Presenters

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Why AI Governance Is Important



The Importance of AI Governance Used to Deliver Healthcare



- When used to support healthcare delivery, clinically valid and reliable
- Safe and of baseline quality
 - De-risk healthcare provider liability
- Secure
- Private
 - Minimum necessary rule for HCO
 - Consent where required
 - Controlled disclosure to Business Associates and third parties
- Transparent and Explainable
 - New state law requirements
- Not unlawfully biased
 - New 42 USC sec 1557 and relevant regulatory reqts under 45 CFR

NIST AI Governance



NIST AI Framework	#	Concept
Valid and Reliable	3.1	Clinically reliable
Safe	3.2	Safety
Secure and Resilient	3.3	Security, redundancy, data integrity
Accountable and Transparent	3.4	To comply with transparency laws like CO
Explainable and Interpretable	3.5	So that t can be validated by outsiders if needed, see row 1
Privacy-Enhanced	3.6	Appropriate privacy given the context
Fair with harmful bias managed	3.7	To ensure that AI meets existing and new fairness requirements (historic law and 1557)

NIST Graphic

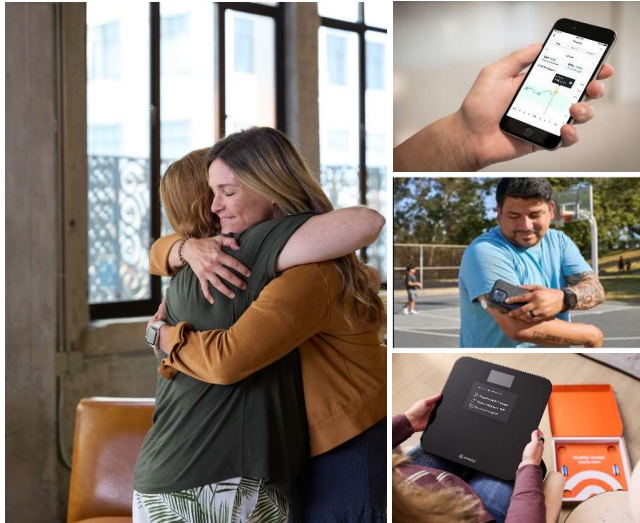


FIGURE 4: CHARACTERISTICS OF TRUSTWORTHY AI SYSTEMS. VALID & RELIABLE IS A NECESSARY CONDITION OF TRUSTWORTHINESS AND IS SHOWN AS THE BASE FOR OTHER TRUSTWORTHINESS CHARACTERISTICS. ACCOUNTABLE & TRANSPARENT IS SHOWN AS A VERTICAL BOX BECAUSE IT RELATES TO ALL OTHER CHARACTERISTICS.

Source: <https://airc.nist.gov/airmf-resources/airmf/3-sec-characteristics/>

Omada Health, Inc.

What is Omada Health, Inc.?

