2nd Annual Meeting Report

November 7-8, 2018

Georgia Tech Hotel and Conference Center
Atlanta, GA, USA

Global Funders Consortium For Universal Influenza Vaccine Development

On 7-8 November 2018 the Global Funders Consortium for Universal Influenza Vaccine Development convened its second annual in-person meeting since its inception in November 2017. The Consortium was established to:

- provide a mechanism for open sharing of information about ongoing investments, strategic plans, institutional perspectives and challenges, and for sharing learnings among organizations engaged in funding research and development related to "universal influenza vaccines;"
- identify critical challenges and knowledge gaps which are likely to delay progress in the field;
- facilitate collaborative approaches to address the challenges and accelerate progress, guided by a common vision; and
- raise awareness of the importance of the work and opportunities in the field, and to encourage additional funders to enter the field.

Since the last meeting, substantial activities have been initiated or completed by Consortium participants, and the Consortium has been expanded to include new members. The 2nd annual meeting was convened to:

- update / renew common understanding of the "universal vaccine" research and development landscape by participants;
- update understanding of the key challenges and priority activities needed to advance the field;
- discuss role of the Consortium in addressing key gaps and in advancing the field;
- discuss best practices related to how the Consortium collaborates and communicates; and
- explore ways in which the Consortium can be most impactful.

The meeting was organized into three sessions (Annex 1)

- 7 November, evening – session attended by Funders to share updates on their respective portfolios, discuss progress and future interests, and discuss goals for the full meeting 8 November.
- 8 November, 0800 - 0900 – side meeting of the Innovation Working Group (summary included below).
- 8 November, 0900 - 1600 – full meeting including both Funders and stakeholders (summary included below).

- 8 November, 1600 - 1800 – Funders-only meeting to review the meeting results, key points and actions to be taken as a result of the meeting.

Meeting Summary

Progress was made towards addressing gaps or challenges identified during the 2017 meeting.

Creating a mechanism for sharing information – During the last year, three teleconferences were convened to allow Consortium members to share progress of their activities and hear from other members. An in-person meeting was convened following the Human Challenge Model meeting in London in June 2018. An e-newsletter was created to facilitate regular sharing of information among Consortium members regarding funding opportunities, developments in the field, and relevant meetings. Finally, in spring 2018, the Consortium website was established as a mechanism to share information and increase the visibility of the Consortium members' work.

Creating a common landscape for stakeholders – Two activities initiated in 2018 to create a common landscape of activities and vaccine candidates among Consortium members were discussed.

- The ***universal vaccine roadmap*** was prioritized from the 2017 meeting as tool needed to advance the field. Wellcome Trust, who leads global efforts to create roadmaps for other vaccine programs, initiated discussion with partners about the need for and design of a universal vaccine roadmap. Further discussion about creation of a universal influenza vaccine roadmap was carried out in London in July 2018 between Wellcome Trust, Consortium members, and the Center for Infectious Disease Research and Policy (CIDRAP). At the time of the November 2018 Consortium meeting, Wellcome Trust announced funding to CIDRAP to create the roadmap, highlighting how the landscape would align with their strategic plans. The roadmap will address research and development needs, both for incremental improvements in seasonal vaccines, as well as for transformational improvements in vaccines against diverse strains, including pandemic influenza strains. The next steps in creation of the roadmap will be to conduct a scientific review of influenza vaccines related to next generation vaccine development, including current initiatives underway and basic science requirements. A task force of subject matter experts will be created to support this work. It was acknowledged that Wellcome Trust's early investment in the creation of the roadmap is a first step, but that maximum utility will require broad engagement of partners, which the Consortium can facilitate. Next steps include development of a roadmap implementation plan. Finally, a monitoring and evaluation program will be required. It was determined that Consortium members would be included in the creation and/or the review of the roadmap.
- A **"product landscape"** of vaccine candidates was suggested during the initial Consortium meeting as a tool to create a common, ongoing dashboard of products in clinical development. Dr. Michael Osterholm presented a plan for creation of such a landscape. The goals of the landscape would be to create, refine and maintain a common source of up-to-date, curated information on universal or broadly protective influenza vaccine technologies in development. The landscape would focus on technologies that represent transformational changes, rather than incremental

