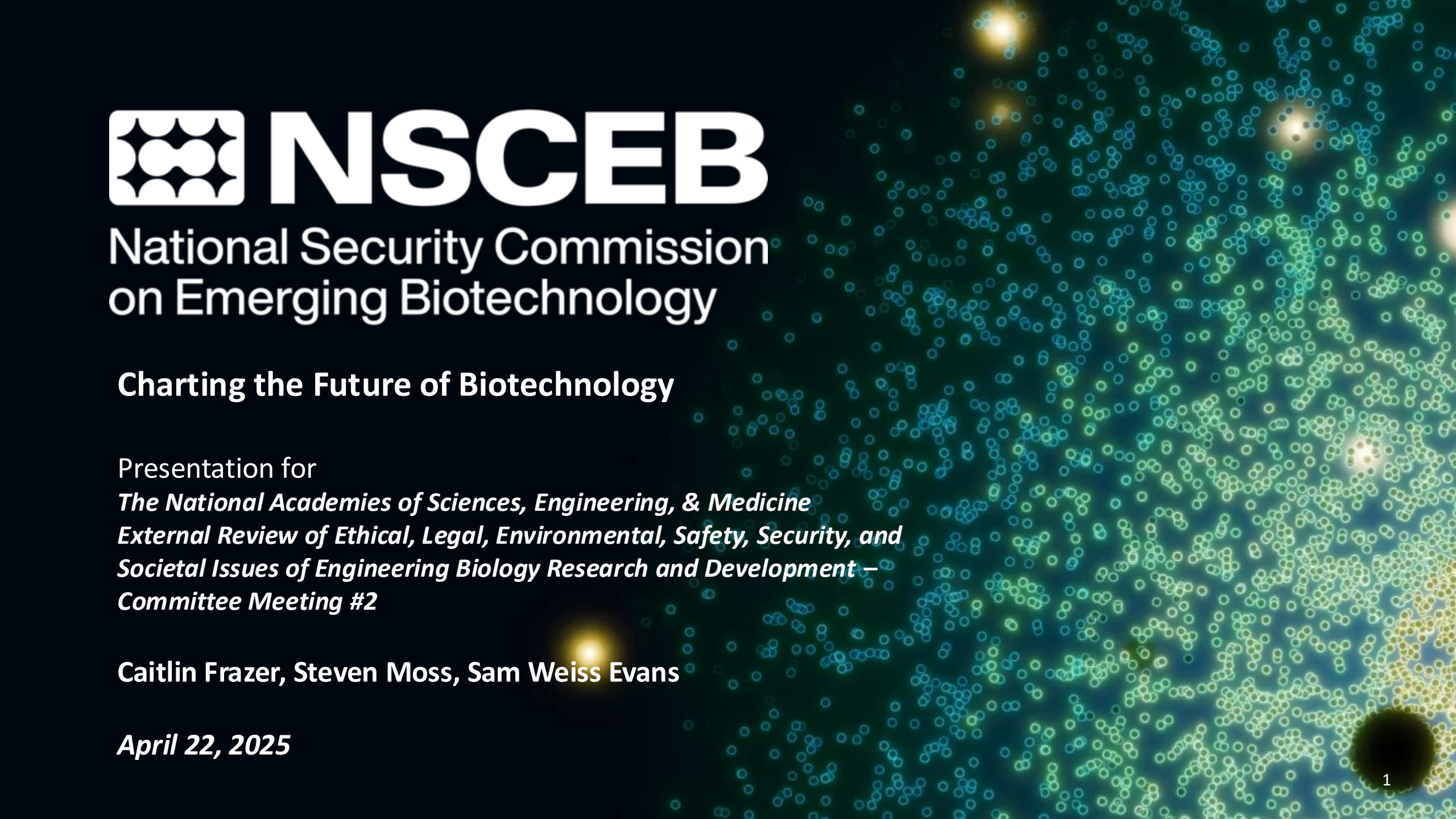


NSCEB

National Security Commission on Emerging Biotechnology

Charting the Future of Biotechnology

Presentation for

The National Academies of Sciences, Engineering, & Medicine External Review of Ethical, Legal, Environmental, Safety, Security, and Societal Issues of Engineering Biology Research and Development – Committee Meeting #2