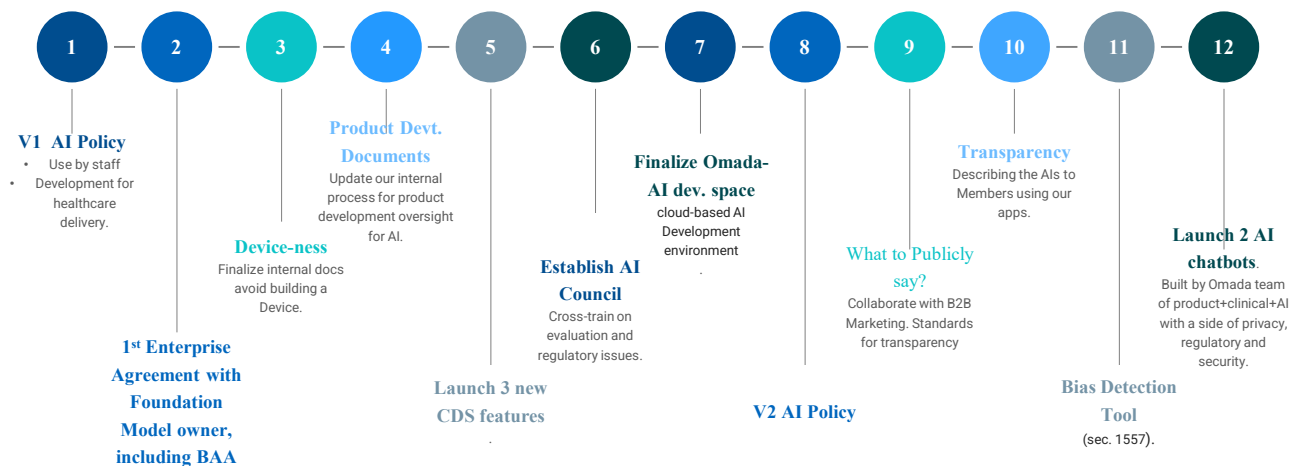


Bending the Curve of Chronic Disease with Between-visit Care

Founded in 2011, Omada supplies healthcare for prevention of diabetes, for management of diabetes and hypertension, and physical therapy from PTs, by connecting individuals to human professionals via a secure apps, augmented by real-time clinical information and data science

Omada's AI Governance Journey

Jan 2024 to May 31, 2025



AI Policy



Applies to both staff needs AND Omada's health care services evolution

- Covers how Omada staff may and may not use the foundation model we contracted with for their everyday needs, like search and writing assistance
- Establishes who makes decisions on AI usage for
 - Omada staff needs
 - Omada development of its health care services.
- Defines required approvals/gates in AI usage.
- Evolves as AI evolves
 - V1 was more cautious than V2.
- Is knit back to/integrates with other Omada policies like our Acceptable Use, Role-Based Access, Security policies, and PHI policies.

Device-ness



Omada provides healthcare services. We don't build FDA devices

- Close analysis of Clinical Decision Support provisions of Title 21, USC, etc.
 - [Clinical Decision Support](#) guidance finalized September 2022
 - [Mobile Health Apps](#) guidance, September 2022
 - Validate with outside counsel.
- Deconstruct and reconstruct guidance to enable product development teams to understand and answer fewer than 10 questions to determine if their proposed functionality would likely be a device.
 - Self-help: This is done by the teams and validated by regulatory.
- Mandatory training for Product, Engineering/Data Science, and Clinical Product SMES.

AI Council



Cross-functionality is key. Camaraderie helps

- AI Council includes: VP of AI, CISO, Chief of Privacy & Regulatory, Medical Director, Senior Architect, Applied AI team members, Product Managers.
- Purpose: Grapple with complex problems that impact strategy, such as:
 - What member PHI is appropriate to include in Omada's AI Development system, if any?
 - How do we evaluate our AI for drift, prohibited bias, safety, clinical fidelity? Can we use an LLM to evaluate another LLM?
- Meets offsite (Omada is 100% remote) and includes fun time activities to build trust and camaraderie.

Transparency



Omada has two key audiences: our customers (payers and health plans, and our Members (individuals who receive our services). This is about Customers

- B2B/Customers: Despite the hype and the fact that many large orgs are building their own AI, there are concerns and sometimes reticence to see AI used in delivering healthcare to those same orgs people.
 - Those RFIs.
- Marketing teams needed to learn the language of AI:
 - What is ML vs NLP vs something generative
 - What is a bot vs an agent?
 - Why our AI use PHI instead of de-identified data (answer: clinical safety and record-keeping).

Transparency, part 2



What to say to Members?

- Transparency to members is
 - Required by certain laws
 - A pledge Omada made when it joined the Health Care AI Commitments.
- Updated ToUs, Privacy Policy and HIPA NPP
- In our app?
 - Limited real estate on a screen demands rafting collaboration
 - Lawyers won't always get "legalistic" language. That needs to be ok to succeed.
 - Ensuring screen designs avoid dark patterns and that engineering gives members choices where appropriate.