improvements in seasonal vaccines. Such a landscape would provide a tool to facilitate research and development among stakeholders by creating a common understanding, illustrating areas of research that represent key gaps, and potentially enhancing collaboration and coordination among funders. The landscape would be neutral in perspective, transparent, maintained by subject matter experts with regular updates, and publically available through open access. The Consortium will provide funding from the BMGF grant through the Task Force for Global Health (TFGH) to CIDRAP to complete the first two phases of the work. In collaboration with the Consortium, CIDRAP will convene an advisory work group to advise on product inclusion criteria, database information variables, scheduled updates, data sources, and uses and impact of the landscape. Core membership for the work group would include key members of the Consortium, and be led by Dr. Osterholm and other experts as needed. Phase 1 will aim to complete design and create an initial version of the landscape by mid-2019. The landscape will be refined and updated in 2019 and 2020. The relationship of this landscape to existing similar products produced by Consortium members such as BARDA and NIAID was discussed. One possible outcome is that this landscape becomes the common landscape for all Consortium members, thereby reducing the need for such investments by Consortium members.

Increasing Advocacy

A consensus role identified for the Consortium is to serve as a voice to advocate for increased and new funding, as well as new partners for research and development of universal influenza vaccines. While there have been many conferences, presentations and manuscripts from Consortium members helping to raise awareness of the value of these vaccines and the need for further investment – two discreet activities were discussed.

- Drs. Rosalind Eggo and Mark Jit, from the London School of Hygiene and Tropical Medicine presented on the development of an investment case for universal influenza vaccines. The goal of the investment case would be to quantify the impact on global demand and market for universal vaccines using dynamic transmission models. Models would incorporate both low-middle and high-income countries, both seasonal and pandemic periods, and different vaccine characteristics. The output of the model would include the incremental benefits of various approaches, measured in number of cases, hospitalizations, deaths, QALYs and DALYs prevented. The audience for the model would include investors and governments. The proposed model could include both direct and indirect effects of vaccine approaches. This sort of model has been used for decision-making with other vaccine approaches such as live attenuated influenza vaccines. The timeline proposes that the work would be conducted over a two and half year period. The group discussed the value of such a model, agreeing that this work was worth pursuing and that it would discuss potential funding options.

Partner Updates – Increasing investment and working together

During the past year, there were notable examples of Consortium members collaborating to increase opportunities for research and development in the field. Those discussed included:

- Bill & Melinda Gates Foundation and Page Family's Universal Influenza Vaccine Development Grand Challenge –a collaboration between BMGF and PF (now Flu Lab) was announced in 2018 to fund innovative, transformational projects to advance universal influenza vaccine development. The initial proposals have been reviewed, with a small number of proposals selected as finalists. Decisions on project funding in various amounts will be made during the first quarter of 2019.

- The European Union–India call for proposals –a collaboration between the European Commission and the Department of Biotechnology, India was announced in 2018 to fund innovative projects to advance influenza vaccine development. The proposals will be collected through the 16th of April 2019, and 6 to 10M€ per proposal will be available. Eligible projects will include those related to pre-clinical or early clinical research on vaccine candidates, proof of concept studies, and the potential use of human challenge models. Grants are available to European Union and Indian institutions.

- The Bill & Melinda Gates Foundation reviewed their portfolio of activities that included several collaborations. They are currently funding development of novel vaccine candidates and novel approaches for vaccination in collaboration with academic, industry, and governmental partners: 1) a chimeric HA stalk-based universal vaccine (Mt. Sinai, PATH, GSK); 2) an mRNA-based multivalent universal influenza vaccine (CureVac); 3) pre-clinical development of a universal flu vaccine (NIAID); and 4) prime boost studies of universal influenza vaccines (NIAID/JHU, JHU). They have also invested in creating international standards for stalk-based antibodies with NIBSC, UK.

- DARPA is working with BARDA to better understand predictors of person to person transmission of influenza using samples from cohorts in human challenge models. This will address some of the basic science gaps and influenza immunology and transmission noted during the November 2017 meeting. DARPA is also planning a study to evaluate antibodies as a compliment vaccination using an RNA/DNA delivery. They will work with Don Milton at University of Maryland.

- Open Philanthropy is focusing on antivirals, diagnostics, and pre-clinical vaccine development. Their focus is a better understanding of influenza immunology, an area highlighted as a need during the 2017 Consortium meeting. One notable project is a collaboration with University of Washington to support research by Professor David Baker and collaborators on the development of a universal flu vaccine, and improved methods for computational design of protein-based therapeutics to treat disease.