Caitlin Frazer, Steven Moss, Sam Weiss Evans

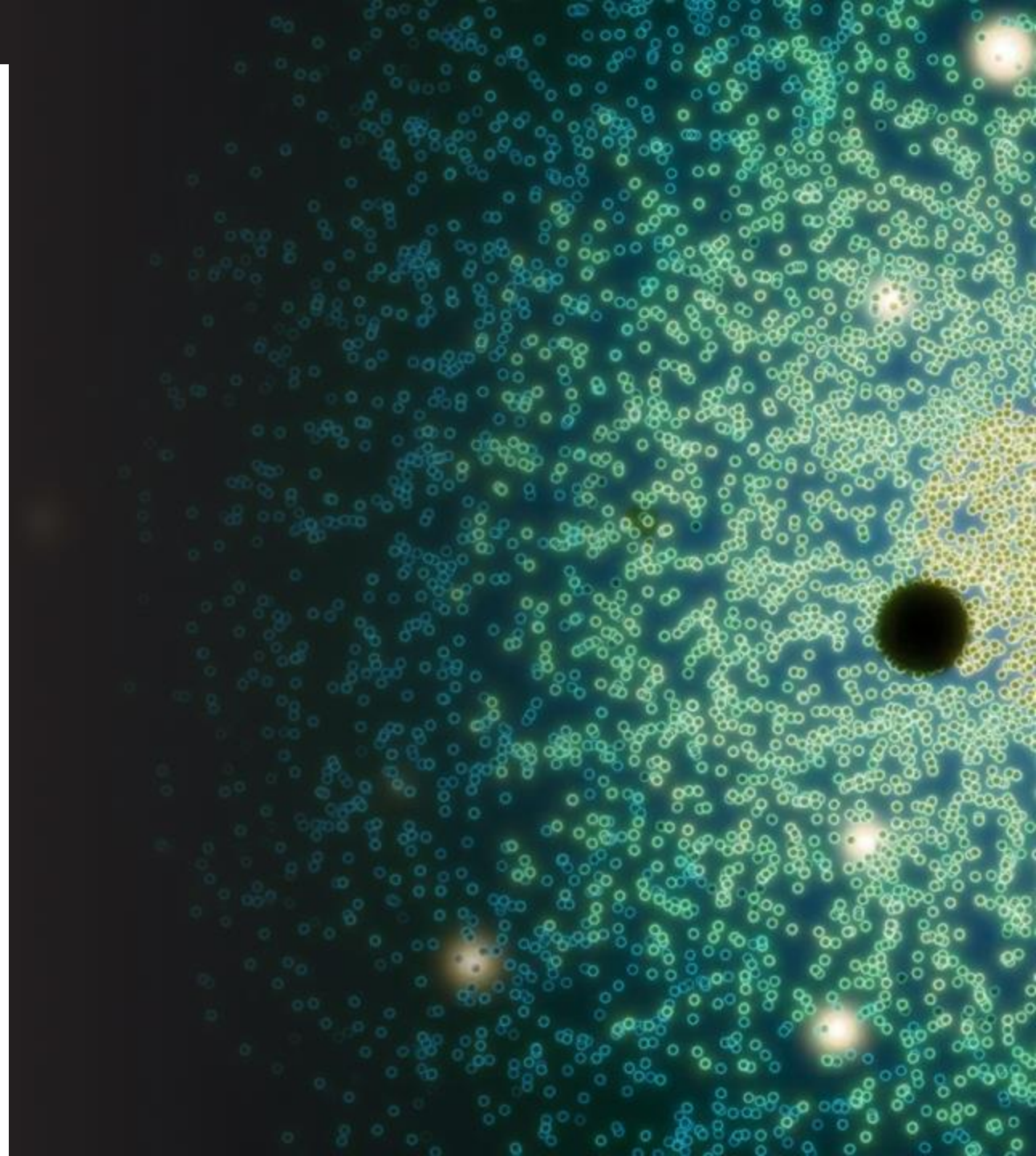
April 22, 2025

NSCEB’s Charge:

to advance and secure biotechnology, biomanufacturing, and associated technologies for U.S. national security and defense

+

to prepare the United States government for the age of biotechnology



Commissioners

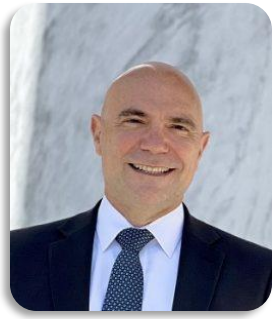
Sen. Todd Young
(IN, Chair)