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Bias detection



ACA Sec. 1557 Regs include prohibition against bias in AI (aka Patient Care Decision Support Tools, 45 CFR 92.210)

- Collaboration between our Equity SME and our AI teams
- Identify and procure an appropriate tool to analyze how our AIs are operating at a data level
 - The teams picked Aequitas, open-source from Carnegie Mellon University
- Ensure we have engineered how our tool works to access the Member demographics it needs to work
- Develop and implement policies that identify who is responsible to
 - Generate analysis
 - Evaluate analysis
 - Mitigate when needed
 - Oversee process.

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Resources and References

**FDA Mobile
Health Apps**

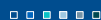
FDA CDS

1557 Regulations

89 Fed. Reg. 37522 (May 6,
2024)

**Bias Detection
Tool**

University of California Health

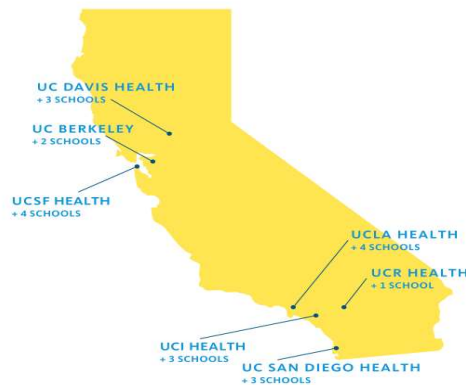


University of California Health

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Health Centers**

**Global Health
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HEALTH



**20 Health
Professional
Schools**

**10 Student Health &
Counseling Centers**

**Employee & Student
Health Benefits**

UC Health Academic Health Centers

UCI Health

UCR HEALTH

**UCDAVIS
HEALTH**

UCLA Health®

UCSF Health

UC San Diego Health

AI governance across University of California

Operationalizing Responsible AI Principles from 2021 Presidential Working Group Report

UC AI Communities

1. UC AI Council
2. Location AI Communities
3. UC Health
4. UC Legal AI Task Force

Reports and Workshops

1. UC AI Transparency Report
2. Systemwide Workshops and Share Fairs

Tools and Resources

1. Risk Assessment Guide
2. UC AI Primer
3. Legal Guidance
4. Procurement provisions

Use case - ambient AI documentation

NEJM Catalyst | Innovations in Care Delivery

COMMENTARY

Ambient Artificial Intelligence Scribes to Alleviate the Burden of Clinical Documentation

Aaron A. Tierney, PhD, Gregg Gayre, MD, Brian Hoberman, MD, MBA, Britt Mattern, MBA, Manuel Balleca, MD, Patricia Kipnis, PhD, Vincent Liu, MD, MS, Kristine Lee, MD
Vol. 5 No. 3 | March 2024
DOI: 10.1056/CAT.23.0404

Clinical documentation in the electronic health record (EHR) has become increasingly burdensome for physicians and is a major driver of clinician burnout and dissatisfaction. Time dedicated to clerical activities and data entry during patient encounters also negatively affects the patient-physician relationship by hampering effective and empathetic communication and care. Ambient artificial intelligence (AI) scribes, which

HEALTH TECH

STAT+

Health care's 'Pepsi challenge': Doctors' offices are testing AI tools in head-to-head pilots

Vanderbilt piloting Nuance DAX Copilot, testing other genAI use cases

The projects mark a "significant step in VUMC's exploration of AI's potential in streamlining clinician workflows and enhancing medical record-keeping while reducing time spent on documentation," said the health system's CMIO.

Kaiser Permanente improves member experience with AI-enabled clinical technology

Assisted clinical documentation tool from Abridge helps doctors reduce time spent on administrative tasks, allowing them to be more present with patients.

Pain points



- Vendor contracting terms
- Many competing vendors
- Lack of assessment resources
- Quickly evolving regulatory and policy environment
- Need to increase transparency
- Demonstrating measurable ROI

Examples of ongoing governance work



- Coalition for Health AI (CHAI)
 - Responsible AI Guide
 - Applied model card
- Health AI Partnership (HAIP)
 - Health Equity Across the AI Lifecycle (HEAAL) framework, a standard to mitigate the risk of AI products exacerbating health inequities
- The Light Collective
 - Patient AI rights initiative

Initial model validation only the first step



Essential to evaluate clinical effectiveness for success – are AI technologies improving patient outcomes, treatment and workflow efficiencies, and cost-effectiveness?