- Human Vaccines Project is focused on a better understanding of human immunology through creating improved influenza vaccines. They have created partnerships that include scientific hubs as well as a variety of affiliated partners. Activities during the last year included creating a webinar lecture series, young investigator prizes, and symposia concerning universal vaccine development. They are also conducting clinical research on the immune response to influenza vaccines. One such study will be conducted using Flucelvax in which 10 vaccinated volunteers will provide numerous serial blood, urine, lymph node, bone marrow, and microbiome samples to assess the immunologic response in great detail.

- NIAID has begun implementing their universal influenza vaccine strategic plan articulated in 2017. They reviewed their preferred product profile for universal influenza vaccine that underpins the strategic plan. The plan articulates three research areas: transmission natural history and pathogenesis; immunological correlates of protection; and rational design of universal influenza vaccines. Progress in each area would be facilitated by a work group to develop and improve animal models, establish longitudinal cohorts, increase capacity for human challenge models, and develop systems biology approaches. To accomplish this, NIAID has issued new administrative supplements, and two new program announcements for investigator-initiated research. They expect to fund multiple, multi-year projects during the next year using these new mechanisms. In addition, they reviewed their current investment in pre-clinical development, clinical phase I, and phase II products, which illustrated a robust portfolio of candidates. They currently have 45 active awards representing 32 unique influenza vaccine candidates. The current portfolio includes multiple antigen targets for the vaccines as well as the use of known and standard adjuvants. To address a need identified during the 2017 meeting, NIAID issued a request for information on existing cohort studies that may allow for assessment of influenza immunity and vaccine effectiveness. They received 30 relevant responses, which led to five new cohorts being funded. They have increased funding to develop improved animal models by investing in producing ferret reagents as well as distributing the reagents to the community. Regarding human challenge models, NIAID has invested in creating two GMP Manufactured strains for distribution (H1N1 and H3N2), and in conducting the phase I natural history challenge studies using the existing challenge strain. They are investing in the creation of two collaborative influenza vaccine innovation centers (CIVICs), to foster innovative influenza vaccine approaches that provide robust durable mucosal and systemic immunity. Finally, NIAID has supported, or will support, several scientific meetings to discuss issues relevant to universal influenza vaccine design.
- PATH is collaborating with several Consortium partners on issues around human challenge model development, and clinical trials. They also submitted a Grand Challenge grant.
- Inserm has a broad research portfolio that includes work on understanding the genetic variation of influenza viruses, the viral host interaction, human responses to influenza infection, and clinical trials to study combinations of vaccines as approaches to enhance humoral and cellular immune responses. They also have a variety of activities involving social scientists founded on their previous HIV work.
- The Canadian Institutes of Health Research (CIHR) Institute of Infection and Immunity (III) is currently evaluating its research strategies going forward to determine the best role for their funding and their collaborators in research and development of influenza vaccines, as part of its strategic plan development. The Institute currently funds centers in Canada that work on immunology platforms, adjuvants, and mucosal immunity. Moreover, Canada is currently developing capacity in the human challenge model under the leadership of Canadian researchers which includes the potential for a human challenge model center and in creating the GMP-grade flu strain (H3N2) for use in the studies.

- The Sabin Vaccine Institute's focus is on advocacy and creating opportunities for transformative change in this field. This involves engaging novel as well as traditional thinkers. They recently held a meeting in Aspen, USA on universal influenza vaccines to create a forum for innovative ideas, and launched www.influenzer.org.
- Wellcome Trust – in addition to funding the universal vaccine roadmap, other investments relevant to the Consortium relate to general investments in basic science research, sample sharing, communication projects, and, potentially, human infection studies. Wellcome Trust is a foundational donor for the Coalition for Epidemic Preparedness Innovations (CEPI), and the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC).

Fostering innovation

Bruce Gellin, Sabin Vaccine Institute, and Casey Wright, Flu Lab, have led the creation of an Innovation Working Group of the Consortium. The work group was formed to look for innovative ideas or innovative partners that can be brought into the field to create transformational changes. The group has met by phone several times during 2018, as well as during the November 8 meeting. The initial focus of the group was to work with the Grand Challenge project to determine if some of the unfunded proposals submitted might contain promising, innovative approaches to vaccine design, or might address data gaps in the field. During the Innovation Working Group meeting, one idea that resonated with the group, and later with the full meeting, was to develop a platform to share unfunded proposals between interested Consortium members. Open Philanthropy shared that they had some experience with this and offered to help with the concept. The concept is that Consortium members would be willing to facilitate the sharing of proposals received by each organization, but which did not ultimately receive funding. Proposals would be shared with other Consortium members through a central dedicated platform. The design of such a platform would require further discussion, but was generally thought to be a valuable tool for ensuring that promising ideas are more likely to receive some funding. Principles of confidentiality and not increasing investigator or funding agency workload were thought to be a priority. It was acknowledged that creating such a mechanism would require addressing the strategic, procedural, and institutional differences between the funders. Another advantage of such a mechanism would be to increase the visibility of investments among funders and to decrease the opportunity for duplicative funding. It was decided that the Innovation Working Group would lead the discussions and the design of this mechanism.

