FINAL REPORT

PUBLIC HEALTH AGENCY OF CANADA

OFFICE OF HIV VACCINES
CENTRE FOR COMMUNICABLE DISEASES AND INFECTION CONTROL
INFECTIOUS DISEASE PREVENTION AND CONTROL BRANCH

CANADIAN HIV VACCINE INITIATIVE RESEARCH AND DEVELOPMENT ALLIANCE CONSULTATION

Submitted to:

Steven Sternthal, Director
OFFICE OF HIV VACCINES, CENTRE FOR COMMUNICABLE DISEASES AND INFECTION CONTROL
Infectious Disease Prevention and Control Branch
Public Health Agency of Canada

October 22, 2010

Prepared by:

ONE WORLD INC.
103-2141 Thurston Drive
Ottawa, ON K1G 6C9

Tel: (613) 562-4073
Fax: (613) 562-4074

Email: scass@owi.ca
tfleming@owi.ca
jdale@owi.ca

PBN: 864984836PG 001

TABLE OF CONTENTS

APPENDICES

1.0 EXECUTIVE SUMMARY

In February of 2007 the Canadian HIV Vaccine Initiative (CHVI) was established as Canada's contribution to the global efforts to develop a safe and effective HIV vaccine. The initiative was a collaborative effort between the Government of Canada and the Bill & Melinda Gates Foundation. In July 2010 the Government of Canada and the Bill and Melinda Gates Foundation announced the renewed CHVI. This renewed CHVI featured the creation of a new CHVI Research and Development Alliance which would be supported by an Alliance Coordinating Office (ACO). The Alliance would be a network that would bring together leading researchers from public and private sectors, as well as the international community, to develop innovative solutions to the challenges facing HIV vaccine research and development.

In order to inform how the CHVI Research and Development Alliance and the Alliance Coordinating Office may be best implemented, and how the Alliance can best contribute to achieving the priorities of the 2010 Scientific Plan of the Global HIV Vaccine Enterprise, a consultation process was conducted with key stakeholders. An independent consulting firm, One World Inc., was engaged to undertake the consultation working in collaboration with the Office of HIV Vaccines, Centre for Communicable Diseases and Infection Control, Public Health Agency of Canada, other CHVI departments/agencies and the Gates Foundation.

1.1 Approach

The consultation took place in September and October 2010 and included three components:

- Web-based consultation
- A face-to-face meeting held on September 23, 2010 in Ottawa, and
- One-on-one interviews with key informants

A broad range of key stakeholders (domestic and international) were consulted including: non-governmental organizations; infectious disease organizations; individual researchers; private and academic research institutions; and private sector companies engaged in relevant vaccine technologies and production.

1.2 Consultation Findings

The following is a summary of the key findings from the consultation process.

1.2.1 IMPLEMENTATION OF THE CHVI RESEARCH AND DEVELOPMENT ALLIANCE

The participants identified a number of factors critical to the successful implementation of the Alliance. Four main themes emerged which included, in order of priority:

1. Building on Canadian strengths in HIV vaccine research and development, and defining a clear and focused Canadian niche so that Canada could have a unique value-added to global efforts in this area.

2. Defining clear, specific and measurable strategic goals for the Alliance, around which stakeholder collaboration could be rallied – sharing a long-term vision.
3. Ensuring effective collaboration, engagement and meaningful involvement of Alliance members, e.g. by breaking down traditional barriers and silo's that exist between key stakeholders, and through transparency and effective communications.
4. Maintaining flexibility and responsiveness, e.g. through efficient decision-making mechanisms.

A broad range of potential Alliance members (both Canadian and international) were identified, but many stakeholders emphasized that clearer goals and outcomes for the Alliance need to first be established if the right players are to be engaged. When goals are clearly communicated and understood, actual and potential members are better able to identify their unique role and value added to the achievement of these goals, and committed long-term engagement of key players is best ensured. Targeted outreach will also be important to ensure that the right players are engaged, and additional incentives may be needed such as financial and special recognition for particular contributions. In addition, scientific credibility and leadership in the network was identified as important for engagement of the research community. Finally, consultation participants noted that offering a range of mechanisms for engagement such as face-to-face knowledge sharing opportunities would also be of value.

1.2.2 Implementation of the CHVI Research and Development Alliance coordinating office

In terms of the Alliance Coordinating Office (ACO), stakeholders were consulted on key factors that would contribute to the ACO achieving its mandate, the guiding principles for ACO functioning and key areas of responsibility. Stakeholders again highlighted the need for clearer and narrower Alliance goals which would better inform the priorities and functioning of the ACO. A number of key success factors to the ACO achieving its mandate were suggested including:

- Ability to foster collaboration through clear and open communications, creating linkages, and education especially regarding Alliance goals and research priorities.
- Strong leadership that is neutral, objective, knowledgeable, has credibility with the research community, and able to actively engage diverse stakeholders and navigate diverse interests.
- Governance and decision-making structures that are clearly defined, efficient and effective.
- Narrower scope of mandate that is doable within budgetary constraints.
- Transparency and fairness of processes.

In reviewing the proposed ACO guiding principles several changes were suggested including adding the principles of: "promotion" of the Alliance on a wide scale; "accountability" i.e. legal, fiscal, and to the membership and funders; and "neutrality", including declaration of conflict of interest. Several participants also advised that the principle of full "community inclusivity"

may not be realistic given the need to narrow the goals of the Alliance and the importance of meaningful engagement of members, and others emphasized that it will be the enactment of these principles that will be of real importance to the overall success of the ACO.

Consultation participants had particular difficulty identifying key ACO roles and responsibilities because of the need to clarify not only the strategic goals of the Alliance and the ACO but also governance roles and lines of decision-making and accountability. Nonetheless, three prospective roles were suggested including: brokering of relationships and collaborations; leveraging funds and partnerships; marketing and communicating in order to engage multiple stakeholders and to assume an educational role on the global stage; and, possibly the coordination of strategic orientations of the Alliance.

A range of models from which lessons might be drawn to inform how the Alliance and the ACO could best be implemented was also suggested by consultation participants.

1.3 Conclusion

The consultation process provided rich information to inform ways forward in the successful establishment of the new CHVI Research and Development Alliance and the Alliance Coordinating Office. Many participants in the process also expressed considerable appreciation for having been consulted on this new initiative and saw this as an important first step in building interest in the new Alliance and future collaboration and engagement.

2.0 BACKGROUND

2.1 Context

The Canadian HIV Vaccine Initiative (CHVI) was established in 2007 as Canada's contribution to the global efforts to develop a safe and effective HIV Vaccine. The CHVI is a collaborative effort between the Government of Canada and the Bill & Melinda Gates Foundation with funding commitments of $111 million from the Government of Canada and $28 million from the Gates Foundation. The Government of Canada partners in the CHVI include the Public Health Agency of Canada (PHAC), Canadian International Development Agency (CIDA), Health Canada (HC), Industry Canada (IC) and the Canadian Institutes for Health Research (CIHR).

On July 20, 2010, during the XVIII International AIDS Conference in Vienna, the Government of Canada and the Bill & Melinda Gates Foundation announced the renewed Canadian HIV Vaccine Initiative (CHVI).[1] The overall funding envelope remains at $139 million, and funds will now be available until 2017. After announcing the renewed CHVI, and its cornerstone, the CHVI Research and Development Alliance, the Government of Canada committed to consulting with stakeholders on the implementation of the Alliance, its membership, and the roles and responsibilities of the Alliance Coordinating Office.

The Alliance is envisioned to be a network that will bring together leading researchers from the public and private sectors, as well as the international community, to develop innovative solutions to the challenges facing HIV vaccine research and development.[2] The Alliance Coordinating Office will support the establishment of the Alliance, prospect innovative proposals and promote synergy between Alliance members.

2.2 Consultation Purpose and Scope

In August 2010, PHAC embarked on planning a stakeholder consultation. The purpose of the consultation was to gather input from key stakeholders on:

- Informing how to best implement the CHVI Research and Development Alliance and the Alliance Coordinating Office;
- The draft Invitation to Submit Applications for the Alliance Coordinating Office;
- Determining how the Alliance can best contribute to achieving the priorities of the 2010 Scientific Strategic Plan of the Global HIV Vaccine Enterprise.

Feedback on the draft ISA gained through the consultations would be used to refine the ISA, which will be launched in December 2010.

[1] http://www.phac-aspc.gc.ca/media/nr-rp/2010/2010_0720-eng.php
[2] Information on the Alliance is available at: http://www.chvi-icvv.gc.ca/chvifs-eng.html.

3.0 APPROACH

3.1 Overall Approach

Planning for the consultation was spearheaded by the Office of HIV Vaccines, Centre for Communicable Diseases and Infection Control, with the input of other CHVI Departments/Agencies and the Bill & Melinda Gates Foundation, which sought input from Canadian and international stakeholders through a three-pronged approach:

- Web-based consultation
- A face-to-face meeting held on September 23, 2010 in Ottawa
- One-on-one interviews with key informants

The Office of HIV Vaccines hired an independent consulting firm, One World Inc., to assist in the consultation design, implementation, analysis and production of the consultation's final report.

3.2 Planning

A consultation analysis framework was developed that included two key areas of inquiry. This analysis framework guided the identification of specific questions and supplemental probes that would be used through the three consultation methods. Upon approval of the framework and questions, the project team developed the consultation materials, including the web-based invitation, face-to-face consultation design, and a key informant interview guide.