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PERSPECTIVE

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A Call for Artificial Intelligence Implementation Science Centers to Evaluate Clinical Effectiveness

Authors: Christopher A. Longhurst, M.D., M.S. , Karandeep Singh, M.D., M.M.Sc. , Aneesh Chopra, M.P.P. , Ashish Atreja, M.D., M.P.H. , and John S. Brownstein, Ph.D.  [Author Info & Affiliations](#)

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Responsible AI requires strong data governance



UC responsible health data governance principles

- Attention to the University's unique responsibility and mission
- Sharing data outside UC for public benefit
- Justice
- Transparency and patient engagement
- Responsible stewardship



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NEWS: President Drake shares new UC Health guidelines for the responsible use of health data



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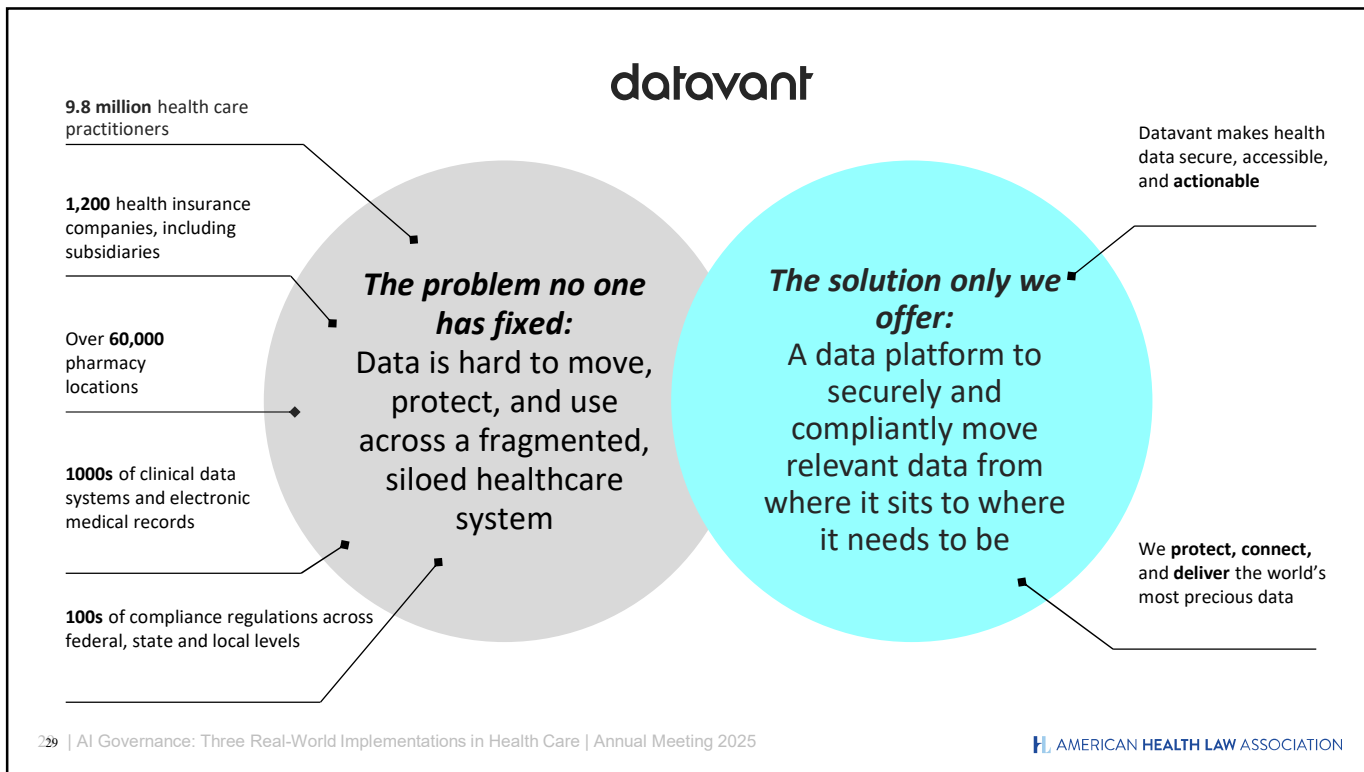
Takeaways for responsible AI in healthcare



