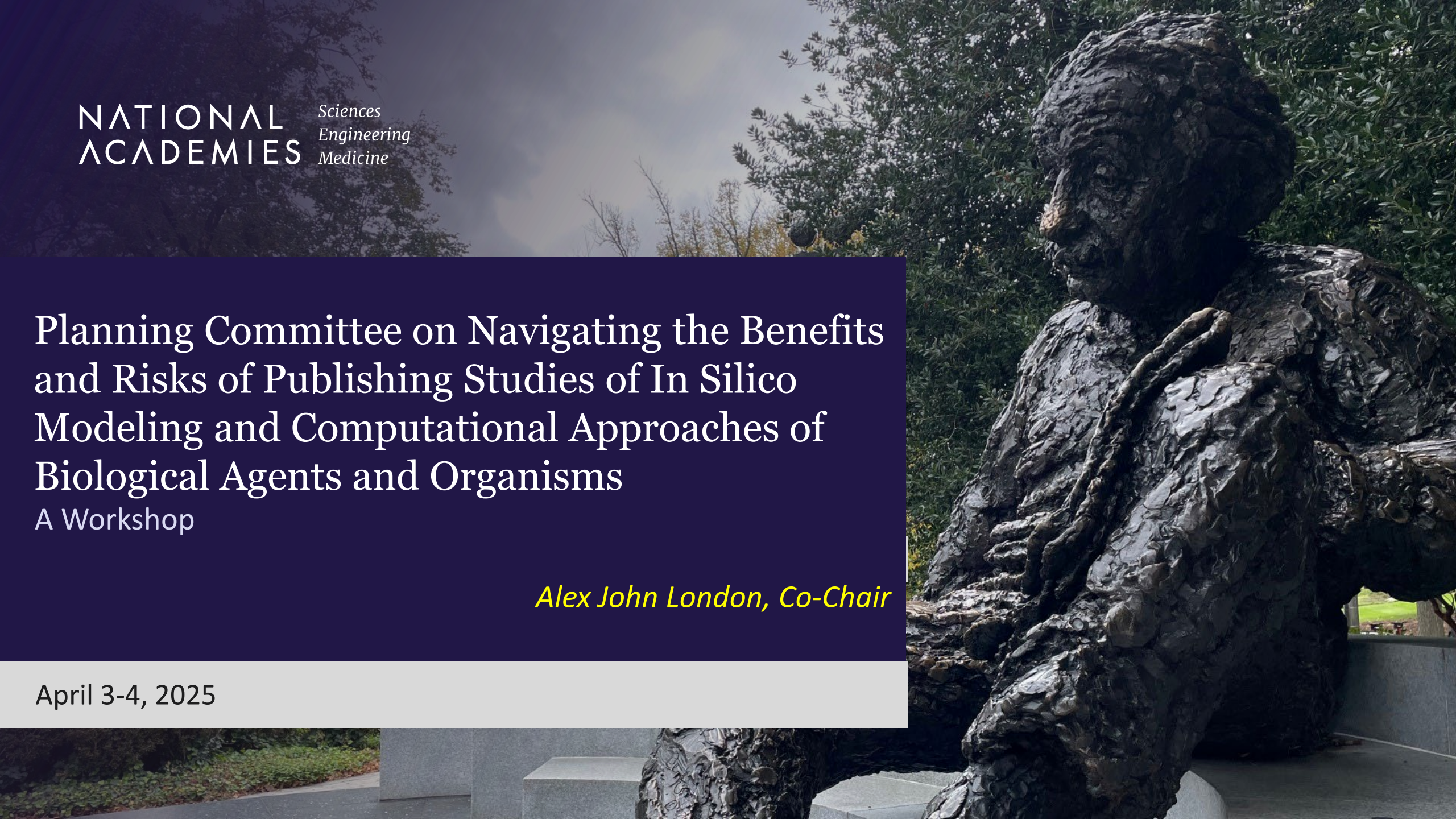


NATIONAL ACADEMIES Sciences Engineering Medicine

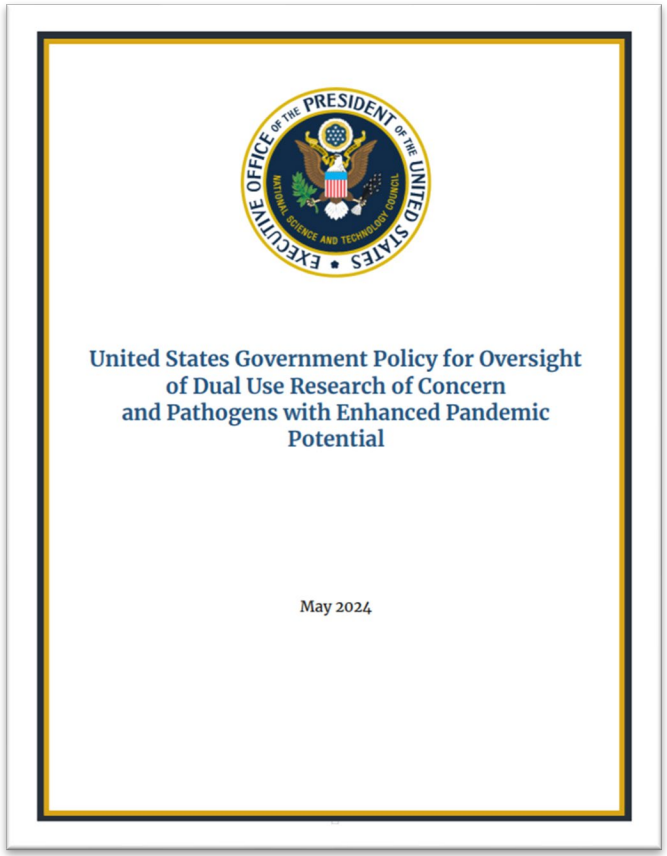
Planning Committee on Navigating the Benefits and Risks of Publishing Studies of In Silico Modeling and Computational Approaches of Biological Agents and Organisms

A Workshop

Alex John London, Co-Chair

April 3-4, 2025

Why this activity?