Each consultation method was built upon the two core areas of inquiry:

1. How might the new CHVI Research and Development Alliance be best implemented?
2. How can the Alliance Coordinating Office (ACO) be best implemented in order to fulfill its mandate?

The specific questions used in each of the three consultation methods are outlined in more details in Table A below. A ✓ indicates that the question was asked within the consultation, and an X indicates it was not.

TABLE A CONSULTATION FRAMEWORK				
MAIN CONSULTATION OBJECTIVES	**PROPOSED KEY CONSULTATION QUESTIONS**	**WEB CONSULTATION**	**ONE-ON-ONE INTERVIEWS**	**FACE-TO-FACE CONSULTATION**
1. To seek input on how to best implement the CHVI Research and Development Alliance	1.1 What do you think are the most important factors that will contribute to the successful establishment of a Canadian HIV Vaccine Initiative Research and Development Alliance?	✓	✓	✓
	1.2a Who are the key players (Canadian and international) that should be part of the Alliance?	✓	✓	✓
	1.2b How can key players contribute to making the Alliance a success?	✓	✓	✓
	1.3a How can these players be best engaged?	X	X	✓
	1.3b What will contribute to their ongoing engagement?	X	✓	✓
	1.4 Any other comments about the establishment of the new CHVI Research and Development Alliance?	X	✓	✓
2. To seek input on how to best implement the Alliance Coordinating Office	2.1 What do you think are the most important factors that will contribute to the Alliance Coordinating Office achieving its mandate?	✓	✓	✓
	2.2 In order for the Alliance Coordinating Office (ACO) to fulfill its mandate, are there any suggestions for how the Guiding Principles currently outlined in the Draft ACO Invitation to Submit Applications (ISA) might be strengthened or any additional principles that the ACO should be required to adhere to?	X	✓	✓
	2.3a Are the key responsibilities of the Alliance Coordinating Office adequately captured in the draft ACO ISA?	X	✓	✓
	2.3b Any recommended changes?	X	✓	✓
	2.4a Are there any models of best practices that should be adopted by the ACO in carrying out its mandate e.g. organizational structure and ways of functioning?	✓	✓	✓
	2.4b Who might be contacted to learn more about these best practices?	✓	✓	✓
	2.5 Any other comments about the proposed mandate and operations of the new Alliance Coordinating Office?	X	✓	✓

3.3 Consultation Participants and Methods

3.3.1 WEB-BASED CONSULTATION

The first consultation method was a web-based consultation which opened September 10, 2010 and closed on October 5, 2010. The web-based consultation provided an opportunity for feedback to possible stakeholders outside the key stakeholder community identified by PHAC for the face-to-face consultation and key informant interviews.

The web-based consultation information was posted on the CHVI website (www.chvi-icvv.gc.ca) and respondents were asked to submit their responses in writing to the Office of HIV Vaccines (secretariat@chvi-icvv.gc.ca).

The invitation to participate in the web-based consultation was forwarded electronically via the CHVI Secretariat e-mail to domestic and international HIV vaccine organizations and/or individuals that have a general interest in the CHVI, had received funding from the CHVI, and/or had provided technical expertise or participated in various CHVI activities. A link was also posted on the website of the Global HIV Vaccine Enterprise and a flyer was included in the registration package for attendees at the Atlanta AIDS Vaccine Conference held in late September 2010.

Table A above identifies the specific questions that were asked in the web-based consultation.

3.3.2 FACE-TO-FACE CONSULTATION

The face-to-face consultation event was held in Ottawa on September 23, 2010. A total of 35 participants attended, including:

- Non-governmental organizations (NGOs);
- Infectious disease organizations;
- Individual researchers;
- Private and academic research institutions;
- Private sector companies engaged in relevant vaccine technologies and production.

The main focus of the face-to-face meeting was to obtain domestic insight on the CHVI Research and Development Alliance and the Alliance Coordinating Office. The specific questions asked during the face-to-face session are identified in Table A. The agenda from the day is found in Appendix 2, and the participant list from the September 23rd meeting is included as Appendix 3.

The process used in the face-to-face meeting consisted of a mixture of small group work and plenary discussion built around the two core consultation objectives identified in Table A. For context, a presentation was delivered early in the day by PHAC representatives, at which point the facilitator managed a follow-up question and answer period and the subsequent gathering of input.

To address the first core consultation objective *(to seek input on how to best implement the CHVI Research and Development Alliance),* the entire stakeholder group was divided into five table groups for small group discussions in which participants answered the related sub-questions. At the end of the allotted time period, the table groups were asked to select 2-3 key highlights of their discussions, which were fed into the afternoon plenary, and to a large degree, became the basis of the findings in section 4.

To address the second core consultation objective *(to seek input on how to best implement the Alliance Coordinating Office),* the entire participant group was divided in half, and participants spent the afternoon engaged in two rounds of dialogue.

The findings from these stakeholder discussions are integrated into section 4 below.

3.3.3 ONE-ON-ONE INTERVIEWS WITH KEY INFORMANT

The final stage of the consultation process was to conduct focussed key informant interviews with a select group of key stakeholders, both Canadian and international. The interviews allowed the gathering of more in-depth input on the core consultation questions from additional stakeholders. Interview participants included:

- Key Canadian researchers who were not available to attend the face-to-face consultation;
- Representatives from key international organizations, alliances and private sector with a high level of experience in HIV vaccine research and development activities as well as some who had knowledge and experience with national and/or international networks.

Fifteen key informants were initially invited to participate and 14 persons participated in 12 separate interviews (including two, two-person interviews) which ranged in duration from 30 minutes to one hour.

Information gathered in the key informant interviews has been synthesized and integrated into section 4, key findings.

3.4 Limitations

The consultation was prepared within a very short time frame. Given the time and resource constraints, the process was based on best consultation practice, in consideration of PHAC's Public Involvement Framework. The consultation captured a good range and depth of qualified stakeholder participation and qualitative data, even though the number of stakeholders was relatively small by intention.

Every effort has been made to apply a neutral synthesis of what was heard during the face-to -face session, interviews and web-based consultation. To conduct the synthesis, the notes from each consultation method have been reviewed, and key themes have been pulled out to create an integrated reflection of the main areas of discussion.

With respect to the results, the authors have reported perspectives as expressed. As is usual in this type of "what-was-heard" data, the authors have not sought to validate opinions offered or

verify any assertions made, except where other available data sources clearly validate input. Nor did we ask that suggestions be backed up with explicit rationales or considerations for how a suggestion might be implemented. Further dialogue would be required to understand the underlying perspectives and rationales for some expressed concerns or suggestions.

4.0 KEY FINDINGS

4.1 Implementation of the CHVI Research And Development Alliance

4.1.1 SUCCESS FACTORS

Four main themes emerged from the consultation process as a whole. These have been summarized below, and include:

1. Building on Canadian Strengths – Defining the Canadian Niche
2. Defining Clear Goals
3. Ensuring Effective Collaboration and Engagement
4. Maintaining Flexibility

THEME 1: BUILDING ON CANADIAN STRENGTHS – DEFINING THE CANADIAN NICHE

Throughout the consultation, participants discussed the importance of building the Alliance network on Canadian strengths, and especially, defining the Canadian niche related to the HIV vaccine challenge. Various strengths were discussed by both face-to-face participants and key informants, including:

- Track record in innovation;
- Strong science;
- Strong infrastructure and funding mechanisms;
- Good existing partnerships;
- Reputation for collaboration;
- International respect as a broker;
- Regulatory capacity as a model for developing countries;
- Strong links to particular developing countries; and
- Usefulness of Canada's bilingualism within Africa.

Of all the suggested strengths, Canada's track record in collaboration and building relationships was highlighted most frequently. This was seen to be a unique value added that Canada could bring to the international HIV vaccine research and development community.

Overall, participants in the sessions and interviews were keenly aware that Canada's contribution on the world stage needed to be highly focused to have a meaningful impact. Participants noted it was critical to 'nail the focus' of Canada's unique contribution based on current strengths and expertise, and to be very clear about goals and priorities.

One key informant likened the HIV Vaccine Alliance to the Canadian space program suggesting that, like the space program, the Alliance needs to focus on one key contribution to the global program, such as was the case with the Canadian 'Canada Arm'. In one small group discussion in the face-to-face session and in several interviews, stakeholders highlighted the importance of understanding where the new Canadian Alliance fits into the international world before determining this niche.

- ***Scientific Niche -*** During the face-to-face session, and in several of the key informant interviews, stakeholders mentioned the cancellation of the CHVI 'facility project' which had been thought by some to be a key Canadian contribution to the global HIV vaccine challenge. Participants struggled with re-defining Canada's scientific contribution and niche, and grappled with the challenge of how to best utilize limited scientific funds for maximum impact.

  There was no consensus on where the best impact could be achieved, although clinical trials were mentioned multiple times as a logical area to emphasize for Canada. This is a current area of strength in Canada. Furthermore, there could be high impact within a 5-year horizon given the current developmental stage of the HIV Vaccine.