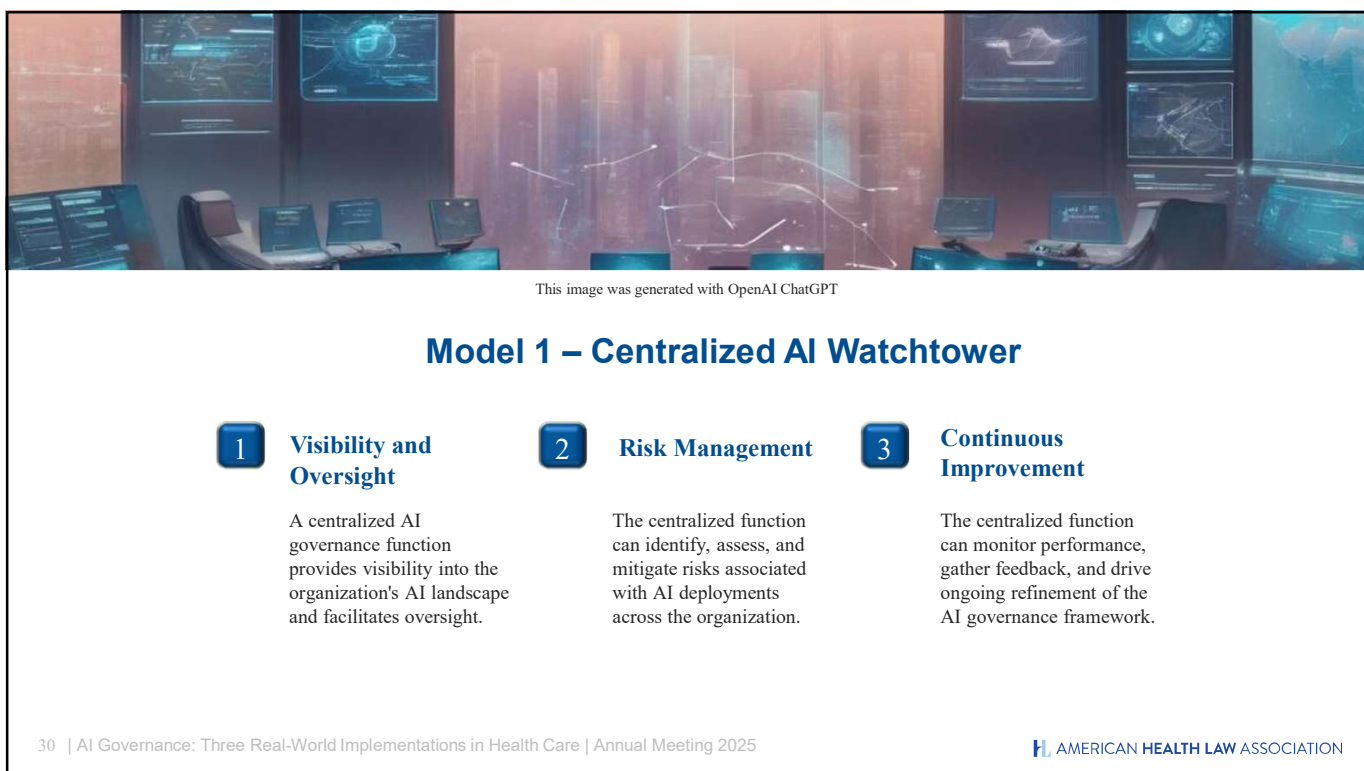
- Start with a need that can be addressed by AI
- AI tools can provide benefit even when they don't save time
- Understanding how AI tools are implemented in workflow is critical to success
- Requires multidisciplinary approach
- Different risks presented by predictive and generative AI