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6.2 Voluntary Guidance for Other Types of Research that May Pose Biosafety or Biosecurity Risks

This subsection provides voluntary guidance to PIs and research institutions for research that is outside of the scope of this Policy but that may pose a potential risk and may warrant oversight and risk mitigation at the institutional level.

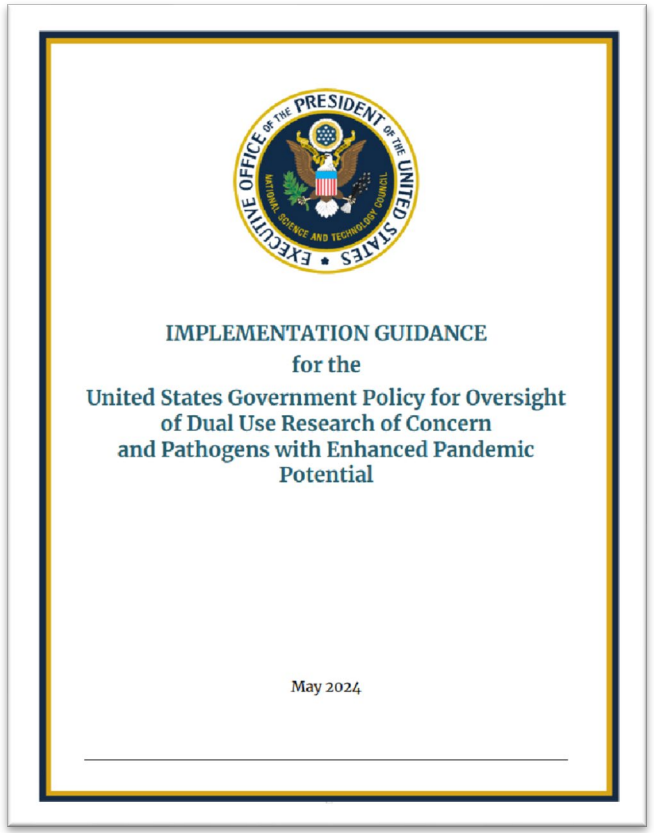
6.2.1 Research with Other Human and Zoonotic Biological Agents and Toxins

This Policy encourages research institutions to oversee any research with biological agents and toxins outside the scope outlined in Section 4, regardless of funding source…

6.2.2 Research Involving In Silico Models and Computational Approaches

This Policy recognizes the rapidly evolving nature of computational biology and the increasing use of computational models and approaches, including the use of artificial intelligence, that potentially contributes to the production of dual-use biological knowledge, information, technologies, and products. This Policy encourages institutional oversight of in silico research, regardless of funding source, that could result in the development of potential dual-use computational models directly enabling the design of a PEPP or a novel biological agent or toxin. This oversight should involve an assessment of the benefits and risks, including the dual use potential of the in silico research to determine if the research should be conducted, and as appropriate, the development of a risk mitigation plan that considers how to responsibly share and communicate research results and datasets related to the biological agents or toxins under study.

Why this activity?



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G. GUIDANCE FOR RESPONSIBLE COMMUNICATION OF CATEGORY 1 AND CATEGORY 2 RESEARCH FINDINGS

G.1.3 Recommendations Regarding Responsible Communication of Research Findings

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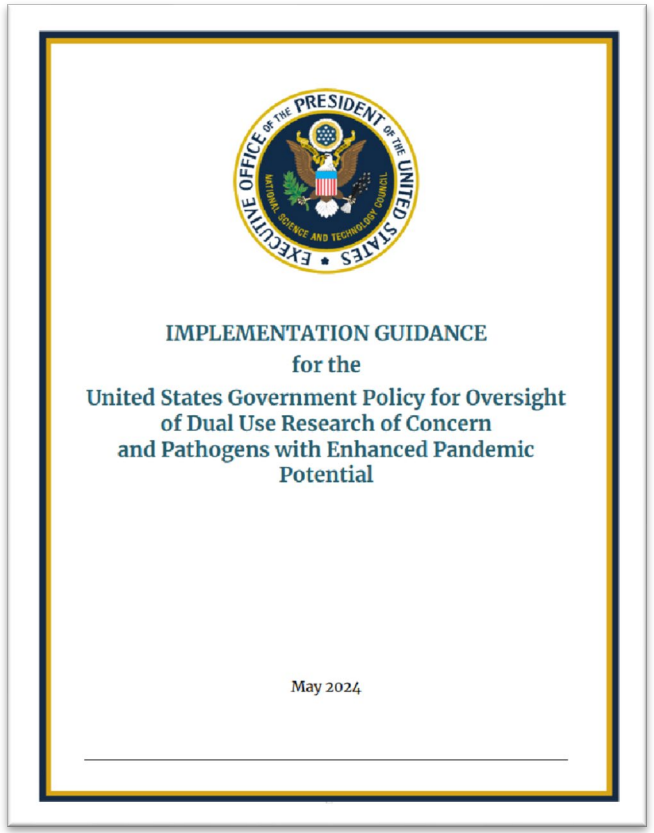
J. FURTHER VOLUNTARY GUIDANCE FOR POLICY IMPLEMENTATION

