5th Meeting of the Gene Drive Research Forum
Bridging Gaps in Stakeholder Engagement
December 13-15, 2021, Virtual

Session #1, December 13, 2021
Connecting theoretical/conceptual and applied stakeholder engagement
Chair: Léa Paré Toé, Ph.D., Institut de Recherche en Sciences de la Santé

Description: Often, conversations and discussions surrounding stakeholder engagement research and the actual practice of this work on the ground appear to be disconnected. That is not to say that these different, but interrelated, approaches are not working towards the same goals, rather that social science researchers and practitioners both may benefit from greater interaction to enable mutual learning and shared advancement. But how can this be facilitated, where is the disconnect, and what mechanisms and resources might be appropriate to create space where effective communication is encouraged, allowed, and supported to narrow the gap.

Participants are charged with drawing from their own experiences no matter what those are (technical research, social science, regulatory science, funding, etc.) to explore disconnects in the translation of stakeholder engagement theory into practice and in the feedback loop from practical experience to theory development and identifying potential mechanisms for resolving issues. Below are questions to facilitate discussion, however, each group leader and group participants should follow interesting avenues of discussion that emerge in the moment and should not feel compelled to address each of these questions.

- What separates theoretical and applied approaches of stakeholder engagement?
- How could the two approaches benefit more from one another?
- What specific initiatives could we pursue that would enhance collaboration among researchers and practitioners
- Who can make these initiatives happen?

AGENDA:
All times below are in EST

9:00 AM - Plenary
- Welcome - TBD
- 9:05 AM - Introduction
  - Chair: Léa Paré Toé, Ph.D., Institut de Recherche en Sciences de la Santé
- 9:15 AM - Deconstructing stakeholder engagement (15 minute talk)
  - Léa Paré Toé, Ph.D., Institut de Recherche en Sciences de la Santé
- 9:30 AM - Applied stakeholder engagement: a perspective (15 minute talk)
  - Vanilson Santos, UCI Malaria Initiative
- 9:45 AM - Theoretical stakeholder engagement: a perspective (15 minute talk)
  - Michael Burgess, Ph.D., The University of British Columbia

- 10:00 AM - End plenary
  - Chair: Léa Paré Toé, Ph.D., Institut de Recherche en Sciences de la Santé

10:00 AM - Breakout Groups

Each meeting participant will be pre-assigned to a breakout group.

- 12:15 PM - Breakout Group discussions end, and a 15 minute break begins

12:30 PM - Plenary

- Summary of outcomes from breakout groups and Q&A with all participants
  - Chair: Léa Paré Toé, Ph.D., Institut de Recherche en Sciences de la Santé

1:00 PM - Adjourn

Session #2, December 14, 2021
Exploring why and how to integrate stakeholder engagement into risk assessment
Chair: Keith Hayes, Ph.D., Commonwealth Scientific and Industrial Research Organisation

Description: Conducting risk assessments are a part of product development and can inform decision-making as a product moves further along the development process. Risk assessments may be developed by a research team, by a project-independent team, or by government regulatory teams to inform decision making. Often, risk assessments do not incorporate stakeholder input – typically the outcomes of an assessment may be notified, and stakeholders permitted to comment, but any subsequent changes to the assessment left to the discretion of the notifying authority. However, the outcomes of a more participatory engagement processes, particularly for novel products such as gene drives, may provide important insight for product development and solution-choice decision making.

Participants are charged with drawing from their own experiences no matter what those are (technical research, social science, regulatory science, funding, etc.) to explore the challenges to obtaining and incorporating stakeholder beliefs and data into a more participatory risk assessment process.

Below are questions to facilitate discussion, however, each breakout group leader and group participants should follow interesting avenues of discussion that emerge in the moment and should not feel compelled to address each of these questions.

- What are the critical challenges for different stakeholder groups (e.g., independent subject matter experts, risk-benefit exposed communities, other non-gene drive researchers, those opposed to the technology) to contribute during the risk assessment process – language, education, role, perspective?
- How do we approach the different groups and how might our approach vary between groups? Who will undertake this activity – the project team, regulatory officials, third parties – or a mixture of each? Depending on the type of stakeholder group, the challenges and the solutions might be quite different.
- How might we incorporate stakeholder concerns and values into a risk assessment?
  - At what point during the risk assessment process does this begin? An issue that we are beginning to see is that stakeholder concerns are often expressed in ways that leave the

incorporation into the RA open to interpretation – e.g. being bitten by a transgenic mosquito is an obvious concern but what is actually being expressed here – a concern about change in vectorial capacity, toxicity/allergenicity concern or a horizontal gene transfer issue?
    - Mapping the concern to an explicit risk assessment endpoint is not always obvious – why is this an issue, how can we improve here, and how might this be achieved among the different stakeholder groups ?
- Is there an alternate approach to documenting stakeholder concerns instead of in a risk assessment format? Are there potential negative consequences of seeking to incorporate stakeholder concerns and values into a risk assessment, and what might those be.
- Is there a citizen science role for stakeholders in risk assessment?
    - A key risk assessment challenge is post-release monitoring and surveillance – is there a citizen science role for stakeholders here – could this provide a cost-effective solution to the potentially large spatio-temporal domain that gene drive risk prediction monitoring may have to address – or should we just rely on existing epidemiological monitoring infrastructure?