Dr. Michelle Rozo
Vice Chair

Sen. Alex Padilla
(CA)

Rep. Stephanie Bice
(OK-05)

Rep. Ro Khanna
(CA-17)



Paul Arcangeli

Dr. Angela Belcher

Dawn Meyerriecks

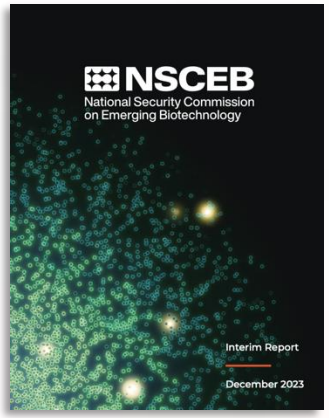
Dr. Eric Schmidt

Dr. Alexander Titus

Dr. Dov Zakheim

Timeline

March 2023
NSCEB established by NDAA 2022



December 2023
NSCEB Interim Report published

April 2025
NSCEB Final Report Published

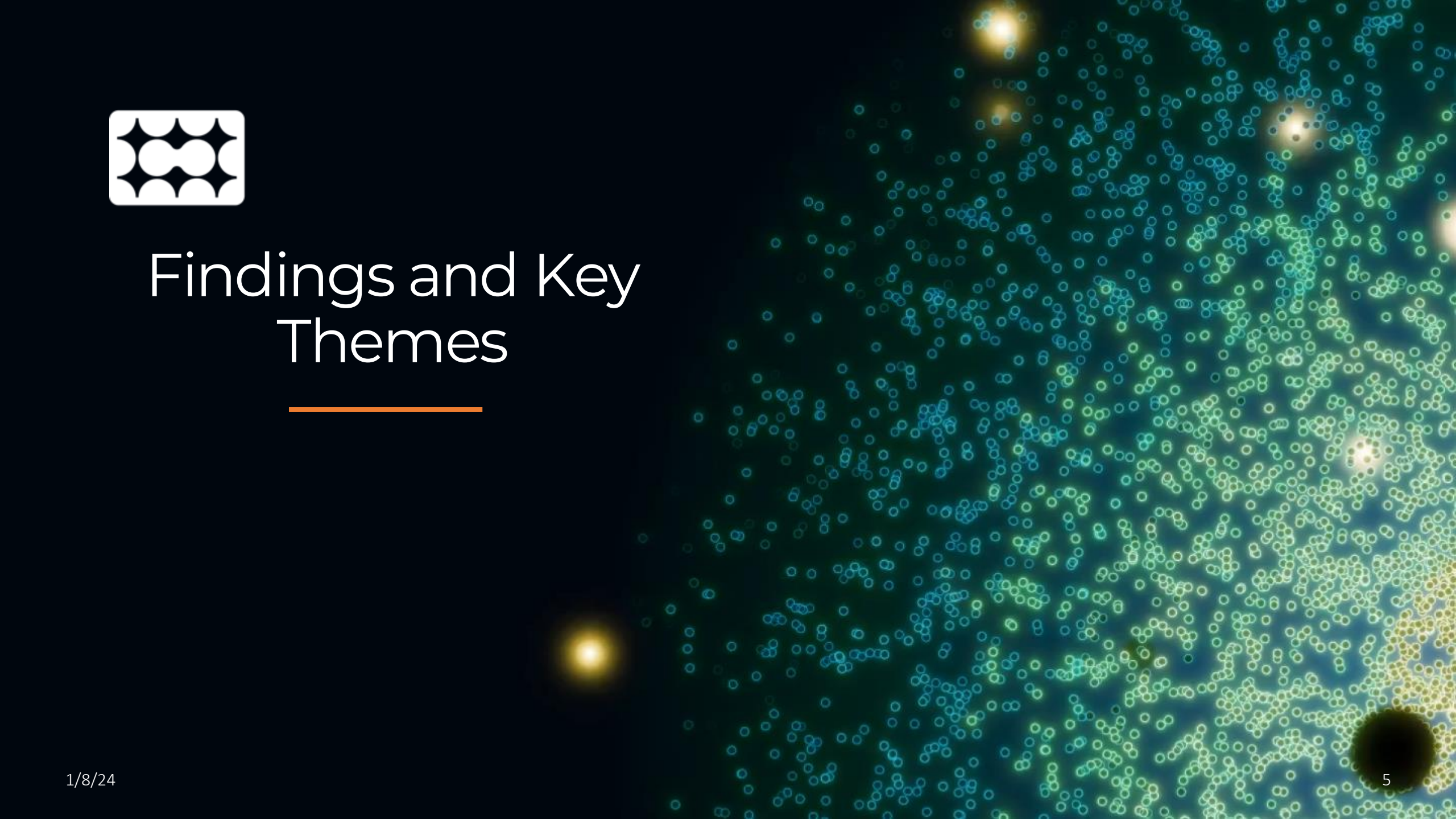
Late 2026
NSCEB sunsets

Initial Growth and Research

Core Work Development

Recommendation Implementation

Findings and Key Themes



Without U.S. action, China will lead global biotech

- The United States risks losing global biotechnology leadership to China.
- The PRC is pursuing an aggressive state-backed roadmap to dominate the next generation of biotechnologies.
- Beijing has prioritized breakthroughs across biotechnology for the last **two decades**.
- By contrast, the United States lacks a coordinated national strategy to compete globally.
- Without urgent federal action, China will **own the infrastructure, supply chains, and intellectual property** behind the most critical biotechnologies of the future.

Breaking China's supply chain grip

- The United States is dangerously **dependent on China** for our most critical supplies, including medicines and pharmaceutical production.
- By scaling capacity domestically and with key allies, the United States can **replace dependencies** for crucial products and make our supply chains more resilient.
- This will protect **security of supply and maintain economic stability** by precluding China from weaponizing critical supply chains against Americans.

Booming biomanufacturing in every state

- Biotechnology is the **key to reviving American manufacturing**, bringing **high-paying jobs** to regions across the country.

- Companies like **Heartland BioWorks in Indiana** prove that **smart investment in biomanufacturing** can create local jobs and strengthen **economic resilience**.

- By **2030**, biomanufactured products could **replace up to 60%** of what we use today, unlocking nearly **$30 trillion in global value**.

Biotech is the future of defense

- Biotechnology represents the next paradigm shift in **how wars can be fought and won**.