J.2 Voluntary Guidance for In Silico Models and Computational Approaches

The scope of the Policy does not cover in silico research. However, the rapidly evolving nature of computational biology and the increasing use of computational models and approaches, including the use of artificial intelligence, can potentially contribute to the production of dual-use biological knowledge, information, technologies, and products, just as in vivo or in vitro Category 1 or Category 2 research outlined in the Policy. As outlined in the Policy, Pis and IREs are encouraged to, on a voluntary basis, conduct similar assessments of the benefits and risks of in silico research, specifically the development of potential dual-use computational models that can directly enable the design of a PEPP or a novel biological agent or toxin, and implement risk mitigation measures as appropriate. For example, this would include modeling tools designed to predict nucleic acid or amino acid modifications anticipated to enhance the virulence or transmissibility characteristics, or likelihood of immune evasion, e.g., antibody escape, of a PEPP or novel or mutated PPP upon synthesis.

To be cont'd…

Why this activity?



J. FURTHER VOLUNTARY GUIDANCE FOR POLICY IMPLEMENTATION
J.2 Voluntary Guidance for In Silico Models and Computational Approaches

…*Cont'd*

Researchers developing or considering the development of tools meeting these specifications, or other in silico tools that appear to have comparable risks, are encouraged to assess the capacity of such models and computational approaches to be misused, such as with the set of questions recommended in Part D and Part E of this Implementation Guidance, to determine a safe and secure way to proceed with the given line of study and responsible communication of the results, models, and datasets. Possible responses to proposed research involving the in silico production of dual use data could include full publication, partial publication, or no publication, as described in Part G.1.3 of this Implementation Guidance.

Best practices for this rapidly evolving field of study remain under development. Researchers and research institutions seeking additional guidance on the benefits and risks of in silico research are encouraged to consult the federal funding agency on a voluntary basis to discuss any questions or concerns. Such discussions may inform continued development of guidance tailored to the benefits and risks unique to in silico research. Researchers and research institutions should also consider consulting with their security and information technology offices as applicable to mitigate physical security and cyber security risks, respectively, in developing a risk mitigation measures.

Statement of Tasks

The National Academies will convene a planning committee to plan and facilitate a **workshop** on opportunities for considering and navigating **benefits and biosecurity risks** of communicating studies involving **computational modeling and analysis**, including the use of generative artificial intelligence, of **biological systems** at the **publication stage**.

The committee will consider:

a) Existing statements, policies and guidance, and risk mitigation practices (or safeguards) on dual-use research of concern and pathogens of pandemic potential, **relevant to communication and publication** of covered scientific activities;

b) **Challenges and needs to effectively safeguard the benefits** and promote the advances of the use of computational models and analysis with biological systems, while also **mitigating the risks** of generating or releasing these models and associated biological information that may present to human, animal, plant, and/or ecological health, and/or national security;

Statement of Tasks – *Cont'd*

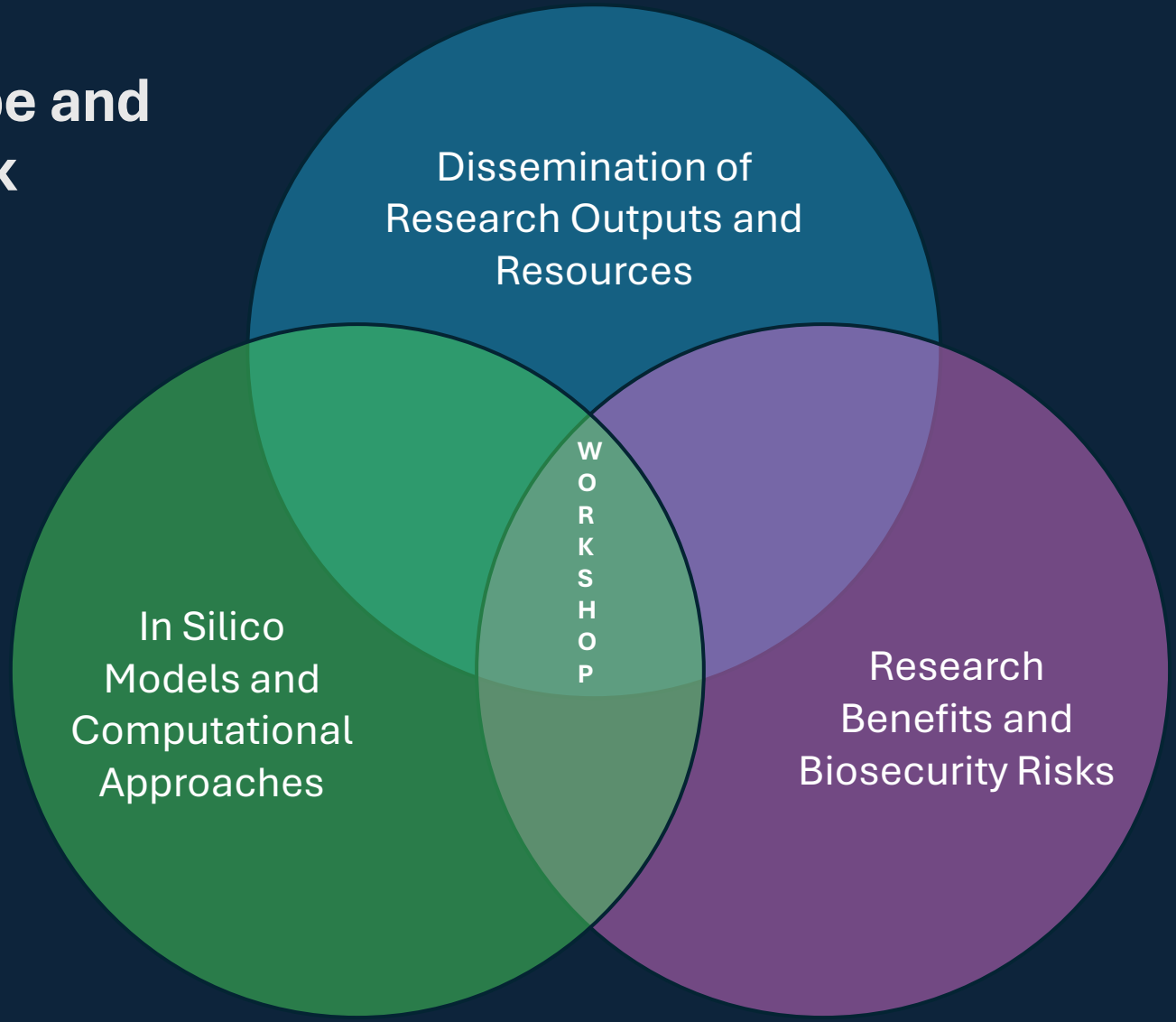
c) Relevance and utility of **evolving efforts on AI safety to communication** of studies involving in silico modeling and analysis and/or generative AI with biological systems; and