  Many participants noted that much more basic science work needs to be done prior to clinical testing and subsequent manufacturing. Others stated their perspective that vaccine manufacturing and process engineering could be a key focus area. From this conversation, participants and key informants frequently came full circle and noted that an understanding of Canada's fit within the scientific HIV vaccine continuum was needed. It became clear that a greater shared understanding of this continuum and a scan of the work being done at each stage is needed.

  Various elements of the HIV vaccine continuum were identified as follows:

  - ✓ Discovery and understanding immunological mechanisms and basic science;
  - ✓ Pre-clinical development;
  - ✓ Primate testing;
  - ✓ Clinical testing, Human Phase 1 Vaccine trials;
  - ✓ Manufacturing and commercialization.

THEME 2: DEFINING CLEAR GOALS

The second most consistent message from stakeholders was that, although the broad goals were understood and generally clear, the specific, measurable, and attainable goals for the Alliance were not.

One key informant interviewee expressed this as being similar to a 'field of dreams' in which the Alliance goals are too wide, high level and vague, and noted that from the way it is currently described, it won't capture people's attention. Participants throughout the various consultations saw a clearly defined Canadian niche and clearly defined goals as the first step in being able to select which individuals and organizations should be in the Alliance, as well as

determining the roles and responsibilities of the Alliance Coordinating Office. Participants recommended the following:

- Clearly articulate that the Canadian HIV Alliance's primary objective is to advance Canada's contribution in the global effort;
- Develop a focused mission and vision for the Alliance with concrete, prioritized and realistic/ achievable strategic goals and long-term commitment to achieve these goals.

Several concerns were voiced related to goals:

- Long-term, goal-oriented funding was identified as a need. Several stakeholders suggested that a long-term funding period (i.e. beyond five years) could set the stage for translation of research, given that at least 7 – 12 years are required to develop a vaccine. Researchers will like to know that they have support for translation when the time comes. Some stakeholders cautioned about spending money on good manufacturing production (GMP) until there was something to produce. One group in the face-to-face session highlighted that access to incremental top-up funding is a key to sustained affiliation with the Alliance (goal-oriented for long-term projects).

- There were differing views regarding the sufficiency of the funding for the Alliance and Alliance Coordinating Office, some participants indicating the funding was more than sufficient but many others indicating the amount was insufficient (i.e. that Canada is a very small player vis-à-vis the wider global network).

- In the face-to-face session, and to an even greater extent in the key informant interviews, stakeholders identified competition and in-fighting as a major factor that could work against successful establishment and functioning of the Alliance. Clarity of mission/goals and vision could help offset this, as could integrating a peer review element even though ultimate decisions will need to be made by funders.

- The absence of a clear articulation of goals, processes seen to be fair and transparent, clean governance and decision-making structures and roles could contribute to mistrust or scepticism of potential members. Confusion exists about whose Alliance it is (ownership), given that the ultimate funding decisions are not made by the Alliance itself. Some concerns were raised regarding stakeholder input not having been solicited earlier in the process. Finally, participants were uncertain about the process by which the clear visions, goals and realistic, attainable deliverables will be established.

THEME 3: ENSURING EFFECTIVE COLLABORATION AND ENGAGEMENT

Participants across all five of the face-to-face small group discussions and many of the key informant interviews identified collaboration and engagement as a key success factor. This too was related to the question of goals and niche. Participants noted that once the goals for the Alliance are clear, it will be easier to identify what discrete roles partners and members could fill.

Several participants in both the face-to-face session and interviews highlighted that one of the main challenges in developing an Alliance is not to create it, but to sustain it over time. To answer this challenge, participants suggested that communication, collaboration and engagement are key factors to ensure the unique value that the Alliance brings is clearly understood.

Four additional points capture the body of input from the consultation:

- ***Break down barriers -*** Stakeholders noted that breaking down barriers and fostering collaboration is a significant success factor for the Alliance. Several stakeholders noted that Canada gets recognition on the world stage for its ability to collaborate but there is further need to coordinate the work with Canada's internal partners. Several key informants pointed out that breaking down barriers between scientists is one of the major challenges that could work against the Alliance, because of a general culture of competition. It was felt that clear goals and funding incentives to encourage collaboration were good solutions to overcome this barrier, with the caveat that breaking down barriers is only valuable if it contributes to the achievement of the Alliance goals.

  Several other barriers were mentioned:

  - ✓ Federal / Provincial / Territorial barriers (e.g. collaboration and equitable levels of engagement);
  - ✓ The challenge of involving the HIV community (including persons living with HIV/AIDS) in a technical research issue;
  - ✓ The need to bridge the fundamental gap that exists between the development of the HIV vaccine (basic science) and its eventual uptake at the consumer level (social science);
  - ✓ Insufficient knowledge-sharing and exchange among researchers;

  An effective Alliance must be a truly multi-sectoral, trans-disciplinary entity, involving the full continuum of stakeholders and expertise from basic science, from development through to the point at which the vaccine is delivered to market. For the HIV/AIDS vaccine to succeed, innovation through communications and collective effort from the various fields of biomedical science is required.

- ***Meaningful involvement –*** Stakeholders suggested that 'meaningful' involvement in the Alliance was a key, with stakeholders mentioning different interpretations of meaningful involvement. Some noted that the Alliance will be meaningful to different partners for a multitude of reasons, and stressed the importance of identifying and recognizing those unique needs.

  The concept of 'cross engagement' was suggested in both the interviews and the face-to-face discussions, where participants used words like 'true partnership' and 'truly inter-disciplinary'. At the root of these comments is the desire for the Alliance to have concrete meaning so that members are not only superficially involved, but contribute as active participants who are moving forward together in concrete terms.

- ***Effective communications and engagement*** **–** Throughout the consultations, communication mechanisms and methods were highlighted as important. Stakeholders seemed to be focused on the Alliance as a conduit for information exchange. One of the face-to-face small group discussions highlighted a series of communication methods, such as: websites highlighting a centralized information source of research results; person to person networking; and, a coordination function to help people connect around and between major Canadian and world meetings. Other mechanisms for engagement included advisory committees and stakeholder panels.

- ***Transparency*** **–** Transparency was a word that came up strongly in the face-to-face discussions, and within several of the key informant interviews. Often, reference to transparency corresponded with the topic of the cancelled facility project, which some participants suggested was handled without sufficient transparency. Other stakeholders noted they were pleased to be part of the consultation around the Alliance, and supported the continuation of this type of transparent, meaningful consultation. At least three key informant interviews suggested that the engagement was a step in the right direction. Stakeholder suggestions included a call for clear, consistent messaging, rules of engagement, and ongoing communication as means to ensure transparency of the Alliance.

THEME 4: MAINTAINING FLEXIBILITY

While not a major theme, stakeholders identified flexibility among the success factors of an effective Alliance. One group raised flexibility as a Canadian strength upon which to build, while others suggested that the Alliance have a quick decision-making mechanism, low bureaucracy, and the ability to adapt to change.

The current research infrastructure and funding mechanisms in Canada are less prescriptive than those found in the United States. This environment increases the likelihood of research innovation, providing a key advantage to the Canadian research community. One small group in the face-to-face session highlighted the idea that a 'new ideas' program for fast access to funding for innovative scientific ideas would help build on this strength and could provide an incentive to researchers from outside the HIV field to become partners and collaborators.

4.1.2 KEY PLAYERS

When asked to identify key players for the Alliance, stakeholders seemed to find the task challenging. Upon reflection, many of them surmised that this was because they felt the Alliance goals needed to be more clearly identified first before being able to determine who the key players in the Alliance should be. For this reason, much of the feedback received during the consultation generically relates to the type of organizations that should be involved.

Participants noted that once the Alliance goals are clear (in terms of achievable, measurable outcomes) membership criteria can be established for who should be engaged, why their engagement is important, what Alliance members will gain, and what is expected of them.

Broadly speaking, participants called for broad stakeholder engagement crossing the spectrum of Canadian stakeholders from persons living with HIV/AIDS (PHAs), private industry, basic

science, social science, regulatory bodies, public sector, and academia. However, participants in both the face-to-face consultation and key informant interviews also cautioned about not duplicating work, and ensuring engagement was targeted and goal-oriented rather than inclusive for the sake of inclusivity.

Participants noted the following possible groups:

- ***People and organizations currently undertaking research work,*** including primary researchers, lab researchers, scientists, clinical researchers, MD's, PhD's. Two sub-groups were highlighted: research champions and promising young scientists from both public and private sector. One web consultation respondent highlighted the importance of bringing together the many Canadian universities and research centres who have already developed experimental HIV/AIDS vaccines ready for human clinical trials.
- ***International partners*** working with clinical trials. Participants noted the linkage with international partners from countries like India and Africa, where the long-term impact of HIV/AIDS is significant. Such involvement is vital in order to generate a meaningful Canadian contribution to the global effort. It was noted that the vaccine will likely be tested in the South, not in Canada. Therefore, large international pharmaceutical companies, academia, researchers and networks from other countries, from both the North and the South, could be linked. But some participants again emphasized that determining international involvement will need to be goal-driven. Canada's bilingualism was seen as an asset because of the strong link between African research organizations, which positions it effectively for international engagement.
- ***Major funding organizations*** were identified as key players to be actively involved in order to coordinate all global funding activities supporting HIV research and work in Canada and internationally, e.g., the Bill and Melinda Gates Foundation, Canadian Institutes of Health Research, the Clinton Foundation, European funders.
- ***Provincial and Territorial governments*** were suggested as prospective partners.
- ***Public Health organizations*** from Provinces and Territories were also suggested as prospective Alliance members.
- ***Organizations and networks from outside the HIV Vaccine community*** were identified because of their potential contribution to innovation and research. One key informant suggested that the HIV vaccine community is known for being historically separate from other vaccine research communities, and that further integration could lead to greater innovation and learning. For example, extensive design and process expertise could be learned from the malaria field.
- ***Community members*** including individuals and organizations representing persons living with HIV/AIDS (PHAs), in recognition of their important role in the translation of science i.e. in keeping with the Greater Involvement of persons living with HIV/AIDS (GIPA) principle.
- ***Social sciences*** because of their crucial role in understanding the behavioural issues related to science.

