

## Summary - September 11-13, 2018 Meeting

The 3<sup>rd</sup> meeting of the Gene Drive Research Sponsors and Supporters Forum brought together researchers working in the gene drive space along with representatives from organizations funding or otherwise interested in gene drive research to report on the status of current research, discuss topics of mutual interest, and continue working towards operationalizing the published [Principles for Gene Drive Research](#). This meeting was co-hosted in Montréal by the CIHR Institute of Genetics, the Foundation for the National Institutes of Health, and the Wellcome Trust.

Presentations, discussions, debates, and outcomes arising during the course of the three-day meeting are summarized by topic below.

### State of the Science

Representatives from 13 different research teams, some of which receive funding from organizations represented at this meeting, spoke about their projects. (Presentation titles and speakers are listed in the [meeting agenda](#).) While not a comprehensive update on all research currently underway, these presentations provided a useful perspective on potential applications of gene drive technology in public health, conservation and agriculture. Most of the talks focused on research in insects and rodents.

Speakers each explained their project concept and rationale, described current status and plans, and solicited questions from meeting participants.

The scientific talks demonstrated important advances across the various potential uses and also highlighted areas where more progress is needed. Several recurring themes emerged from the discussions. The importance of ensuring safety for humans and the environment was reiterated in many of the talks. The need for and utility of collecting ecological and social data prior to field testing was raised; modeling results utilizing such data will inform the research and development process. In addition, the importance of ensuring transparency with all stakeholders, including other researchers, local communities and other publics, national authorities and international agencies, was comprehensively discussed. This would include early engagement to open an ongoing dialogue about research and development processes. Participants agreed on the value of such shared conversations among those pursuing different gene drive applications for addressing many common technical and non-technical challenges, with opportunities for co-learning and co-development of norms.

### Global Governance of Gene Drive Technologies

The Convention on Biological Diversity (CBD) is focused on conservation of biological diversity and genetic resources. Several Forum participants had attended the July 2018 meeting of the CBD Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), which dealt with issues of synthetic biology and risk assessment that are relevant to gene drive research, and conveyed their experiences, reflecting on the process and outcomes. There was widespread agreement among most Forum participants on the importance of academic experts sharing their knowledge and credible, evidence-based information through CBD-organized mechanisms (such as online forums, upcoming meetings and calls for information) and other proactive outreach efforts. Participants with knowledge of developments underway within the International Union for the Conservation of Nature described the policy development process taking place there and noted the current opportunity to comment on the draft report, "Genes for Nature? An assessment of Synthetic Biology and Biodiversity Conservation."

Efforts to contribute to these activities collectively will be coordinated by the regulatory capacity strengthening working group of the Forum for those participants who are able to and interested in doing so; some participants indicated an interest in engaging individually, as well.

### Knowledge and Information Sharing

A large portion of the Forum meeting was devoted to consideration of the needs for communication and information sharing about the technology. Many emerging technologies share similar issues, and much of the discussion highlighted the importance of talking about gene drive in this context. Meeting participants discussed the importance of engaging in a clear dialogue with all stakeholders, including those opposed to the technology. Communicating about gene drive technology and gene drive-containing products can be technically complex, and would be facilitated by establishment of standard terminology, a “common language,” with clear definitions (such as definitions for the variety of products along the spectrum of gene drive technology from self-limiting to self-sustaining strategies). Standardization of terms would help in communication, in both technical and non-technical settings, and have potential benefits for engagement, policy making and regulation. This will be pursued further under the auspices of the research and technical capacity working group of the Forum.

The discussions in these sessions considered different levels of information sharing and different audiences. It is important to note that information may need to be shared in various forms according to the interests of the recipient stakeholder group. Also, it was noted that there is need for empirical evidence to clearly identify what information the stakeholders – scientists, government officials, communities and other publics – want to receive.

### Transparency

The importance of transparency for building public confidence around the development and use of innovative emerging technologies, including, but not limited to, gene drive, was acknowledged. In addition, transparency is important to support informed decision making and counteract misunderstandings about gene drive technology. The importance of being factual about potential risks as well as benefits of the technology was discussed, and it was noted that uncertainties on these points will decrease as research moves forward therefore necessitating ongoing interaction and explanation.