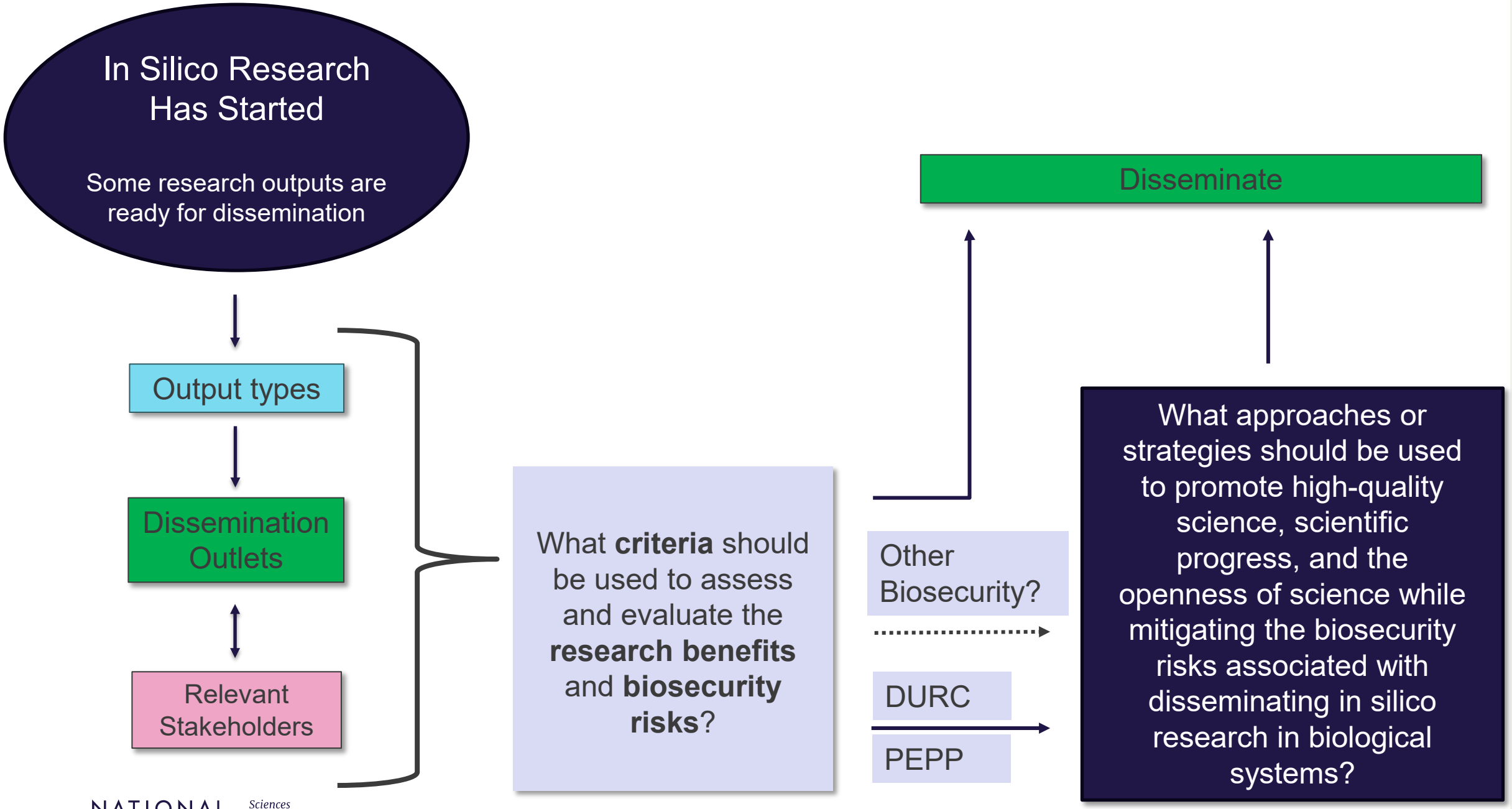
d) **Policy options and norms** for safeguarding the benefits and advances while reducing the risks.

The committee will engage experts from leading scientific journals that publish research in biology and associated fields, professional societies and associations, Academies of Science, academia, industry, and other nongovernmental entities in the workshop.

Critical themes from the workshop discussion will be summarized in a workshop proceedings.