AGENDA:

All times below are in EST

3:00 AM - Plenary

- Welcome - TBD
- 3:05 AM - Introduction
    - Chair: Keith Hayes, Ph.D., Commonwealth Scientific and Industrial Research Organization
- 3:15 AM - A Stakeholder engagement primer (15 minute talk)
    - Isabelle Coche, Outreach Network for Gene Drive Research
- 3:30 AM - Stakeholder engagement: a project perspective (15 minute talk)
    - Lina Finda, Ph.D., Ifakara Health Institute
- 3:45 AM - Stakeholder engagement in risk assessment (15 minute talk)
    - Geoff Hosack, Ph.D., Commonwealth Scientific and Industrial Research Organization
- 4:00 AM - End Plenary
    - Chair: Keith Hayes, Ph.D., Commonwealth Scientific and Industrial Research Organization

4:00 AM EST - Breakout Groups

Each meeting participant will be pre-assigned to a breakout group.

- 6:15 AM - Breakout Group discussions end, and a 15 minute break begins

6:30 AM - Plenary

- Summary of outcomes from breakout groups and Q&A with all participants
    - Chair: Keith Hayes, Ph.D., Commonwealth Scientific and Industrial Research Organization

7:00 AM - Adjourn

Session #3, December 15, 2021
Exploring stakeholder collaborations for regulatory capacity strengthening/building
Chair: Brinda A. Dass, Ph.D., Foundation for the National Institutes of Health

Description: What does "strengthening regulatory capacity" mean? Is capacity building a multi-directional process through which all parties can benefit? Join us as we explore scenarios and consider ways that collaborations among various gene drive stakeholder groups might build and strengthen regulatory capacity across these groups.

Participants are charged with drawing from their own experiences no matter what those are (technical research, social science, regulatory science, funding, etc.) to engage in an open discussion that will explore knowledge building needs and collaborations that could facilitate the success of knowledge building. This includes what scientists might need to know about regulatory processes as they conduct research and development activities, as well as what regulators might need to know about the technology and potential products as they prepare for possible future regulatory submissions. What might a conversation and exchange of knowledge look like between those working on the technical development side and those working on the regulatory side look like?

Below are questions to facilitate discussion, however, each breakout group leader and group participants should follow interesting avenues of discussion that emerge in the moment and should not feel compelled to address each of these questions. It is highly recommended that conversations be at a high-level, i.e., do not get bogged down in a discussion about the need of a specific country or region.

- What capacity building is needed to establish fit for purpose frameworks (i.e., for policy and implementation) and to establish forward looking operational requirements (i.e., for sustainable operations)?
    - What aspects should be strengthened in regulatory capacity according to scientists?
    - What aspects should be strengthened in regulatory capacity according to regulators?
- How would a capacity strengthening approach be similar or different for gene drive regulatory decisions made at a national versus regional level?
    - How might this impact where capacity should be established?
    - What represents "gene drive regulatory decision-making capacity" (who, what, where)? Is it possible to identify possible categories (e.g., risk analysis competency and local capacity to generate relevant environmental management data) and sub-categories (e.g., Category 1 = experienced risk assessors, accessible training courses, Cat 2 = Environmental Risk Assessment research program at local university) of activities, operations, or programs that would facilitate, and support capacity being built in practical terms?
- Why, how, and with whom might collaborations between scientists and regulators be established?
    - How might appropriate interactions be facilitated, established, and sustained? And what resources would be needed?
    - Should regulators engage with technical experts (scientists), and, if so, then which experts (national, international, different disciplines, etc.)?
    - Are there issues such as "impartiality" & "undue influence" that need to be addressed?

- How might regulators contribute to building regulatory knowledge among non-regulatory stakeholder groups, such as researchers?
- How might research teams contribute to building technical understanding among regulators?
- What are the possible forms that collaborations between scientists and regulators might take and would they change during the course of the product development process?
- Should other expertise be involved in these collaborations such as the broader community? If so what types?

AGENDA

All times below are in EST

5:00 AM - Plenary

- Welcome - TBD
- 5:05 AM - Introduction
  - Chair: Brinda A. Dass, Ph.D., Foundation for the National Institutes of Health
- 5:15 AM - A Gene Drive Primer (12 minute talk)
  - Fredros Okumu, Ph.D., Ifakara Health Institute
- 5:27 AM - Regulatory Science (10 minute talk)
  - Camilla Beech, Ph.D., Cambea Consulting Ltd
- 5:37 AM - Capacity building: a regional perspective (12 minute talk)
  - Heidi Mitchell, Ph.D., Office of the Gene Technology Regulator, Australia
- 5:50 AM - Capacity building: a regulator's perspective (10 minute talk)
  - Carla Saenz, Ph.D., Pan American Health Organization
- 6:00 AM - End Plenary
  - Chair: Brinda A. Dass, Ph.D., Foundation for the National Institutes of Health

6:00 AM - Breakout Groups

Each meeting participate will be pre-assigned to a breakout group.

- 8:15 AM - Breakout Group discussions end, and a 15 minute break begins

8:30 AM - Plenary

- Summary of outcomes from breakout groups and Q&A with all participants
  - Chair: Brinda A. Dass, Ph.D., Foundation for the National Institutes of Health

9:00 AM - Adjourn