

# Opportunities for Encouraging the Consideration of Alternative Methods

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## Introduction

- Currently, there is little incentive for investigators who have long used specific in vivo models and well-established protocols to work toward adopting new approach methodologies (NAMs).
- Moving to NAMs could provide an opportunity to improve established methods of conducting toxicology testing and research. However, incentives are needed to encourage investigators to actively seek out, validate, or research NAMs.
- The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) established its Consideration of Alternative Methods Workgroup (CAMWG) to explore opportunities to encourage scientists to consider using NAMs that could replace, reduce, or refine tests using live animals.
- Between May 2022 and May 2023, the CAMWG held a series of informational meetings with different stakeholder groups to document their perspectives on the consideration and use of NAMs in their respective organizations.

## CAMWG Charges

- Work with stakeholders to publish a white paper on approaches that could potentially be used to foster the consideration and use of NAMs to replace or reduce live animal use in painful/distressful procedures or refine the work, so it is less painful/distressful, by organizations currently using animals for testing.
- Foster collaborations with authorities outside of the U.S. to share ideas and progress to promote greater harmonization for considering NAMs.
- Refer the community to available grants devoted to the development of alternatives to live animal use.
- Identify/improve communication efforts/opportunities that help promote the use of NAMs.
- Where appropriate and feasible, encourage agencies to promote avenues (i.e., suggestions for improvement of best practices) where NAMs can be better considered and leveraged.

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## CAMWG Participating Agencies



## CAMWG Scope

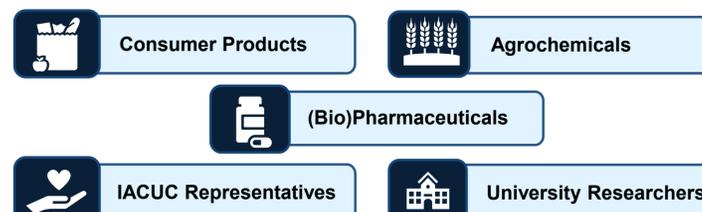
- Work with stakeholders to develop incentives that could be used to encourage proposals for NAMs in conjunction with existing in vivo test methods.
- Review current requirements for considering NAMs, and how those might be modified or expanded to foster additional consideration by stakeholders.
- Consider how efforts could be broadened beyond toxicology testing to other areas of testing and research that involve animal use.