Workshop Scope and Framework





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Upstream Conduct and Oversight Mechanisms for Physical Research are Not in the Scope of this Workshop

Institutional Review Boards, Institutional Biosafety Committees, Export Controls, Government Regulations, Security Clearances, etc.

but Some are Relevant to the Conversation

Pre-registration, Funding Review, etc.

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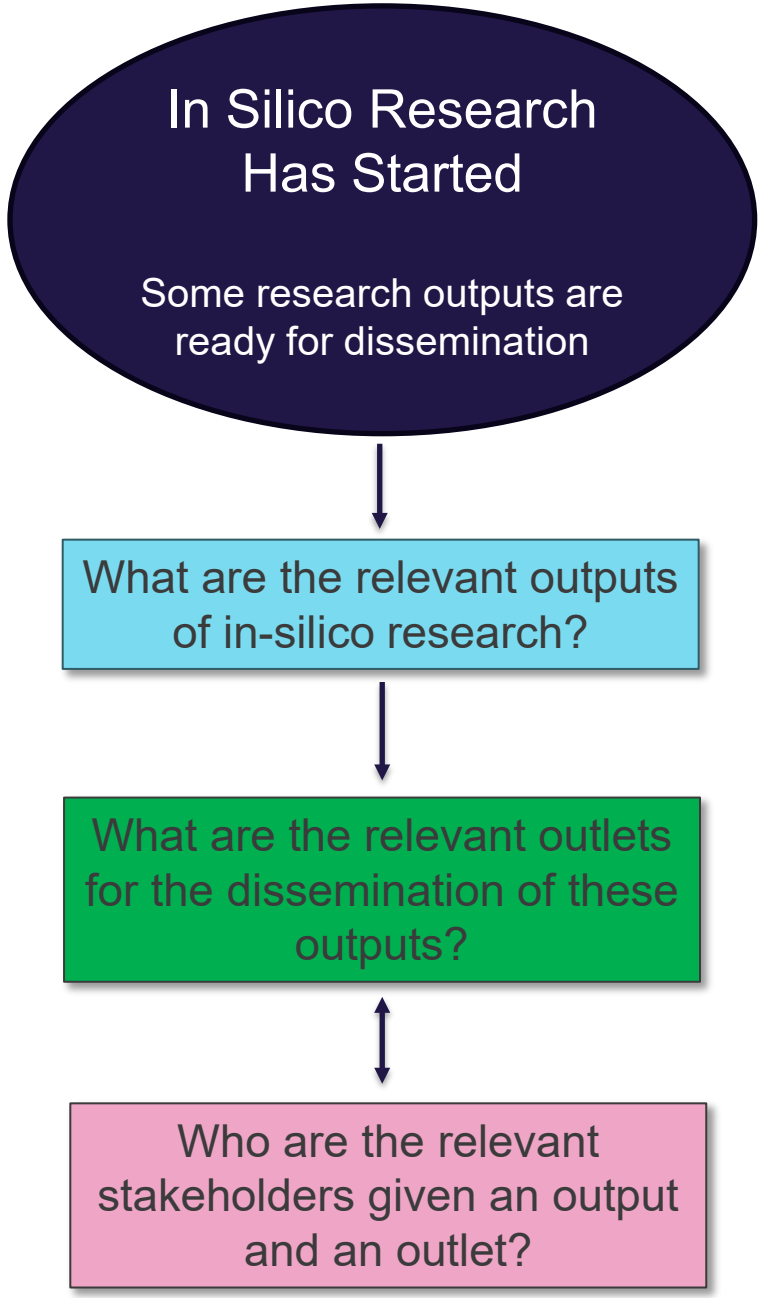