### Data sharing

Importantly, researchers as well as most sponsors and supporters at this meeting were supportive of sharing data to move the field forward safely, ethically and efficiently. This discussion began with a brief review of the current policies of several major funding organizations participating in the Forum. It was noted that all support data sharing; most have data sharing or open access policies in place and most require timely dissemination of data. This suggests that sufficient alignment already exists on which to base norms for sharing of data from gene drive research. However, it is important to determine how the data will be used and by whom. Here the audience may include both researchers and regulators. One question that requires further clarification is what data from existing and future data sets will be useful for research efforts? Another question for data sets being collected – such as, for example, ecological data – is at what point is such a data set considered sufficiently complete to be useful for others to utilize?

Most participants agreed that utilizing existing database platforms would be most efficient for sharing gene drive-related data and study protocols. Some of these may be more useful for genomic data while others may be better suited for ecology data, but compatibility between systems is desirable. A Forum working group will continue looking into existing databases and whether they can be used or modified to accommodate different data sets from gene drive research and product development. There is an immediate need to clarify with researchers what types of data will make the greatest contribution to enhancing research. Moving forward, participants suggested assessing the collective status of knowledge, experiences, expertise, data, etc. of researchers and developers to identify real gaps and address perceived gaps in knowledge to inform research efforts.

### Intellectual Property

Intellectual property (IP) is an issue that relates to data sharing since it must be addressed early in research when decisions on publication will be made. There was discussion about whether there is value in patenting gene drive technology given the general absence of a profit motive in the anticipated health and conservation uses. It was suggested that IP ownership could facilitate access to the technology: for not-for-profit organizations, the purpose of patenting gene drive-containing products would be to enable unrestricted licensing to those who need the technology for public good, rather than commercialization or to block access to the technology. It was noted that many funders of research have global access policies that include such public good patenting. Licensing can be done without cost implications but may allow the developer to maintain some control over the integrity and quality of the product and ensure its use for public good. Many meeting participants indicated that the IP rights of product developers should be explored on a case-by-case basis. Alternative strategies to patenting and licensing that might achieve the same assurance of product integrity also were discussed.

### Capacity Strengthening

Continued support for technical and regulatory capacity strengthening at the level of individual organizations was discussed, and, many meeting participants agreed that the Forum also should continue to explore capacity strengthening opportunities as a group. It was stressed that regulatory capacity strengthening must be done through organizations with the appropriate mandate, such as intergovernmental agencies, but that others may be able to assist, for example with technical support.

### Outcomes

The value of including researchers at this year's meeting was considered, which led to the determination that Forum participation in future will be expanded to other stakeholder groups as well. One outcome of this meeting was a decision to change the name of this coalition to "Gene Drive Research Forum," which recognizes the evolving nature and activities of the Forum and the desire to bring additional perspectives into the discussions. Whereas initially the group was formed by research sponsor and supporter organizations in response to the 2016 NASEM report, "[Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values](#)," it is clear that interactions with other stakeholders should be encouraged moving forward. Although the scope and activity of the Forum is evolving, the sponsors and supporter organizations will continue to work towards operationalizing the [Principles](#) through working groups addressing data sharing, research and technical capacity strengthening and regulatory capacity strengthening activities as described.

Suggestions for future meeting topics and venues will be explored and reported back to Forum participants. Any additional ideas for meeting topics or other group activities should be submitted for consideration to [GeneDrivePrograms@fnih.org](mailto:GeneDrivePrograms@fnih.org).

Organizations represented (in alphabetical order):

- Bill & Melinda Gates Foundation
- Biotechnology & Biological Sciences Research Council (UK)\*
- CIHR Institute of Genetics
- Commonwealth Scientific and Industrial Research Organization (CSIRO)
- Defense Advanced Research Projects Agency (DARPA)
- Genome Canada
- European Commission\*
- Foundation for the National Institutes of Health
- Imperial College London
- Island Conservation
- Japan Agency for Medical Research and Development
- Jikei University School of Medicine
- Massachusetts Institute of Technology
- McGill University
- McMaster University
- New Partnership for Africa's Development
- North Carolina State University
- Outreach Network for Gene Drive Research
- The Pirbright Institute
- Texas A&M University
- University of California, Berkeley
- University of California, Irvine
- University of California, San Diego
- University of Delaware
- University of Minnesota
- US Department of Agriculture
- US National Institutes of Health (Office of the Director and National Institute of Allergy and Infectious Diseases)
- Wellcome Trust
- World Health Organization

\* Attended as observers