- From biothreat detection to bio-based materials for defense, **a strong biotech sector ensures the U.S. military is prepared** ahead of emerging threats.
- The Pentagon is already investing in biotech to secure supply chains, strengthen operational capabilities, and prepare for emerging threats.
- A resilient biotech sector means a stronger, more self-sufficient Department of Defense. **Investing in biotech is investing in national security.**

Unleash private innovation with effective governance

- Government bottlenecks are stifling biotechnology investment and slowing innovations that Americans need.
- The U.S. biotechnology sector is ready to boom, but we must lead with **forward-thinking policy**.
- **The government's role is clear: focus on what only it can do—and do it well.**

Recommendation Overview

Policy Objectives

Policy objectives:

1. Prioritize biotechnology across the U.S. government
2. Mobilize the private sector to get products to scale
3. Maximize biotechnology for defense
4. Out-innovate adversaries
5. Secure the biotech workforce of the future
6. Maximize the collective strengths of allies and partners

Policy Objectives

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Grand Research Challenges

Out-Innovate our Strategic Competitors:

Grand Research Challenges

Recommendations:

- 4.3B: Congress should initiate a grand research challenge focused on making biotechnology predictably engineerable.
- 4.3C: Congress should initiate a grand research challenge focused on making biomanufacturing scale-up predictable, rapid, and cost-competitive.

Out-Innovate our Strategic Competitors:

Grand Research Challenge #1

1. Component Challenges:
   a) Solve the genotype-to-phenotype relationship
   b) Develop more precise engineering tools
   c) Create a digital twin of the cell
   d) Identify indicators of successful bioengineering scale-up

2. Keystone Challenges
   a) Build minimally synthetic cells
   b) Improve mapping and measuring of molecular interactions
   c) Advance organoids and organs-on-a-chip models

Out-Innovate our Strategic Competitors:

Grand Research Challenge #2

1. Specific areas for Scale-up:
   a) Chassis
   b) Biomass and Feedstocks
   c) Process Technology and Equipment
   d) Critical Inputs