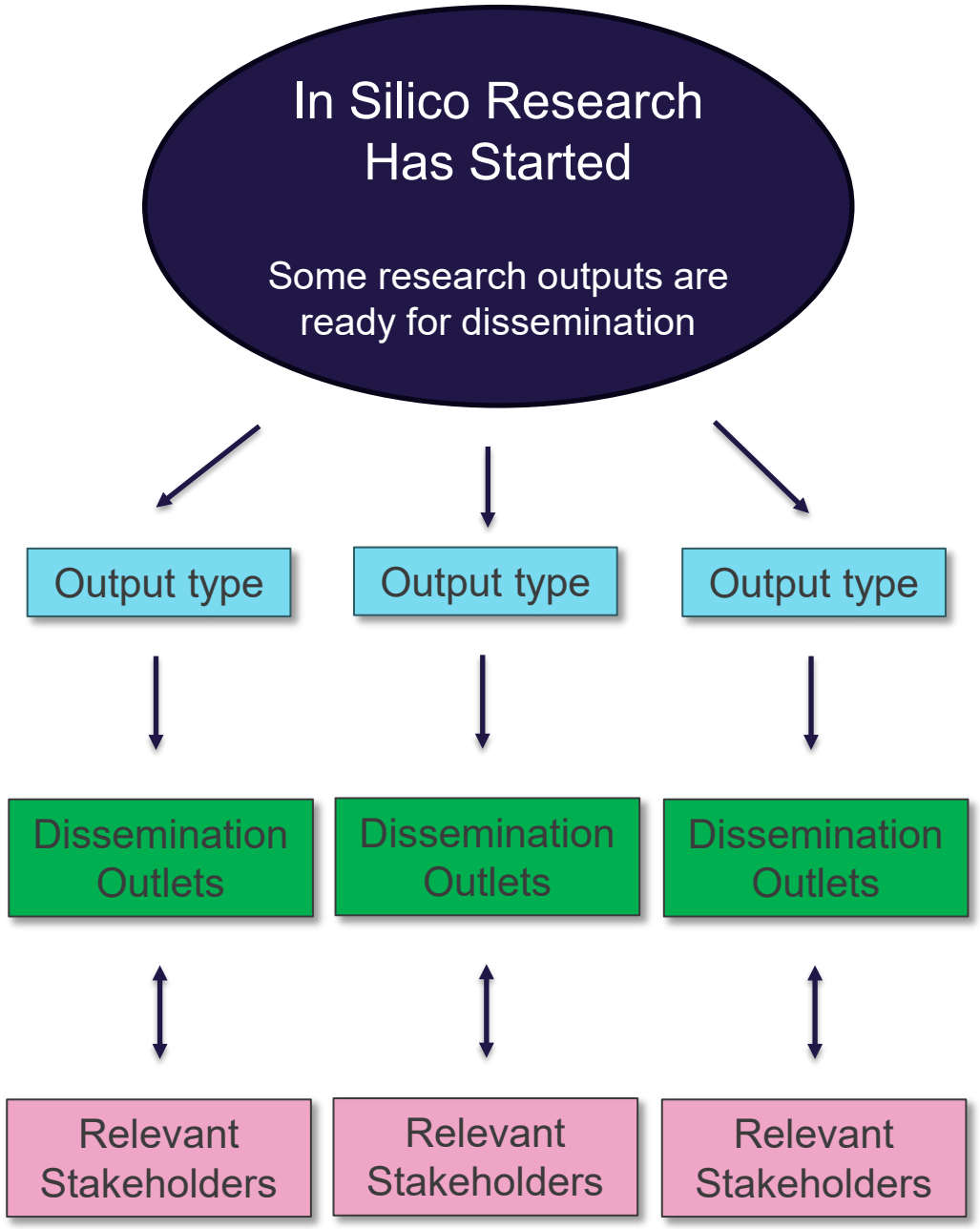

WHAT ELSE?

DAY 1 – April 3

Outputs: research results and resources
Peer-reviewed paper, preprint, working code, final code, models, data, user interface

Outlet: ways to share/disseminate the outputs
Journal, archive, data repository, working environment (e.g., GitHub, CoS), application

Stakeholders: Create, review, evaluate, or receive the outputs
Authors, editors, reviewers, industry (may create applications without publishing), data/code curators, funders (checking compliance), users

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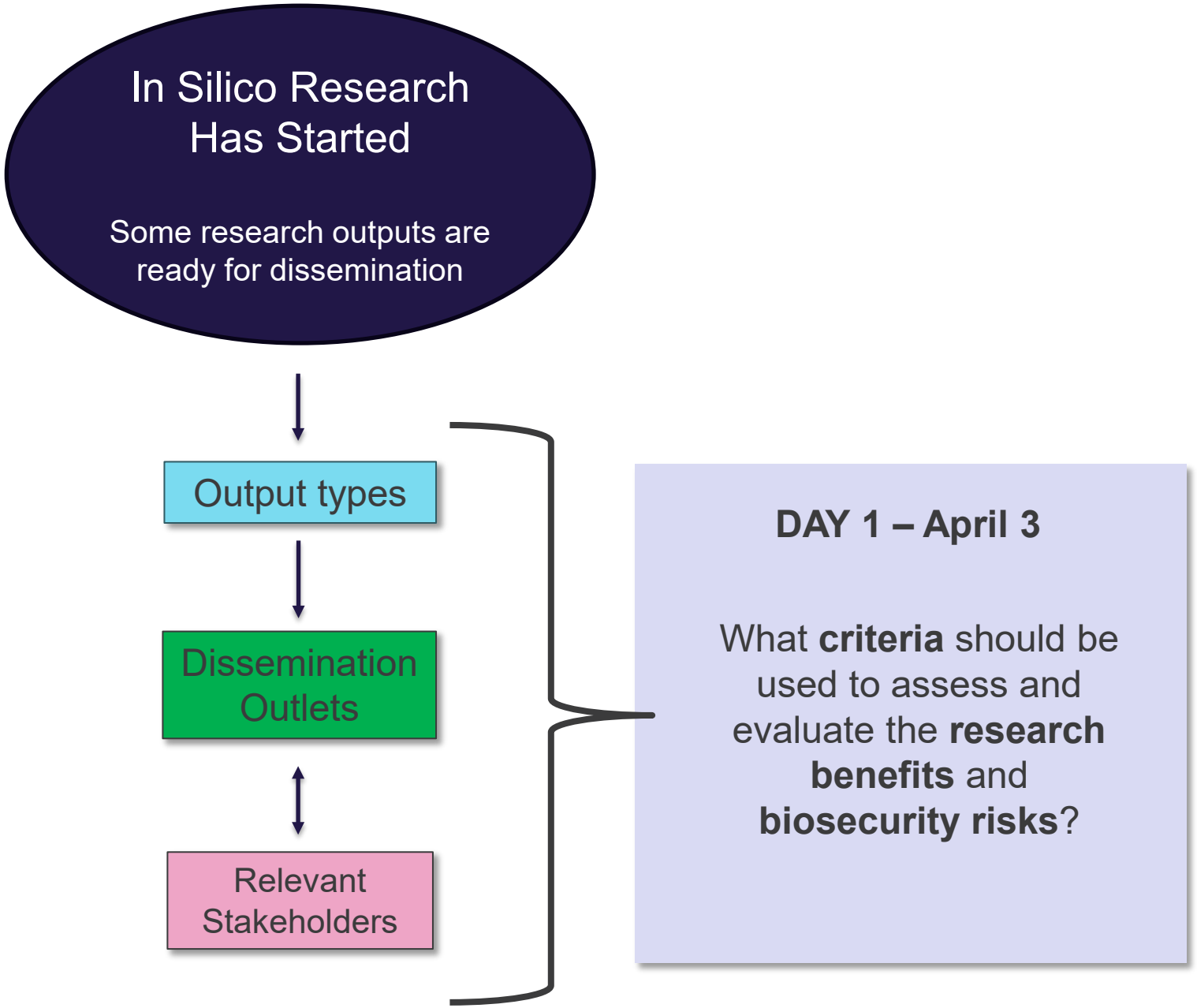