- ***Vaccine industry*** including biotech and pharmaceuticals manufacturing industries because of their significant role in production and distribution.
- ***Regulators***, such as Health Canada who help put in place necessary regulations and interim policies to assist in advancing the work.

Some specific organizations mentioned by participants were:

- African Aids Vaccine Programme (AAVP)
- BIOTECanada - Canada's Voice for Biotechnology
- Canada / Africa Prevention Trials Network (CAPT Network)
- Canadian Association for HIV Research (CAHR) – National HIV Inventory
- Canadian Institutes of Health Research Canadian HIV Clinical Trials Network (CIHR HIV CTN)
- Canadian Institutes of Health Research (CIHR)'s Institute of Aboriginal Peoples' Health (IAPH)
- Canadian Institutes of Health Research (CIHR)'s Social Science Centre for Research Evidence in Action for Community Health (REACH in HIV/AIDS)
- Canadian Network for Vaccines and Immunotherapeutics (CANVAC) (former)
- Centre for Operations Excellence (COE) – Vancouver
- Canada's Research-Based Pharmaceutical Companies (Rx&D)
- Canadian Public Health Association (CPHA)
- Fonds de la recherche en santé du Québec (FRSQ-AIDS) and Infectious Disease Network/ Le Réseau SIDA et Maladies Infectieuses (SIDA-MI)
- Global Alliance for Vaccines and Immunisation (GAVI)
- Health Canada (HC)
- Public Health Agency of Canada's National Microbiology Laboratory in Winnipeg (NML)
- International AIDS Vaccine Initiative (IAVI)
- International Vaccine Centre - University of Saskatchewan (InterVac)
- International Vaccine Institute in Korea (United Nations) (IVI)
- Ontario HIV Treatment Network (OHTN)
- Public Health Agency of Canada (PHAC)
- National Institutes of Health Vaccine Research Centre in the United States (NIH VRC)
- World Health Organization (WHO)
- One key informant generically identified similar groups and Alliances in France that are taking similar approaches to vaccine research.
- Another respondent suggested pharmaceutical companies such as Merck, Sanofi, VaxGen, and Sumagen

4.1.3 EFFECTIVE ENGAGEMENT

Participants in the face-to-face session and key informant interviews were asked to identify how the key players could be best engaged, and what will contribute to their ongoing

engagement in the Alliance. At several points in the face-to-face consultation and interviews, individuals suggested that it was not the creation of the Alliance that will be the main challenge, but rather, it will be the long-term sustainability of the Alliance. Several stakeholders noted that Canada's ability to demonstrate ongoing and committed engagement of diverse key stakeholders could in fact be a model for the international community. Some of the suggestions brought forward by participants about how to foster continued engagement in the Alliance include:

- ***Clearly communicated goals.*** Again, participants reiterated that strong, clearly defined goals are the key to successful engagement. These will help define who to engage, and how to engage them. Many session participants and interviewees suggested that, the level of engagement and sustained involvement of prospective members would be greater once they understand and support the Alliance goals and their own unique contribution to achieving these goals. Participants recommended defining the value added contribution of the Alliance, and demonstrating to prospective Alliance members 'what's in it for them' in order to successfully engage. People will 'vote with their feet' if they see this connection.

- ***Reach out to the right players.*** Successful targeted outreach based on clear goals was noted repeatedly. Underscoring this was the recognition that for a far-reaching network to be successful, significant marketing, initiation, prospecting, and relationship-building would be required. Reaching out through established networks, such as the CIHR Networks, or key individuals, such as directors of research services at universities, were noted as possible paths to generate interest in the Alliance. One key informant also suggested ensuring that all important players are engaged from the beginning.

- ***Incentives.*** Several forms of incentives were suggested, such as:
  - ✓ ***Access to specialized funding*** (i.e. funding that rewards collaboration and innovation, and supports smaller research interests);
  - ✓ ***Opportunity to collaborate meaningfully*** with other researchers on new, innovative, high profile, high calibre research or research that is already initiated;
  - ✓ ***Opportunity to share knowledge*** and successes;
  - ✓ ***Public recognition of individual and organizational contributions*** was suggested as a means to sustain engagement;
  - ✓ ***Opportunity to contribute meaningfully to the strategic direction*** and a sense of ownership in that direction; and,
  - ✓ ***Payment for specific expertise and time*** committed (e.g. grants for funding applications and leadership work).

- ***Scientific Control / Credibility***. A significant theme throughout the consultation was that science wants its own 'niche control'. Participants indicated a need for strong scientific leadership, and frequently suggested the need for scientific advisory bodies. This suggests that the issue of scientific credibility is important for continued engagement of the research community. Participants consistently suggested that the initiative needs a champion who has the charisma necessary to lead the engagement, and the scientific credibility to sustain it.

- ***The right methodology to engage.*** Participants noted that integrating a variety of mechanisms for engagement would increase the likelihood of sustained interest. Face-to-face mechanisms were identified as a major incentive that supports the sharing of knowledge and successes. However, stakeholders cautioned about the dangers of spending too much money on this costly form of engagement, suggesting that such efforts be highly strategic. Examples were:

  - ✓ Bring together people at conferences – i.e. in tandem with the Canadian Association for HIV Research (CAHR) meeting to allow the network to collaborate.
  - ✓ Community Advisory Boards – for example, bring persons living with HIV/AIDS together to advise and harness ideas from across the country.
  - ✓ Larger meetings, such as a Canadian conference, or further consultations to bring Alliance members together to lead the Alliance's direction.

4.1.4 USEFUL MODELS OF IMPLEMENTATION

Participants highlighted several models from which to draw lessons about Alliance implementation, both from inside and outside of the HIV/AIDS field.

Models from within the HIV/AIDS field:

- The former Canadian Network for Vaccines and Immunotherapeutics (CANVAC) was identified as an important model because it included a five year investment in good laboratory practices (GLP). It would be valuable to review the lessons learned from this initiative, i.e., what worked well / what did not work. For example, the network had a lot of short-term momentum, but lost its energy over the long-term.
- Canadian Institutes for Health Research Canadian HIV Clinical Trials Network (CIHR HIV CTN) was suggested several times because of its skill in network management. Specifically, it has a staff and a coordinating office that links researchers and other key players, along with good processes to assist researchers in such things as preparing applications for ethical review and approval.
- Canadian Association for HIV Research (CAHR) was suggested because some perceived it to be the best model currently for bringing Canadian researchers together.
- Genetically Engineered AIDS Vaccine (AIDSVAX) was suggested, led by virologist Robert Gallo.
- ZOR, Inc. - Social and Behavioral Health Solutions (referred to as aid 'AIDS Zoro' in the face-to-face consultation)
- Global HIV Vaccine Enterprise (The Enterprise). Several key informants sited the 'Global Enterprise' as an Alliance model that worked well.
- The Global Alliance for Vaccines and Immunisation (GAVI) was suggested because of their long-term perspective.

- U.S. National Institutes of Health (NIH) HIV Vaccine Trials Network (HVTN) has undertaken some successful collaboration with industry on a smaller scale.

Models from sectors outside of the HIV field included[3]:

- The Network Centres for Excellence. There were several lessons learned from this model:
  - ✓ This organization gives a small amount of top-up money to an investigator who commits to push certain work/research in a particular direction. This funding model offers an extra pair of hands toward existing work and encourages collaboration.
  - ✓ Protein Engineering Network of the Centre for Excellence of Canada is a 15 year old collaborative network which has produced a whole generation of scientists who do not hesitate to ask to be part of collaborative partnerships.
- U.S. gene therapy network – not a single institution but an effective network for the work of translating the research.
- The Canadian Centre for Vaccinology at Dalhousie University was identified as an interdisciplinary network with a clear governance structure.
- The Vaccine and Infectious Disease Organization (VIDO) has had success and may be a good source of information.
- Child Health British Columbia is a network that grew out of Child and Youth services that has been relatively successful because of a strong coordinating body.
- The Human Genome Project is an example of a well functioning Alliance
- There is some work in the Cystic Fibrosis world that has been good at developing clear vision and good levels of engagement.
- Global Tuberculosis Alliance.
- Southern Alberta Child and Youth Network was identified because it has conducted a literature review on best practices in network architecture and design.

4.2 Establishing an effective Alliance Coordinating Office (ACO)

4.2.1 KEY FACTORS FOR ACHIEVING ACO MANDATE

Many stakeholders expressed difficulty in clearly identifying success factors for establishing an effective Alliance Coordinating Office (ACO). This difficulty was linked to the mandate and goals of the Alliance being unclear and far too broad at this stage. With this in mind, participants identified the following four main success factors.