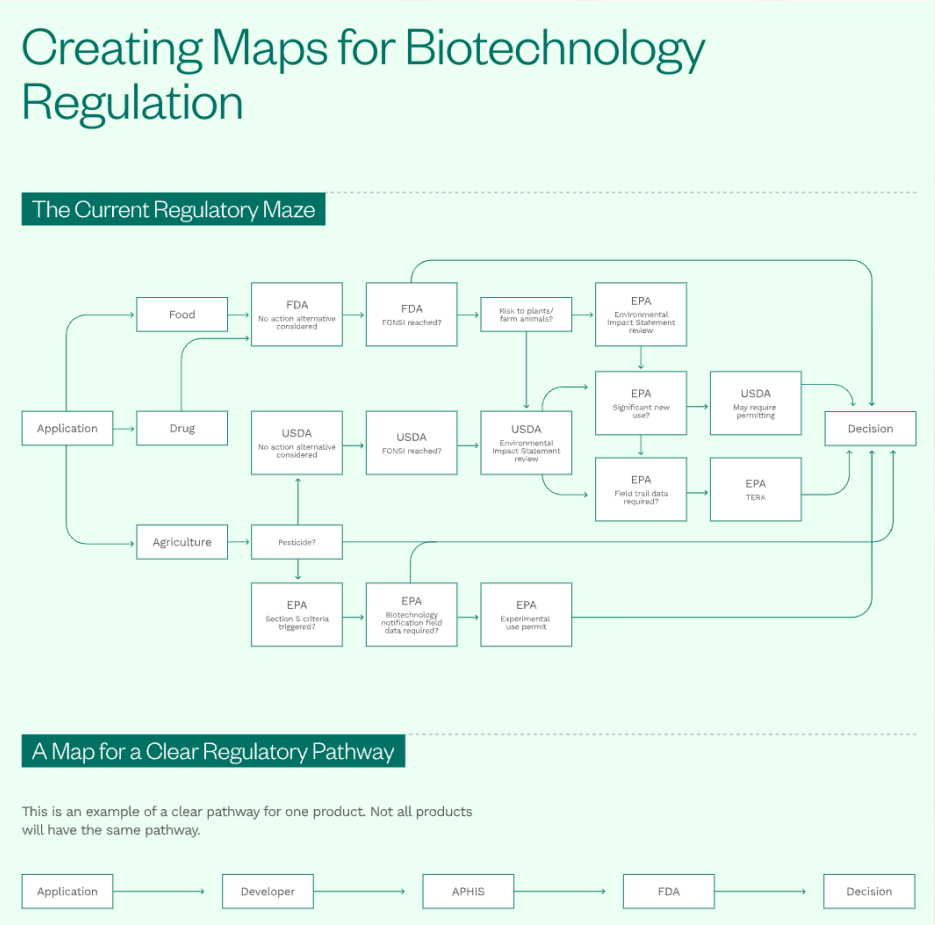
Simplify Regulation

Mobilize the Private Sector:

Simplify Regulation for American Biotechnology Companies

Recommendations:

- 2.1A: Congress must direct federal regulatory agencies to create simple pathways to market and exempt familiar products from unnecessary regulation.
- 2.1B: Congress should direct federal regulatory agencies to prepare for novel products to come to market.



Simple Pathways to Market

- Create Simple Pathways and exemptions
- Map clear regulatory pathways that resolve regulatory overlaps, gaps, and ambiguities
- Conduct regulatory trials to inform clear regulatory pathways
- Verify voluntary standards for biotechnology
- Build digital infrastructure to simplify biotechnology regulation
- Communicate clearly and consistently about biotechnology regulation
- Work on regulatory guides, developer outreach, public outreach, and regulatory diplomacy

Preparing for Novel Products to come to Market

- Bolster Regulatory Agency Capacity
- Establish a foundation to enable biotechnology innovation
- Establish a federal biotechnology regulatory research program

- Infrastructure: Utilize the DOE National Laboratories to create a center for biotechnology focusses on biotechnology risk assessment.

Protect Against the Harms of Biotechnology

4.4: Protect Against the Harms of Biotechnology

- Our current governance tools are blunt and reactive
- Government leadership is fragmented
- Policy tools are unable to keep up with innovation

- Recommendation
  - 4.4a: Congress must direct the executive branch to advance safe, secure, and responsible biotechnology research and innovation.

