



NExTRAC Framework Working Group

Gigi Gronvall, PhD

Margaret Riley, JD

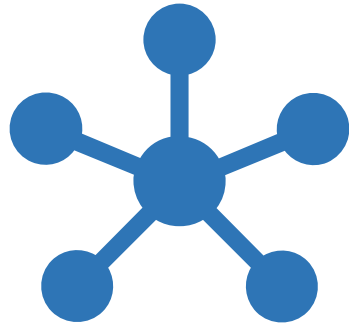
NExTRAC Meeting - November 10, 2020



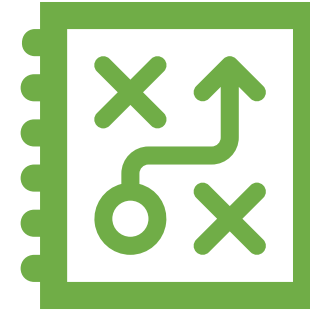
Background

- In December 2019, Dr. Francis Collins charged the NExTRAC with two tasks, and announced that NIH would convene two Working Groups of the NExTRAC to:
 - **Establish a framework for a thoughtful approach to assess the potential issues associated with new biotechnologies and their applications.**
 - Assist in the development of a path forward for biomedical research involving gene drive-modified organisms.

The Working Group to Establish a NExTRAC Framework is charged with:



Describing effective approaches for prospectively identifying emerging biotechnologies or specific applications with reasonable potential to have important scientific, safety, or ethical considerations; and



Conceptualizing a framework for NExTRAC deliberation of issues surrounding emerging biotechnologies and applications, including:

- Guiding principles for when an emerging biotechnology or its applications would significantly benefit from further public deliberation; and
- A potential process by which the NExTRAC will consider or evaluate any given emerging biotechnology or its applications.

The Working Group was asked to consider:



- Applications of emerging biotechnologies, given that the way the biotechnology is used often generates the safety, social, or ethical issues
- Effective horizon scanning approaches; focusing on biotechnologies and applications that are reasonably anticipated vs. hypothetical
- Cross-cutting issues that may be relevant for a variety of emerging biotechnologies and applications
- Strategies for committee engagement and soliciting feedback

Working Group Roster



Co-Chairs

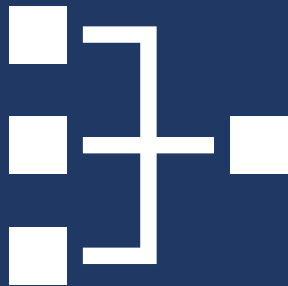
- Gronvall, Gigi (Johns Hopkins University)
- Riley, Margaret (University of Virginia)



Members

- Albritton, Lorraine (University of Tennessee)
- Cho, Mildred (Stanford University)
- Leshner, Alan (American Association for the Advancement of Science)
- McCarty, Douglas (Pfizer)
- Ossorio, Pilar (University of Wisconsin)
- Thiboldeaux, Kim (Cancer Support Community)
- Turner, Leigh (University of Minnesota)
- Whitley, Richard (University of Alabama)

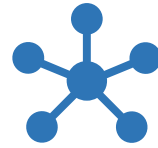
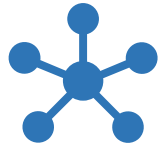
Approaches for prospectively identifying emerging biotechnologies or specific applications



“Horizon scanning” basic steps

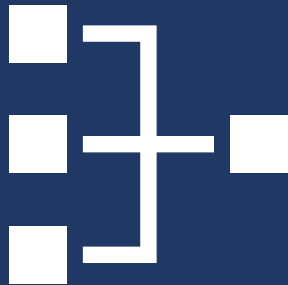
1. Signal identification and detection
2. Criteria and methods of filtration and prioritization
3. Assessment, dissemination and updating of information
4. Overall evaluation of the process

Approaches for prospectively identifying emerging biotechnologies or specific applications- effective sources of information and filtering



| | Types | Consideration(s) |
|-----------------------------|---|--|
| Sources | Highly flexible and uses a variety of credible sources of information | Confirmation of reliability of information sources when possible. |
| | Diverse set of voices | |
| Filtering Techniques | Quantitative approaches (e.g., portfolio analysis tools) | <ul style="list-style-type: none">• For quantitative approaches, human input may be needed particularly at the filtering stage.• Identification of the appropriate pipeline for gathering input from different sources.• Identification of appropriate criteria and methodology for filtering. |
| | Qualitative approaches (e.g., workshops) | |

Desired components of NIH approach(es) for prospectively identifying emerging biotechnologies or specific applications



The horizon scanning focuses on and identifies...

- emerging biotechnologies and applications that fall within or are related to the NIH mission space.
- input from diverse groups.
- “convergence” (i.e., when technologies that were previously separate or distinct begin to align) as a harbinger of an emerging biotechnology or application.
- early indicators of issues that would require an NIH response.