- ***Ability to foster collaboration***

[3] PREVENT was referred to in the face-to-face consultation as a good model for the pipeline of discovery-clinical trials- industry take-up but the researchers were unable to find references for this organization on-line.

Although the goals were observed to be unclear, the vast majority of stakeholders identified that collaboration was a key success factor for the Alliance, and valued the ability of the Alliance Coordinating Office to foster collaboration through communication, creating linkages and education.

Stakeholders were clear that their concept of collaboration included ensuring that investments are synchronized, and that lines of networking and communication are built. They often saw the Alliance Coordinating Office's role as an educational one, and envisioned an administratively lean staff whose primary role is to be able to clearly communicate the Alliance's mission, concrete goals, the products and services that will be achieved, as well as transparently communicating funding relationships.

Participants in the web-based consultation, and frequently in the key informant interviews noted the importance of the ACO first being able to identify gaps. Then, when gaps are understood, the ACO's role would be to facilitate the process of recruiting others to collaborate and take ownership for addressing those gaps.

Many individuals throughout the consultation noted that this role was a significant one, and would be extremely challenging to implement on a small budget. Several participants suggested that two to four supporting staff would be required, whose role would be to support the education and communication needs of the Alliance. Others suggested that having the ACO embedded in a research-driven organization may be an asset.

- ***Strong Neutral Leadership***

Stakeholders from across the face-to-face consultation and interviews suggested that good leadership was essential to the success of the Alliance Coordinating Office. While the emphasis was clearly on the communication capacity and ability to bring people together, participants defined good leadership in a variety of ways:

- ✓ ***Neutrality*** was raised as a primary concern. Stakeholders clearly gave the message that the leader needs to be able to set aside their personal agenda (e.g., is the ACO leader able to receive funds if he/she is a scientist? If so, how will conflict of interest be avoided and communicated?)
- ✓ ***Ability to talk to diverse stakeholders and interests***, and 'weave together' stakeholders through linking people effectively. Some saw this as a 'brokering' role, engaging stakeholders from across the HIV vaccine chain from discovery to clinical testing.
- ✓ ***Knowledge, capacity and willingness to use existing networks*** and resources. For example, participants noted that there are existing resources, e.g., CAHR has an on-line inventory of HIV research that can be tapped into, and the ACO must be able to leverage existing work easily and efficiently.
- ✓ ***Credibility:*** Someone who is knowledgeable enough to have the respect of the science community, and who is an accepted champion by those outside of science. The leader must have a good understanding of the full research chain, i.e., of what it takes to

commercialize a product as well as how to understand the basic science and identify research gaps.

- ✓ ***Objectivity, fairness and the ability to make good decisions*** through consultation and effective engagement.
- ✓ ***Thoughtful and visionary*** with the ability to inspire, coupled with a reputation for openness, diplomacy and clear communication.
- ✓ ***Strategic,*** with an ability to move from vision to action.
- ✓ ***Ability to act as a 'funding lever'*** that would leverage funds related to the Alliance's concrete goals, and leverage partnerships such as F/T/P alliances.
- ✓ ***Political acuity*** and the ability to build and represent Canada's global role / reputation.

- ***Clearly defined governance and decision-making structures***

  Participants in the key informant interviews and face-to-face sessions identified that the mechanics of the mandate are unclear, especially around the governance structure, lines of accountability and decision-making processes. The role of monitoring bodies and others needs to be clarified.

  Participants observed that in its current description, the Alliance governance structure appears to have "too many cooks in the kitchen," i.e. it is overly complicated and complex. Others observed that governance support may be required due to the complexity and immensity of the challenge facing the ACO.

  Some participants suggested additional mechanisms such as having funders represented on a Board of Directors (approval body) or having people participate in other advisory groups /committees, such as a scientific, community or manufacturing advisory committees, depending on the needs. The role of such advisory bodies would be to help identify gaps, review and assess feasibility, costs, options and rank priorities. Some noted that science needs to be a strong driver, but the selection will be challenging due to the potential for bias.

- ***Be realistic about what can be done with available funding***

  Many participants were concerned that the task of the ACO is too broad to be accomplished realistically with the available funding. Some suggested that the budget does not allow for depth of experience and knowledge to successfully bridge the communities. Others suggested that an environmental scan as indicated in the ISA is a huge undertaking, and may not be realistic.

  Participants noted that it will be important not to duplicate work that has already been done elsewhere; they called for a streamlining of the Alliance through clear, achievable goals that are narrowed significantly into an area where a realistic and meaningful Canadian contribution and progress can be made (within the five year funding window), and cautioned against becoming scattered over full chain from discovery to delivery.

- ***Transparency***

  A final success factor for the ACO was around the transparency of process. The community needs to see that there has been fairness in the selection process. To achieve this transparency and to provide an incentive to developing an application, one key informant suggested a first screening round of applications followed by a second round where those selected in round one are assisted in completing the application process in order to level the playing field (e.g. provide a fairer process for smaller organizations or groups that may be well qualified).

  - ✓ ***Addressing Conflict of interest:*** A second element of transparency relates to openness about how funds will be used and the protection against conflict of interest. Many participants flagged the importance of the ACO's leadership being neutral and without ties to research organizations. For example, there could be a high degree of criticism if the ACO director is granted research funding. However, many participants noted the difficulty of attracting highly qualified, scientifically credible leader without the opportunity for them to receive funds.

4.2.2 GUIDING PRINCIPLES FOR ACO FUNCTIONING

Participants made the following suggestions as revisions, additions or adaptations to the guiding principles:

- A principle of 'promotion' includes publicity in wider forum. Promotion should extend beyond just the promotion of vaccine research; it should include telling the wider community about Canadian HIV researchers and their research initiatives.
- 'Community Inclusivity' as a principle was a problematic term for several participants:
  - ✓ Suggestion to replace this term with 'Stakeholder engagement'.
  - ✓ Community inclusivity can be a limiting term, and therefore, it might be more useful to explicitly define various stakeholders, e.g., would persons living with HIV/AIDS and their representatives be included?
  - ✓ Consider explicitly naming the range of stakeholders based on: (1) goals - from pre-testing to production to regulation, to ethics; (2) content expertise - industry, regulators, AIDS service community organizations, and ethicists.
  - ✓ Add language: 'Respect for multiple forms of expertise' to replace the term "inclusively", because different types of stakeholders have different inclusion needs. The idea is to be inclusive of a range of partners for meaningful engagement, not just for the sake of being inclusive, which could result in a great amount of unnecessary engagement.
  - ✓ Consider the concept of 'trans –disciplinary' engagement.
  - ✓ Consider the concept of genuine partnership as a principle. This goes beyond and is more active than 'community inclusivity'.
- Ease of entry could be a new guiding principle that may add value. This principle should answer why people would come to the Alliance and why their involvement adds value.

- Meaningful involvement is a key principle. At the core, some form of experience is needed for involvement, with a track record showing demonstrated experience as part of the application.
- An accountability principle is needed. Participants suggested that the ACO be accountable for spending funds wisely, and that it should be accountable to the Alliance group.
  - ✓ Clarity is needed regarding the nature of the ACO accountability to government, i.e., would it be an arms-length body with decision-making authority, or would there be a line of political accountability to the Minister?
  - ✓ Legal accountability is a concern that needs to be addressed in the principles. For example, how would accountability relate to a non-governmental organization that houses the ACO? It was noted that NGO's have their own chain of accountability. Reference to this is needed in RFP.
  - ✓ Affirm transparency as a principle related to accountability. Participants noted that declaration of conflict of interest is important.
  - ✓ Productivity is an element of accountability: The ACO needs to aim for maximum efficiency and effectiveness with limited resources.
- Create a "Neutrality" principle.
  - ✓ Include the concept of declaration of conflict of interest to build transparency. For example participants noted that any scientist working with vaccines will have to waive neutrality as they would likely be in conflict of interest.
  - ✓ Clarify the level of independence of this body.
  - ✓ Address how we balance accountability (e.g. to funders, government bodies) and independence.
- Affirm in the principles that this initiative is about producing a vaccine, not just about dividing funding and politics.
- Eliminate vague terminology, such as 'meet and/or exceed standards of excellence', which means very little without measurable success indicators (i.e. how would the ACO know that it has succeeded toward such a principle?).
- Participants in several key informant interviews suggested that more effort be placed on how the principles will be acted upon in practice. This could involve developing a flow chart to demonstrate how principles will be played out.

4.2.3 KEY ACO RESPONSIBILITIES

Participants had the most trouble discussing key ACO responsibilities because the general feeling was that the Canadian niche, mission, and strategic goals of the Alliance and ACO were not clear, making it difficult to respond to the question.

Generally speaking:

- Greater clarity about roles and responsibilities is needed, particularly around the range of responsibilities with which it will be tasked (to enable, facilitate, establish programs, etc).

Participants wanted to understand if the vision was for the ACO to house expertise, or to simply coordinate others who identify research and development gaps and prospects. These two tasks were noted to require very different skill sets.