## Stakeholder Discussion Questions

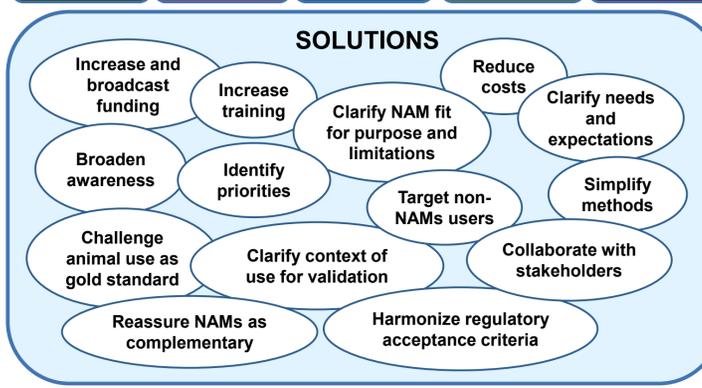
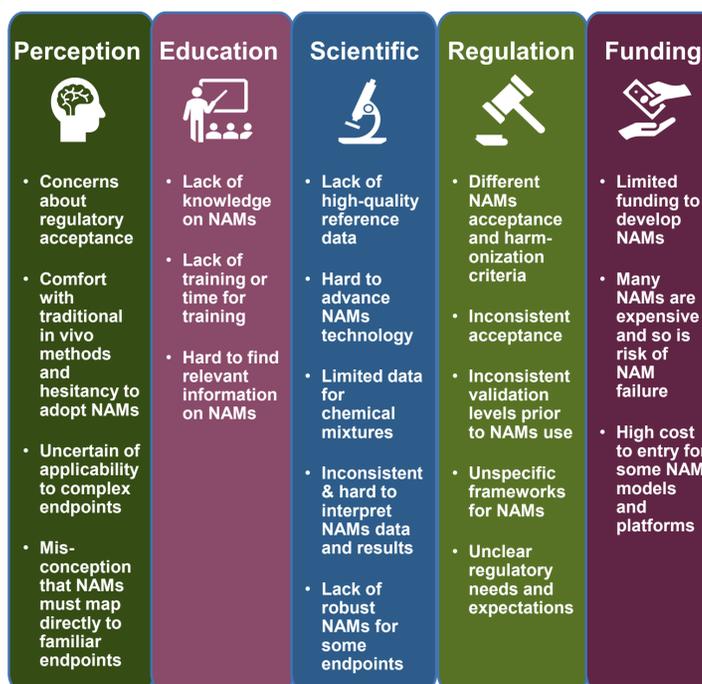
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|----|---|
| 1  | Barriers to implementing NAMs?  |
| 2  | Suggestions to overcome those barriers?   |
| 3  | Areas where NAMs are currently unavailable?   |
| 4  | Areas where NAMs are used but are inappropriate?  |
| 5  | Funding opportunities to research or validate NAMs?   |
| 6  | Does your group consider or employ the use of NAMs?   |
| 7  | Methods to prescreen drug or substance candidates? Examples?  |
| 8  | Thoughts on the availability of NAMs (in academia, pharma, etc.)?   |
| 9  | Thoughts on the current state of NAMs in toxicology testing?  |
| 10 | Examples of successfully using an alternative approach?   |
| 11 | Suggestions on communication to promote the use of NAMs?  |
| 12 | Are NAMs used for down selection of product or dose range assessment? Is this information included in the IAUAC protocol, including number of animals not used because of NAMs? |
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|---|--|
| 1 | How do IACUC members stay up to date on NAMs?                    |
| 2 | Does IACUC or institution offer NAMs training? Kind? Frequency?  |
| 3 | NAMs subject matter experts to consult when reviewing protocols? |
| 4 | Ways IACUC ensures NAMs were considered and documented?          |
| 5 | Resources for PIs and IACUC to improve their NAMs knowledge?     |

\*Institutional Animal Care And Use Committee (IACUC)

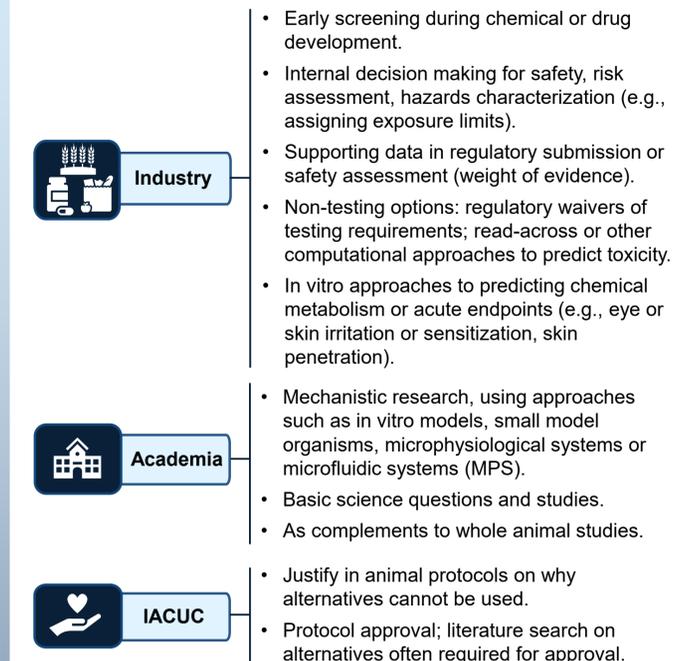
## Stakeholder Groups



## Common Themes, Barriers, and Solutions



## How NAMs Are Being Used



## Conclusion and Next Steps

- In general, NAMs are available for certain endpoints and are used by a variety of stakeholders.
- There are areas and application domains where NAMs are not yet suitable, while some areas (e.g., topical toxicities) have ample supply of NAMs.
- Increased communication is needed on the wins, limitations and needs between stakeholders, regulators, NAMs developers, and end users.
- There is a need to target non-NAMs users for support and education on using NAMs.
- Increased funding would support development and incorporation of NAMs in research and regulatory applications.
- The CAMWG aims to publish a white paper with stakeholder responses and recommendations to implement solutions.

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