- Synthetic nucleic acid screening guidelines
- Digital-physical cyber protection issues

- Lab oversight
- National Science Advisory Board on Biosecurity
- Recombinant DNA research guidelines
- Novel and Exceptional Technology and Research Advisory Committee

- Bio-specific cybersecurity protection
- Gene synthesis security stress testing

- Exec. Order on Safe and Secure AI
- Framework for Nucleic Acid Synthesis Screening
- DURC/PEPP Oversight

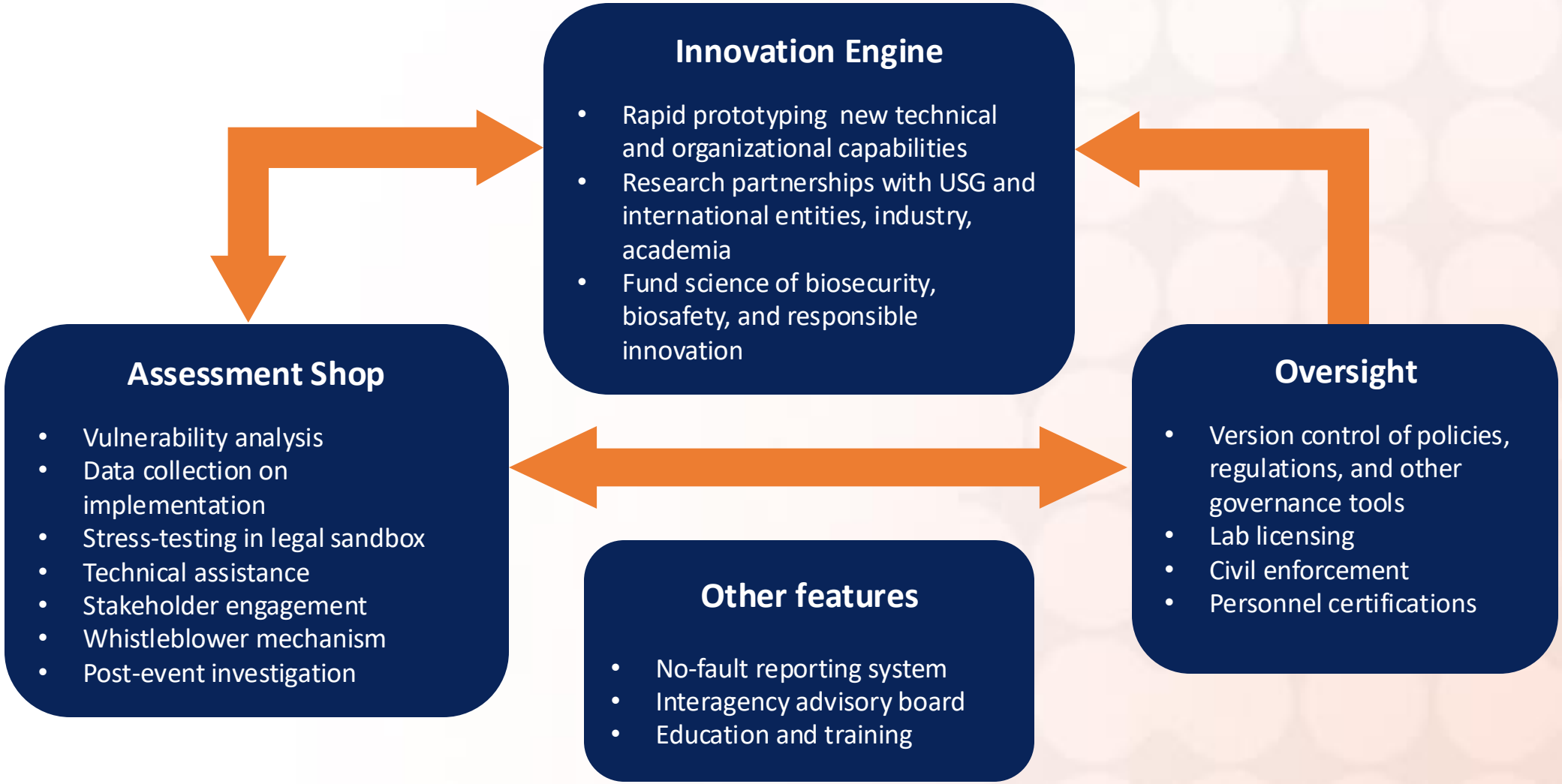
- Select Agent Program, Lab oversight

- Lab Oversight
- No-fault reporting system
- Biosecurity and Biosafety training
- Post-event investigation board
- Others…

A Consolidated Approach

- Identify emerging risks & vulnerabilities
- Fund applied innovation & tool development
- Incentivize the adoption of best practices
- Consolidate and oversee relevant policies
- Collaborate with the international community

Proposed structure of new biosecurity, biosafety, and responsibility entity



Questions?