- Definition of governance roles was requested by participants, possibly in the form of a chart, which would help explain responsibilities. Some suggested that when you start to break the model down, the ACO begins to look like a communications office. This calls to question if the ACO would be responsible, for example, for facilitating the process of defining strategic directions.
- Participants noted that reporting relationships and lines of decision-making are not clear and asked for a description of the lines of accountability in the document. They were also unclear if the vision was for the ACO to be a scientific leader in the vaccine world, or to be primarily an administrator. Some felt that section 4.3 (Selection Criteria) needed to ask for both: a scientific champion and a skilled administrator. However, the concept of 'neutral broker' was identified as problematic because scientific champions will likely have interests in the field, making neutrality a challenge.
- Several participants noted that some of the terminology requires further definition and greater depth. For example, the word 'catalyst' triggered one key informant to question how such a role would be carried out in practice.

Despite a perceived lack of clarity on the goals of the Alliance, three prospective roles emerged from participants.

- ***Broker:*** To broker relationships and collaboration from discovery to clinical testing which spans pre-clinical and production, with researchers, industry and regulators at the table.
- ***Funding Lever:*** Attempt to leverage funds related to the concrete goals, and leverage partnerships such as FPT alliance.
- ***Marketer / Communicator:*** Participants discussed at length the need to engage multiple stakeholders such as industry, science and regulatory bodies and that the ACO would play a role in bringing knowledge to its members through ongoing engagement (i.e. to capture new knowledge and convey this knowledge to the wider network).

  Another interpretation of the communication role was for the ACO to play an educational role internationally, specifically around the coordination of education and capacity building activities. Canada can utilize its communication strength to provide education for the HIV Vaccine Community. Some participants felt this is a Canadian strength that Canadians do better than the United States; for this reason, Canada is already a hub of international training. Some participants distinguished that provision of education is the role of the Alliance members, but not the ACO, suggesting instead that the ACO should promote education and coordinate training, but not actually provide training.
- ***Strategic Coordinator:*** One of the key areas of discussion, and uncertainty was whether the ACO would be expected to assume a leadership role in defining strategic objectives for the Alliance. Many participants suggested that gaps were well known and documented (in particular, but the Global Enterprise), where others noted that there was uncertainty about

where Canadian expertise fits into global Vaccine picture. The scope of this task was highlighted as potentially large, and challenging to implement in practice. Regardless of how the strategy was developed, participants seemed to suggest a strategic coordination role for the ACO.

4.2.4 MODELS OF OPERATIONAL BEST PRACTICE

Several useful models were suggested by participants from which lessons learned (either from approaches that worked well or that didn't) might be drawn regarding how to best implement an Alliance Coordinating office. They generally provided limited detail about the best practices, presumably assuming that the ACO would be responsible for researching and considering these models while establishing its own best practices. Some of the organizations suggested were (in no particular order):

- Organizations such as the Canadian Institutes for Health Research (CIHR) were suggested as models for best practice because of their strong advisory groups' mechanisms.
- The National Centers of Excellence (NCE) model is a hybrid model that may offer best practices for rules, use of in kind contributions, networks, etc. It is an example of an organization embedded within a research-driven organization in which the administrative function follows but does not lead, and in which dollars go to researchers.
- Canadian Centre on Substance Abuse (CCSA) is an organization with a multitude of people working in several areas.
- Consider the International AIDS Vaccine Initiative (IAVI) to look at best elements and ask for suggestions of other models.
- 'PREVENT' has a model that follows the NCE model and has a Canadian-based mandate.
- The former Canadian Network for Vaccines and Immunotherapeutics (CANVAC) can potentially provide of wealth of information on best practices through an exploration of its successes and failures.
- Grand Challenges in Global Health was sited as a grant giving organization that could provide best practices.
- Vaccine Research Center (VRC) in the USA (Part of the National Institute of Allergy and Infectious Diseases (NIAID))
- Center for HIV/AIDS Vaccine Immunology (CHAVI). This organization was identified because it is led by an individual who has multiple allegiances and is still a researcher, but still the lead of a similar network. CHAVI model is a good partnership model focused on expediting research.
- The HIV Clinical Trials Network was suggested because of its central office structure, expertise and the support services it offers.
- The Canadian Paediatric Society was suggested as a model because of its success in playing the role of honest broker, its guiding principles and its ability to balance advocacy.

- The Gates Foundation was sited because if its model of decision-making demonstrated by the relationship with the Government of Canada.
- The Global Alliance for Chronic Diseases was suggested because if its success in partnering with various countries, and its governance structure.

5.0 CONCLUSION

The consultation was designed to explore how both the new CHVI Research and Development Alliance, and its Alliance Coordinating Office can be best implemented.

It is clear from the input gathered during the consultation that there is a recognized need for more clarity about the vision and specific goals of the Alliance before the membership can be selected, and before the ACO can develop an implementation plan. Additionally, feedback from stakeholders suggests that there is not clear and common understanding about the niche that Canada should occupy related to the global efforts to create the vaccine, or where Canadian efforts can be most useful. Stakeholders highlighted that, because Canada is a relatively small player in the global effort, Canada needs to be extremely focussed in defining and addressing a specialized niche if we are to have real value-added on the international stage.

Stakeholders to a large extent expressed agreement with the concept of an Alliance as a logical mechanism for increasing and supporting collaboration around the HIV vaccine challenge. Most stakeholders in the scientific community in particular recognize and understand that for a HIV vaccine to be successfully created, greater collaboration and innovation will be necessary, as will overcoming the traditional silos that have been prevalent in the HIV/AIDS field. Several stakeholders also highlighted the strength of scientific collaboration with those both inside and traditionally outside of the HIV field.

Throughout the consultation stakeholders identified that meaningful and sustained engagement was important. To a large extent stakeholders supported multi/trans-disciplinary, broad-based, inclusive engagement and collaboration provided that those engaged were clearly aligned with, and contributing to the defined Alliance goals.

In terms of the Alliance Coordinating Office, stakeholders called for a neutral, administratively lean coordination hub, led by a strong scientifically knowledgeable leader with exceptional ability to build and navigate relationships. Stakeholders also called for a high degree of transparency in the lines of accountability and funding relationships, and flagged potential conflict of interest of the leadership as a top concern.

The Invitation to Submit Applications (ISA) was generally thought to be clear at a high level, but concerns were voiced about the specific principles, roles, responsibilities and lines of accountability as they were presented. Most stakeholders perceived that the goals needed to be made more tangible, and expressed concern that the task as it was outlined in the ISA may not be achievable within the budget and timeframe identified.

Finally, one key informant interviewee noted that in research conducted by the Gates Foundation and Duke University on alliances, two key causes of alliance failure were found to be lack of common understanding of goals and lack of trust. It is clear from the perspectives gathered in the consultation that stakeholders are acutely aware of the subsequent success factors. Stakeholders across the consultation are clearly driven by the desire to contribute meaningfully to the creation of an HIV vaccine and to the saving of lives around the world, and are cautiously optimistic about the potential the new Canadian Alliance brings to achieving this end.

APPENDIX 1

WEB CONSULTATION INVITATION

CONSULTATION
CANADIAN HIV VACCINE INITIATIVE RESEARCH AND DEVELOPMENT ALLIANCE

The Canadian HIV Vaccine Initiative (CHVI) participating departments and agencies (Canadian International Development Agency, Public Health Agency of Canada, Industry Canada, Canadian Institutes of Health Research, and Health Canada) and the Bill & Melinda Gates Foundation would like to invite you to provide input on the CHVI Research and Development Alliance. **This consultation will close on Tuesday, October 5, 2010.**

On July 20, 2010, during the XVIII International AIDS Conference in Vienna, the Government of Canada and the Bill & Melinda Gates Foundation announced the renewed CHVI http://www.phac-aspc.gc.ca/media/nr-rp/2010/2010_0720-eng.php.

The cornerstone of the renewed CHVI is a new Research and Development Alliance which will enable Canada to be a leading contributor to global efforts in developing safe, effective, affordable and globally accessible HIV vaccines. The Alliance is envisioned to be a Canadian network that will bring together leading researchers from the public and private sectors, as well as the international community, to develop innovative solutions to the challenge facing HIV vaccine development. Information on the Alliance is available at: http://www.chvi-icvv.gc.ca/chvifs-eng.html.

The objectives of the consultation are to seek input on how best to implement the CHVI Research and Development Alliance, the Alliance Coordinating Office and to determine how the Alliance can best contribute to achieving the priorities of the 2010 Scientific Strategic Plan of the Global HIV Vaccine Enterprise.

Input from Canadian and international stakeholders will be sought through a three pronged approach:

- Web-based consultation (geared to the wider community);
- A face-to-face meeting taking place on September 23, 2010 in Ottawa (targeted to a small group of key stakeholders such as Canadian HIV community groups, research institutions engaged in HIV vaccine activities, infectious diseases organizations and the private sector); and
- One-on-one interviews (with a small number of selected key international stakeholders).

A summary report of the consultation findings will be posted on the CHVI website once the consultation has been completed. This will be followed by the launch of the Invitation to Submit Applications to establish and operate an Alliance Coordinating Office to assist in establishing and maintaining the CHVI Research and Development Alliance.

Please provide us with your comments and/or suggestions in response to the questions below via email, at the following email address: secretariat@phac-aspc.gc.ca

CONSULTATION QUESTIONS

Respondent information:

1. Please indicate your area of work, interest or involvement relevant to this initiative (e.g. Canadian clinical or academic researcher, staff of a non-governmental or public health organization, person living with HIV/AIDS, etc):

2. (optional) Please provide your name and contact information:

Regarding the CHVI Research and Development Alliance

1. What do you think are the most important factors that will contribute to the successful establishment of a Canadian HIV Vaccine Initiative Research and Development Alliance?