Addressing key knowledge gaps

During the 2017 Consortium meeting, several gaps in understanding of the immunology, virology, and epidemiology of influenza and influenza-vaccines were noted. One recommendation from that meeting was to conduct activities to increase the use of influenza human challenge models, as a tool both to make vaccine evaluation more efficient and timely, and to create data to address key knowledge gaps.

- On May 31 and June 1, 2018, a meeting entitled **"BMGF convening on the influenza human challenge model for universal influenza vaccine development"** was held in London. The meeting

objectives were to collect perspectives and to build consensus on how to improve the utility of and access to the standard controlled human influenza virus infection model. The two-day meeting results are expected to facilitate the use of human challenge models by ensuring that the meeting output and consensus was placed in the public domain and would support cooperative research and development, fund raising, and efficient allocation of resources in this area. The first day was comprised of discussions regarding the value of such models, with lessons from other human challenge models for other infectious diseases and the regulatory ethical implications of human challenge models in the design of human challenge viruses. The second day included discussions around the methods of conducting such studies, methods to increase standardization and accessed materials, and collecting industry perspectives. It was acknowledged that the current models were limited by lack of standardization, poor access to limited resources, too few challenge virus pools available, and potentially inappropriate study designs. The group articulated the desired features of human challenge models that would include a standardized model using best practices, increased capacity for conducting such studies in low and middle-income countries, increased access to relevant challenge viruses, and coordination of human challenge model studies that could accelerate qualification of vaccine candidates using clinical endpoints relevant to the community. The full discussion of consensus recommendations and gaps that require addressing is being included in a peer reviewed paper from the meeting that should be completed early in 2019.

Priority areas for investment, priority gaps to address, & refining role and function of the Consortium

1. A mechanism to share proposals for funding between Consortium members – Casey Wright, Stacy Knobler and Heather Youngs will proceed with the development of a proposal to establish a platform by which interesting but unfunded research proposals can be shared among interested members of the Consortium. This activity will be part of the Innovation Working Group. They will report back to the Consortium members during the next teleconference. (Update: an initial teleconference was convened in December 2018 to discuss information gathered by the Innovation Working Group.)

2. Developing the Product Landscape – the full group agreed to support CIDRAP to create the Product Landscape as a mechanism to increase visibility of candidate vaccines under development among Consortium members and other stakeholders. Dr. Michael Osterholm, Julie Ostrowsky, and colleagues will finalize the proposal and the development work will be funded by Consortium funds based at The Task Force for Global Health. A small advisory group will be established and include Consortium secretariat, NIAID, BARDA, European Commission and the CIDRAP staff. In addition, the Consortium members will be asked to review and provide feedback to the early and final editions of the landscape. An update will be provided to the Consortium members of the next teleconference. (Update: TFGH has completed the grant application review for the proposal submitted by CIDRAP, and has approved the funding for development of the tool.)

3. Universal influenza vaccine roadmap – Wellcome Trust has engaged CIDRAP to begin development of influenza vaccines roadmap, based on the models previously used for similar roadmaps previously

developed. Consortium members agreed to provide technical and strategic guidance to the roadmap as needed.

4. Industry involvement in the Consortium – participants again agreed that mechanisms to engage industry partners in Consortium meetings and discussions would be of great value. An industry engagement work group will be established to develop an engagement plan. An initial plan is to increase the length of the next annual meeting of the Consortium by 0.5 days to accommodate industry participation. It is clear that the Product Landscape and the Roadmap will require industry involvement as well. In addition, inclusion of IFPMA or Bio might be helpful. The subgroup of participants to work on this issue was solicited during the meeting, and participants were asked to respond to Joe Bresee if they are interested. Mark McKinlay, Bruce Innis, Josie Golding, Charlie Weller, Wayne Koff and Armen Donabedian agreed to participate.