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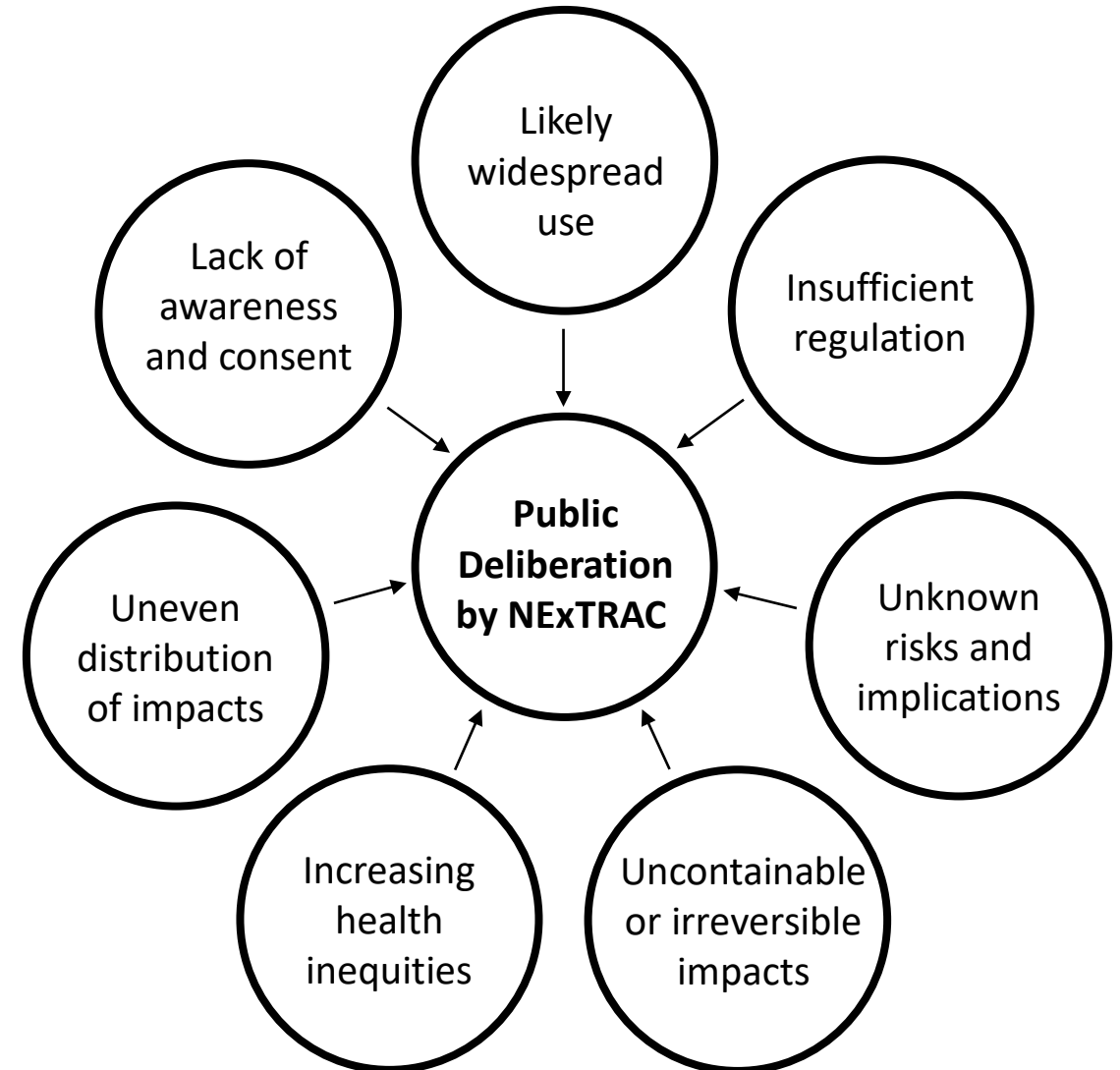
The horizon scanning process...

- integrates and builds on previous work of others to detect emerging technologies/research and gaps.
- is iterative.
- includes both (1) continuous horizon-scanning processes in strategically important areas and (2) stand-alone projects/processes designed to answer explicit questions.
- includes explicit and deliberate strategies for recognizing and mitigating the effects of biases and psychological heuristics.
- appreciates time frame appropriately tied to the purpose (likely 5-10 years).
- has periodic re-evaluation of approaches to identify weak spots and gaps.



Prompts for NExTRAC Deliberation

- Meant to bridge the gap to existing scientific, safety and bioethical principles, which still apply to this framework.
- Not meant to be all encompassing or in priority order.
- Not intended to be used as a checklist.



Prompts for Public Deliberation and Examples of Relevant Guiding Principles/Values

| Prompts for public deliberation | Examples of relevant principles or values |
|--|--|
| Likely widespread use | Relevance and timeliness |
| Insufficient regulation | Oversight and transparency |
| Unknown risks and implications | Nonmaleficence and justice Safety and risk management |
| Uncontainable or irreversible impacts | Nonmaleficence Safety |
| Increasing health inequities | Equity and Justice |
| Uneven distribution of impacts | Fairness |
| Lack of awareness and consent | Autonomy and Respect for Personhood Nonmaleficence |



Potential Process