2. In both the Canadian and international context, who are the key players (individuals/organizations) that should be part of the Alliance and how can they contribute to making the Alliance a success?

Regarding the Alliance Coordinating Office

1. What do you think are the most important factors (e.g. guiding principles) that will contribute to the Alliance Coordinating Office achieving its mandate?

2. Are there any models of best practices that should be adopted by the Alliance Coordinating Office in carrying out its mandate (e.g. organizational structure and ways of functioning)? Who might be contacted to learn more about these best practices?

Thank you for your collaboration.

Please forward your responses to: secretariat@phac-aspc.gc.ca no later than October 5, 2010.

For more information please refer to:

Memorandum of Understanding between the Government of Canada and the Bill & Melinda Gates Foundation: http://www.chvi-icvv.gc.ca/mou-eng.html
CHVI News Release: http://www.phac-aspc.gc.ca/media/nr-rp/2010/2010_0720-eng.php
CHVI Fact Sheet: http://www.chvi-icvv.gc.ca/chvifs-eng.html
Draft Invitation to Submit Applications**:** (link)

APPENDIX 2

FACE-TO-FACE CONSULTATION AGENDA - September 23, 2010

AGENDA

CANADIAN HIV VACCINE INITIATIVE (CHVI)
CONSULTATION ON THE CHVI RESEARCH AND DEVELOPMENT ALLIANCE
Thursday, September 23, 2010 (08:30 am – 4:30 pm)
Delta Hotel, 361 Queen Street, Room Delta B, Ottawa, Ontario

Objectives of the Event:

1. To provide information regarding the renewed CHVI, CHVI Research & Development Alliance and Alliance Coordinating Office

2. To provide an opportunity for key stakeholders to give their input on:

    1. How the new CHVI Research & Development Alliance may be best implemented
    2. How the Alliance Coordinating Office will be best implemented in order to fulfill its mandate

TIME	TOPIC / ACTIVITIES	SPEAKER / RESOURCE PERSON
08:00 – 08:30	***Registration, Networking and Refreshments***	
08:30 – 08:45	Opening and Welcoming Remarks	Dr. Rainer Engelhardt, Assistant Deputy Minister, Infectious Disease Prevention and Control, PHAC
08:45 – 09:00	Introductions and Overview of the Day	Facilitator
09:00 – 9:45	Overview of renewed CHVI, CHVI Research & Development Alliance and Alliance Coordinating Office ▪ Presentation followed by facilitated question and answer period	Dr. Howard Njoo, Director General, Centre for Communicable Diseases and Infection Control, PHAC
09:45 – 10:00	Introduction to small group discussions	Facilitator
10:00 – 10:20	***Health Break***	
10:20 – 11:45	What will it take to make this new CHVI Research and Development Alliance work? ▪ Small table group discussions Main discussion topics: 1. Key Alliance success factors (and models we can draw from) 2. Key players and their contributions 3. Getting and keeping all players engaged	Facilitator, All

	4. Unique contributions that this Canadian Alliance can make to Global goals to develop safe and effective HIV vaccines	
11:45 – 13:00	***Lunch*** Including teleconferenced presentation by Bill & Melinda Gates Foundation ▪ HIV Strategy 2012-2016	José Esparza, Senior Advisor on HIV Vaccines & Siobhan Malone, Program Officer, BMGF
13:00 – 13:40	Plenary of AM discussions Introduction to PM discussions	Facilitator, All
13:40 – 14:30	How can the Alliance Coordinating Office (ACO) be best implemented in order to fulfill its mandate? ▪ Small group "café" discussions: *Part 1* *Topic A)* What will be the most important success factors to the ACO achieving its mandate? Are there operational best practices and/or models we can draw from? *Topic B)* What must be the key ACO responsibilities and the guiding principles that will inform its functioning?	Facilitators / Topic Hosts, All
14:30 – 14:35	Groups rotate	
14:35 – 15:20	Small group "café" discussions: *Part 2*	Facilitators / Topic Hosts, All
15:20 – 15:35	***Health Break***	
15:35 – 16:10	Final Plenary	Facilitator
16:10 – 16:30	Wrap-Up & Closing Remarks	Facilitator & PHAC

APPENDIX 3

PARTICIPANT LIST – SEPTEMBER 23, 2010 CONSULTATION SESSION

CHVI RESEARCH & DEVELOPMENT ALLIANCE CONSULTATION
PARTICIPANT LIST - SEPTEMBER 23, 2010

STAKEHOLDERS	
Naveen Anand Chief Executive Officer Pan-Provincial Vaccine Enterprise (PREVENT)	Luis Barreto, Vice President Immunization and Science Policy Sanofi Pasteur Ltd.
Michel G. Bergeron, Professor Centre de recherche en infectiologie (CRI) Université Laval	Nicole Bernard Department of Medicine McGill University
Louise Binder, Chair Canadian Treatment Action Council	John Borody, President & CEO International Centre for Infectious Diseases
Mark Brockman Associate Professor Department of Molecular Biology and Biochemistry Simon Fraser University	David S. Burt Head of Research and Site Director GSK Biologicals North America
Bill Cameron President, Canadian Association of HIV Research & Professor of Medicine University of Ottawa at The Ottawa Hospital	Jeremy Carver CEO & CSO International Consortium on Anti-Virals Trent University
Éric Cohen Directeur de l'Unité de recherches Institut de recherches cliniques de Montréal	Marnie Davidson Project Coordinator, HIV Prevention Technologies Canadian Public Health Association
Francisco Diaz-Mitoma (Co-founder and Advisor to the company) Variation Biotechnologies Inc.	Monique Doolittle-Romas Executive Director Canadian AIDS Society
Keith Fowke, Professor Department of Medical Microbiology & Community Health Sciences Laboratory of Viral Immunology University of Manitoba	Robert Geneau, Senior Program Officer Global Health Research Initiative International Development Research Centre
Amine Kamen Group Leader Animal Cell Technology National Research Council Canada	C. Yong Kang Professor of Virology Department of Microbiology and Immunology Schulich School of Medicine and Dentistry University of Western Ontario

Renée Larocque, Program Officer Global Health Research Initiative International Development Research Centre	Robert Lorway Assistant Professor Department of Community Health Sciences University of Manitoba
Marc Mansour Vice President R&D ImmunoVaccine Technologies Inc.	Gibril Muddei Manager, Policy & Research BIOTECanada
Stephanie A. Nixon, Assistant Professor Social & Behavioural Health Sciences Department of Physical Therapy Dalla Lana School of Public Health University of Toronto	Bob O'Neill Executive Director Canadian Association of HIV Research
Michel Ouellet, Project Leader & Adjunct Professor, Laboratory of Human Immunoretrovirology, Infectious Disease Research Center Université Laval	Jim Pankovich Chief Scientific Officer CIHR Canadian HIV Trials Network
James Richards, Director General National Research Council Canada NCR Institute for Biological Sciences	Tim Rogers, Director Knowledge Exchange, Canadian AIDS Treatment Information Exchange
Ken Rosenthal, Director Pathology & Molecular Medicine McMaster University	Paul Sandstrom, Director National HIV and Retrovirus Laboratories Public Health Agency of Canada
Wendy Schettler Director of Public Health Programs International Centre for Infectious Diseases	Walter Schlech, Assistant Professor Microbiology and Immunology Dalhousie University
Dan Sinai Associate Vice-President of Research University of Western Ontario	Nicci Stein Executive Director Interagency Coalition on AIDS & Development
Louis-Philippe Vézina Chief Scientific Officer Médicago Inc.	
GOVERNMENT OF CANADA - CHVI DEPARTMENTS/AGENCIES	
Rainer Engelhardt, Assistant Deputy Minister, Infectious Disease Prevention and Control Branch Public Health Agency of Canada	Howard Njoo, Director General Centre for Communicable Diseases and Infection Control Public Health Agency of Canada
Steven Sternthal, Director Office of HIV Vaccines Public Health Agency of Canada	Lilja Jónsdóttir, Senior Policy Analyst Office of HIV Vaccines Public Health Agency of Canada
Christine Cryan, Program Consultant Office of HIV Vaccines Public Health Agency of Canada	Patricia Milsom, Program Consultant Office of HIV Vaccines Public Health Agency of Canada

Gillian Badger, Communications Advisor Public Affairs Division Public Health Agency of Canada	Marc Ouellette, Scientific Director Institute of Infection and Immunity Canadian Institutes of Health Research
Jennifer Gunning, Associate Director HIV/AIDS Initiative, Institute of Infection and Immunity Canadian Institutes of Health Research	Andrew Matejcic, Associate Director HIV/AIDS Initiatives, Institute of Infection and Immunity Canadian Institutes of Health Research
Cathy Parker, Director Health Products and Food Branch Health Canada	Christine Harmston, Senior Policy Advisor International Affairs Directorate Health Canada
Christine Reissmann, A/Director AIDS and TB Programming and Health Institutions Division Canadian International Development Agency	Amrita Paul, A/Manager AIDS and Health Institutions Unit Canadian International Development Agency
Renee McKenzie, Analyst AIDS and Health Institutions Unit Canadian International Development Agency	Robert Main, Senior Director Competitive Business Climate Industry Canada
Hélène Forest, Policy Analyst Life Science Industries Branch Industry Canada	
BILL & MELINDA GATES FOUNDATION (VIA TELECONFERENCE)	
José Esparza, Senior Advisor on HIV Vaccines, Global Health Program	Siobhan Malone, Program Officer Global Health Program
FACILITATORS	
Sue Cass, Senior Associate One World Inc.	Tim Fleming, Managing Director One World Inc.
Beth Allan, Associate One World Inc.	