5. Partner Engagement Work Group – continued focus on increasing stakeholders in the Consortium will be part of the 2019 work plan. It was agreed that a subgroup will be established to develop a plan for expanding the Consortium membership.

6. Increase the presence and name recognition of the Consortium in the field – to maximize the value of the Consortium, participants suggested that it could expand its role as a convener around relevant scientific and policy issues – noting that the Consortium was a co-convener of the CHIVIM meeting in 2018. Three options for this during 2019 are 1) develop recommendations for clinical outcomes used as part of human challenge models (or some other facet of MCMs) by convening experts to develop a white paper that might be published. This was based on work with RSV; 2) Support the upcoming 2019 meeting in Siena on immune correlates of protection; 3) Discuss with colleagues at regulatory agencies the possibility of supporting a meeting of regulatory issues related to next generation influenza vaccines. Other ideas were welcomed. In addition, write a peer-reviewed paper outlining the purpose of the Consortium. (Update: a paper was published in *Vaccine* in December 2018 summarizing the work and the goals of the group.)

7. Business case for universal vaccines – participants viewed the creation of a business case for universal vaccines favorably. It was noted that other modeling groups are also working in this general area, and consideration to creating a collection of modelers to inform this area should be undertaken. A small group of Consortium members including Wellcome Trust, Flu Lab, BMGF and TFGH will discuss next steps. It was acknowledged that thinking through stakeholder perspectives on the value of such models will be an important first step.

8. There was general agreement on the value of the Consortium, and agreement on plans for convening another annual meeting next year, as well as teleconferences.

Annex 1 – Meeting Agenda

November 7		
17:30 – 19:00	Pre-meeting of Funding Organizations (* in list below) - Agenda to be shared	Gold Room
19:30	Group dinner for all participants	Ecco Restaurant
November 8		
7:00 – 8:15	Meeting of Innovation Work Group	Private Dining Room 2
8:30	Registration and coffee	
9:00	Welcome and Introductions	Joseph Bresee, Keith Klugman
9:15	Review of Consortium activities and goals of the meeting	Joseph Bresee
9:30	WHO's influenza strategic plan and influenza vaccine development activities	Philipp Lambach
9:45	Report from Innovation Work Group	Bruce Gellin / Casey Wright
10:00	Break	
Updates on Consortium-led or recommended activities		
10:15	Universal influenza vaccine Roadmap – value, implementation and role of the Consortium	Josie Golding
10:35	Human challenge model meeting review	Bruce Innis
10:45	Consortium's Technology Landscape Project – review of goals and feedback on methods	Michael Osterholm
11:10	Model for exploring the business case for universal influenza vaccines	Rosalind Eggo
Updates on member activities		
11:25	NIAID's universal influenza strategy and update on implementation*	Diane Post

11:45	Update on recent calls for proposals for new vaccine development - BMGF and Flu Lab's Grand Challenge - European Union – India open call	Casey Wright / Padmini Srikantiah Adoracion Navarro-Torne (TC)
12:15	Lunch	
Updates on participant activities (continued)		
13:30	Roundtable updates from participants *Objective: Participants have a common understanding of the landscape of currently funded work in this area* Series of short, structured overviews of participants' portfolios and goals/strategies (that have not been discussed in the sessions above) [5-10 min each] Each organization is asked to review: -Any changes in the organization's vision/goals for a universal / next-generation vaccine -Current focus of funding -Specific activities ongoing or planned European Commission* Bill and Melinda Gates Foundation* DARPA* Open Philanthropy* Sabin Institute	Adoracion Navarro-Torne (TC) Padmini Srikantiah Matthew Hepburn Heather Youngs

	Wellcome Trust* BARDA* Human Vaccines Project PATH Inserm* CIHR* Flu Lab*	Bruce Gellin Josie Golding Robert Johnson Wayne Koff Bruce Innis Gustavo Gonazalez-Canali Charu Kaushic Casey Wright
15:15	Break	
15:35	Priority areas for investment and priority gaps & refining role and function of the Consortium The discussion is designed to identify consensus areas of need that the group thinks are particularly important to address in order to advance the field, and how the Consortium can support this work	All
16:00	Summary of the meeting	Joe Bresee
Closed Funders discussion		
16:30	Group discussion regarding priorities, gaps, needs	Group
17:45	Adjourn	

Appendix 1 – List of Participants

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