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In Silico Research Has Started

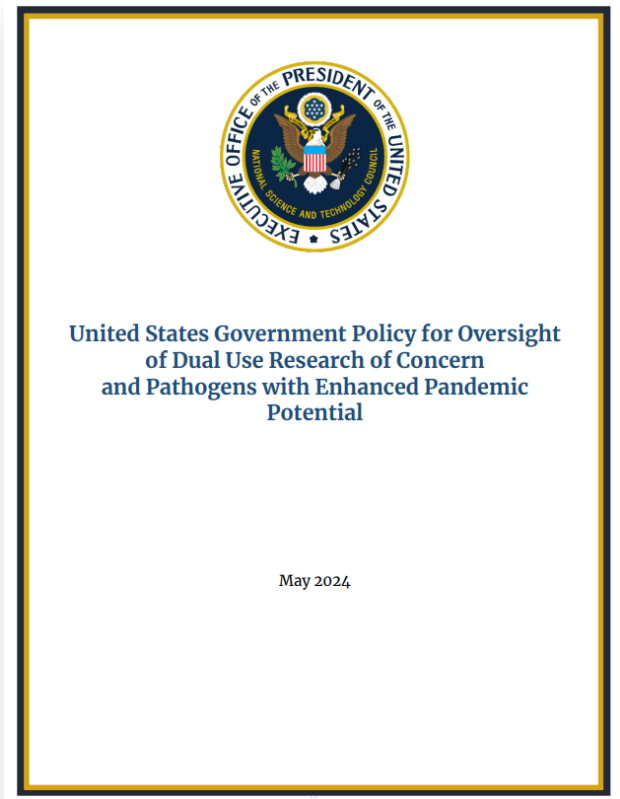
Some research outputs are ready for dissemination

Output types

Dissemination Outlets

Relevant Stakeholders

Upstream Conduct and Oversight Mechanisms for Physical Research



Existing guidance focuses on:

- Physical research
- DURC and PEPP potential
- Little emphasis on dissemination

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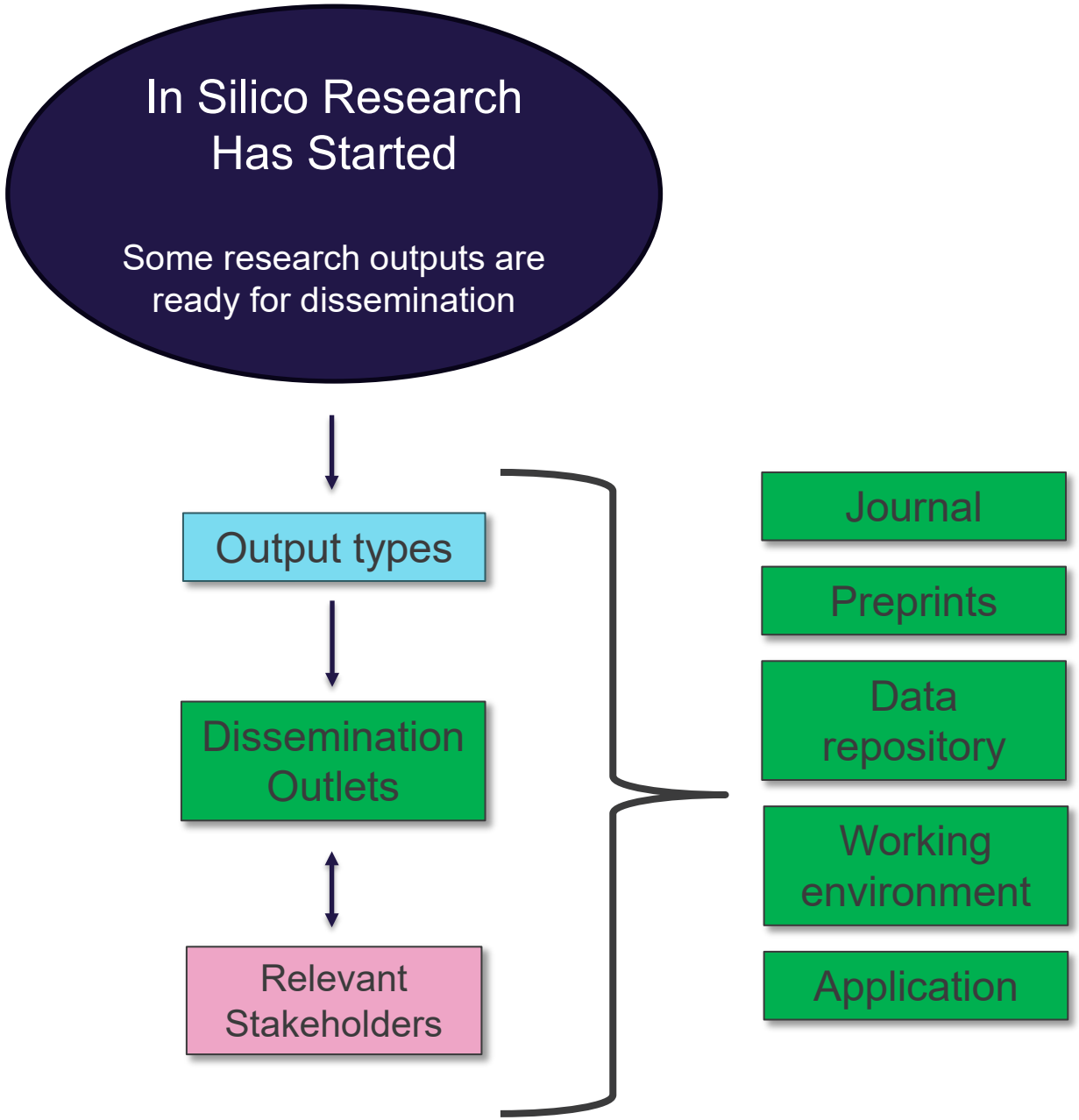