APPENDIX 4

LIST OF KEY INFORMANTS

FINAL LIST OF INTERVIEWEES FOR CHVI CONSULTATION ON R&D ALLIANCE

NOTE - 14 persons interviewed. Categories as follows:

Clinical researchers (2), Funders (2), NGO's/Research Institutes (Canadian and International (5), Industry (1), Academic researchers (4)

DOMESTIC	
Dr. Scott Halperin Director, Canadian Center for Vaccinology Dalhousie University Halifax, NS	Dr. Michael Grant Professor of Immunology Memorial University St-John's, NF
Andrew D. Taylor (Managing Director) and Rebecca Lackman (Program Officer) McLaughlin-Rotman Centre for Global Health, University Health Network and University of Toronto	Dr. Andrew Potter Director and CEO Vaccine and Infectious Disease Organization (VIDO) International Vaccine Centre Saskatoon, SK
Dr. Mark Wainberg Director & Professor of Molecular Biology McGill University Montreal, QC	Dr. Richard Harrigan, Director, Virology Laboratory, B.C. Centre for Excellence in HIV/AIDS
Dr. Robert Peterson, Executive Director The Drug Safety and Effectiveness Network (DSEN) Canadian Institutes of Health Research (CIHR) Ottawa, ON	Dr. Jonathan Angel, Senior Scientist Chronic Disease, Ottawa Hospital Research Institute University of Ottawa Ottawa, ON
INTERNATIONAL	
Siobhan Malone (Program Officer) and Dr. José Esparza (Senior Advisor), HIV Vaccines, Global Health Program Bill and Melinda Gates Foundation	Dr. Seth Berkley President & CEO International AIDS Vaccine Initiative (IAVI) New York, NY
Mitchell Warren Executive Director AIDS Vaccine Advocacy Coalition (AVAC) New York, NY	Dr. Mark Feinberg, Vice-President Medical Affairs & Policy, Vaccine Department Merck US West Point, PA

APPENDIX 5

KEY INFORMANT INTERVIEW SCRIPT

CANADIAN HIV VACCINE INITIATIVE RESEARCH AND DEVELOPMENT ALLIANCE INTERVIEW GUIDE

Respondent name: _____

Contact information: _____

Date/Time of Interview: _____

Interviewed by: _____

Respondent area of work, interest or involvement relevant to this initiative (e.g. Canadian clinical or academic researcher, staff of a non-governmental or public health organization, person living with HIV/AIDS, etc):

SCRIPT

Introduction (provide summary as required):

Thank you for making yourself available for this call. (If relevant e.g.) My name is _____ and I am a Senior Consultant with One World Inc. an independent consulting firm based in Ottawa that has been engaged to undertake a consultation process with key stakeholders regarding elements of the renewed Canadian HIV Vaccine Research Initiative (CHVI). The consultation process has been initiated by the Canadian HIV Vaccine Initiative (CHVI) and participating departments and agencies including:

- Canadian International Development Agency,
- Public Health Agency of Canada,
- Industry Canada,
- Canadian Institutes of Health Research,
- Health Canada, and the
- Bill & Melinda Gates Foundation

As you know, the renewed Canadian HIV Vaccine Initiative (CHVI) features the establishment of a new CHVI Research and Development Alliance which will enable Canada to be a leading contributor to global efforts in developing safe, effective, affordable and globally accessible HIV vaccines. The Alliance is envisioned to be a Canadian network that will bring together leading researchers from the public and private sectors, as well as the international community, to develop innovative solutions to the challenge facing HIV vaccine development. This Alliance will be supported by an Alliance Coordinating Office (ACO).

The purpose of the consultation that we are in the process of undertaking is to seek input from stakeholders on how best to implement the CHVI Research and Development Alliance, the Alliance Coordinating Office and to determine how the Alliance can best contribute to achieving the priorities of the 2010 Scientific Strategic Plan of the Global HIV Vaccine Enterprise.

We are seeking input from Canadian and international stakeholders through 3 methodologies:

- Web-based consultation (geared to the wider community) which will close on Oct 5;
- A face-to-face meeting that took place on September 23, 2010 in Ottawa (targeted to a small group of key stakeholders such as Canadian HIV community groups, research institutions engaged in HIV vaccine activities, infectious diseases organizations and the private sector); and
- One-on-one interviews (with a small number of selected key international stakeholders, such as yourself).

A summary report of the consultation findings will be posted on the CHVI website once the consultation has been completed, and your input is essential to helping us round out this summary report.

The report will be followed by the launch of the Invitation to Submit Applications to establish and operate the CHVI Research and Development Alliance Coordinating Office. Have you had an opportunity to review the draft of the Invitation? (Note: draw attention to section 2.0 – p. 8-9 in particular)

We value your input and therefore would very much like to hear your thoughts on this new Alliance and the Coordinating Office soon to be established. During our conversation I will be taking detailed notes. We hope that you will be quite candid in sharing your thoughts and rest assured that in our final report there will be no direct attribution to any comments made.

Do you have any questions before we begin?

INTERVIEW QUESTIONS:

Regarding the CHVI Research and Development Alliance

The first set of questions I would like to explore relate to the establishment of the Alliance itself.

1. What do you think are the most important factors that will contribute to the successful establishment of this new Canadian HIV Vaccine Initiative Research and Development Alliance i.e. a network that will bring together leading researchers from the public and private sectors, as well as the international community, to develop innovative solutions to the challenge facing HIV vaccine development?

   Interview probes:

   - What would make this Alliance unique i.e. what would be the unique "value added"?

- What do you think should be the priority goals of this alliance?
- What might work against (or is currently working against) the successful establishment of this new Alliance?
- What will need to be done to counter any opposing forces?

2. Who are the key players that should be part of the Alliance?

Interview probes:

- Who are the key players in Canada?
- Who are the international partners that must be engaged?
- Why is their involvement important?

3. How can these key players contribute to making the Alliance a success?

Interview probes:

- Are there particular roles that you can envision for these different players?
- Do you see them as equal collaborators or are there differential roles or different levels of involvement that will be required from particular players?
- Any thoughts about criteria for membership?

4. How can we ensure the ongoing engagement of these various players in the Alliance?

Interview probes:

- What would ensure your ongoing engagement?
- Have you seen other models of Alliances of this type that have been particularly successful in maintaining active engagement of members? What contributed to that success?

5. Do you have any other comments about the establishment of the new CHVI Research and Development Alliance?

Regarding the Alliance Coordinating Office

I would like to ask you now to share your thoughts on the Alliance Coordinating Office. This will be the administrative, communications and coordinating hub of the new alliance. It will be operating independent of, but accountable to the funders. Of the $60 million dollars allocated for the renewed CHVI over the next 5 years, up to $3 million dollars will be allocated for the establishment and administration of the Alliance Coordinating Office (e.g. p 10-11 of ISA).

6. What do you think are the most important factors that will contribute to the Alliance Coordinating Office achieving its mandate?

Interview probes:

- At this point in time, do you think the high level goals and mandate are sufficiently clear? If not, what needs to be clarified before the Invitation to Submit Applications is launched?

- What might work against (or is currently working against) the Alliance Coordinating Office achieving its mandate?
- What will need to be done to counter any opposing forces?
- Do you have any thoughts about how the governance and decision-making structure could work most effectively (e.g. efficiency and effectiveness, potential role of advisory bodies, etc?)
- Based on your experience what would you imagine to be the ideal leadership qualities of the Alliance Coordinating Office?

7. There are a number of Guiding Principles that have been outlined in the Draft ACO Invitation to Submit Applications (ISA). Have you had the opportunity to review these (if not, refer to p.8 of ISA)? In order for the Alliance Coordinating Office (ACO) to fulfill its mandate, are there any suggestions for how the Guiding Principles currently outlined in the Draft ACO Invitation to Submit Applications (ISA) might be strengthened or any additional principles that the ACO should be required to adhere to?

Interview probes:

- Why are these changes or additions important?

8. Key Responsibilities of the Alliance Coordinating Office are also outlined. Have you had the opportunity to review these (if not, refer again to p. 8)? Are all key responsibilities adequately captured in the draft ACO ISA?

Interview probes:

- Do you have any recommended changes?

9. Are there any models of best practices that should be adopted by the ACO in carrying out its mandate, for example in terms of organizational structure and/or ways of functioning?

Interview probes:

- Who might be contacted to learn more about these best practices?

10. Do you have any other comments about the proposed mandate and operations of the new Alliance Coordinating Office?

11. Any other concluding remarks?

CONCLUSION

Thank you again for sharing your views with us. We appreciate your input. As was mentioned previously, a report on the results of our consultation will be available for your reference on the CHVI website in the near future