Datavant





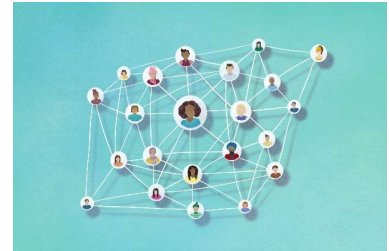
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Model 2 – Use-Case Based Governance

- “Federated” responsibility model for AI governance that makes individual teams accountable for:
 - Understanding the purpose of the AI tool and how it will be deployed
 - Identifying appropriate stakeholders , including those who could be impacted by the AI tools
 - Analyze the type of decisions or content the AI tool will be support and potential consequences
 - Determine the location and timing (aka context) of when the AI tool will be used
- Legal and compliance remain responsible for addressing the legal and regulatory requirements for AI use cases



Microsoft Office Stock Image

But first, what are our Accountability Points?

-  Customer Expectations and Contractual Commitments
-  Industry Standards
-  Customer Audits and Questionnaires
-  Board
-  Enterprise Risk Management
-  Security Certifications (SOC 2 Type II, HITRUST, FedRAMP)
-  Regulatory Compliance
-  Internal Audit
-  **Patients + Members, whose data is entrusted to us**

Our customers are asking...

Describe how the AI/ML Solution will be monitored for performance once it is deployed

Confirm the human-in-the-Loop process through the lifecycle of the AI features in scope and currently in production

List and attach the detail of the top features used by this AI/ML Solution and their associated coefficients of SHAP (SHaply Additive exPlanations) values

Describe the approach to identify and mitigate data bias and verify if any bias was found

Our AI Governance Approach

- Developing a comprehensive, but *federated* AI governance framework to manage risks and ensure responsible AI deployment
- Two-pronged approach covering:
 - Internal AI tool usage by employees, contractors, and vendors
 - AI integration in Datavant products
- Aligned with emerging industry standards and regulatory guidance (e.g., NIST, ASTP)

For what we use internally...

- *AI Acceptable Use Standard*
- *Approved list of tools and intended use cases*
- *Procurement / vendor management*
- *Regular monitoring and assessment*

For what we build and sell to our customers...

- *AI Inventory*
- *AI Governance Task Force*
- *Responsible Development of AI Systems Policy*

10 Data Questions for Health AI

**Good AI Governance
starts with
Good Data Governance**

What data elements do you need to be successful?

How do you plan on obtaining this data?

Where did this data come from?

Are there any terms to using this data?

Where is this data now?

Where do you plan to keep the data?

How long do you need this data?

Who needs access to which data?

Does the data need to be interoperable with other systems?

What security measures have been applied to the data?

My AI Governance To-Do List

Harmonize AI Definitions

Not all AI is the same.

Establishing a common language and definitions for AI terms across the organization is crucial for effective oversight

Develop and publish AI policy, use standard, or principles

Based on the organization's mission, this is typically a statement of values, principles, and ethical commitments around responsible AI

Publish and promote these commitments internally.

Develop a risk review process

Establish intake points and triggers for when a review should take place, and take into account ethical, technology, security, compliance, legal, reputational, liability, and related considerations

Assemble a cross-functional task force; leverage existing committees

A multi-disciplinary team with legal, technical, compliance, operational, and ethical expertise

Use product, executive compliance, security, data governance and other committees to address questions in context.

Inventory all AI/ML tools and systems

Not just generative AI, could also include rules-based engines and "old" AI, such as Optical Character Recognition deep learning models



This image was generated with OpenAI ChatGPT

Final Reminders



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Govern AI with a Plan & Purpose

- Avoid OVERWHELM—you got this.
- Serve as a thought partner to the business, understand the issues, and source specialized expertise as required.
- Develop a systematic approach to self-education and organizational education, evaluate AI-related opportunities, and monitor regulatory and legislative changes.
- Be the voice in the room encouraging others to align AI use with organizational goals and culture. Evaluate and counsel on AI initiatives in the context of your organization's strategy, mission, and objectives.

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Q&A



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Thank You!



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