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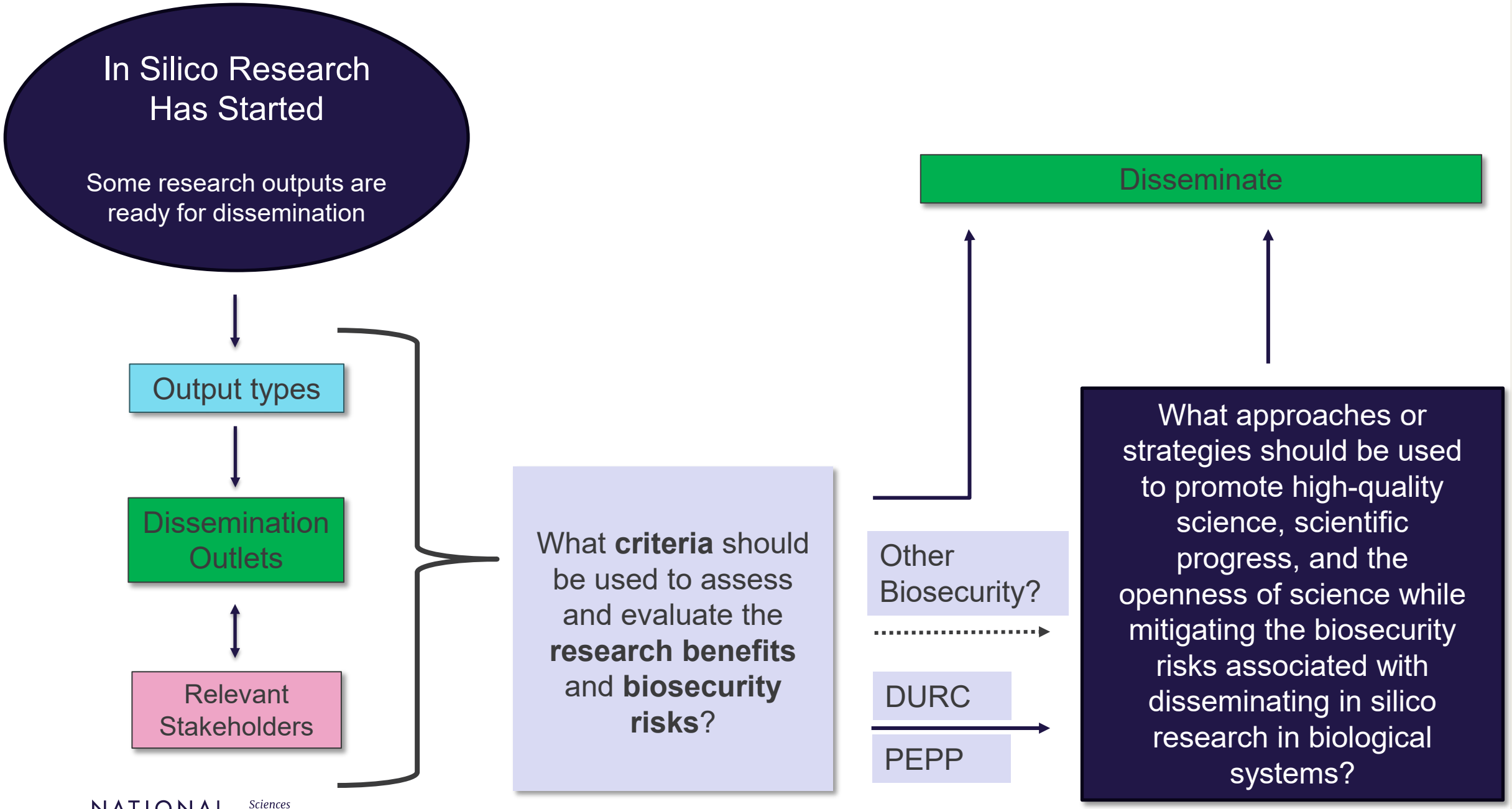
DAY 1 – April 3
Breakout

What do you see as current **challenges and gaps** in assessing and evaluating the possible **benefits** and the **DURC and PEPP** potential of **disseminating in silico** research in biological systems?

Do the **different dissemination** outlets present different risks?

What **additional** criteria (if any) should be used to assess **biosecurity risk** of in silico research in biological systems for **each dissemination outlet**?



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Agenda at a Glance – Day 1

Navigating the Benefits and Risks of Publishing Studies of In Silico Modeling and Computational Approaches of Biological Agents and Organisms

Session 1

Setting the Stage – Context and Scope

Session 2

Benefits and risks of disseminating studies, models, and tools involving computational approaches: What's hype, and what's reality?

Session 3

Challenges and Needs to Effectively Safeguard the Benefits and Mitigate the Risks of Disseminating Studies, Models, and Tools Involving Computational Approaches – Thematic Breakout Rooms

Session 4

Reflection & Ah-ha moments