Regulation of Clinical Research Related to HIV Cure Conference

Bethesda, Maryland – January 25th, 2018

Table of Contents

Table of Contents ........................................................................................................................................ 3
Introduction ................................................................................................................................................ 5
Aims and Objectives .................................................................................................................................. 5
Organization ............................................................................................................................................... 6
Conference Planning Committee ............................................................................................................. 6
Conference Sponsors ................................................................................................................................. 7
Registration and Participation .................................................................................................................... 8
Agenda ....................................................................................................................................................... 9
Conference Evaluation ............................................................................................................................. 9
Motivation to Participate in the Conference ............................................................................................. 10
Evaluation of the Conference Sessions .................................................................................................. 11
  Setting the Stage .................................................................................................................................... 11
  PANELS I-IV: Perceptions of the Relevance of the Topics and Time ..................................................... 12
  Perceptions of Conference Achievements ............................................................................................... 12
Logistics and Organization ....................................................................................................................... 13
  Organization .......................................................................................................................................... 13
  Technical aspects of the conference ....................................................................................................... 14
  Opinions/perceptions and others .......................................................................................................... 14
Topics for further Discussions ................................................................................................................ 14
Conclusion .................................................................................................................................................. 15
Introduction

The Forum for Collaborative Research at the University of California Berkeley School of Public Health (the Forum) organized the full day conference, “Regulation of Clinical Research Related to HIV Cure” on January 25th, 2018 in Bethesda, Maryland.

HIV cure research poses an excellent opportunity to establish a collaborative partnership among stakeholders, to discuss matters of social value, scientific validity, fair selection of participants, a favorable and acceptable benefit-risk balance, independent scientific and ethical review, informed and voluntary consent, and respect for enrolled patients and their communities. Ongoing dialogue is needed to review issues in light of emerging new science.

The Forum started its HIV Cure project in 2013 to address specific scientific and regulatory hurdles in HIV cure interventions and to enable opportunities for open public input from the broader HIV community on regulatory issues in HIV cure research. The Forum hosted the “Regulatory Pathway for HIV Cure Research: Developing Consensus” meeting on June 17th, 2014, in Washington D.C. with 411 participants from 13 countries. Participants in the 2013-14 project continued discussions around the absence of comprehensive communication among the contributors essential to development and regulatory approval of an HIV cure. The Conference on “Regulation of Clinical Research Related to HIV Cure” directly addressed issues left open in 2014.

Aims and Objectives

The conference aimed to facilitate the development and regulatory approval of HIV curative strategies by addressing communication gaps among scientists, regulators, ethicists, patient community and industry as it pertains to the ethical hurdles, the patients’ perspectives and expectations, and community concerns around the conceptualization, design and conduct of HIV cure clinical studies.

The objectives of the conference were:

- To convene representatives from the US-FDA, the US National Institutes of Health (NIH), academic investigators and researchers, ethicists, sponsors, funders, women and men affected by the HIV epidemic, including people living with HIV and their advocates, the pharmaceutical industry and other stakeholders, to focus on specific questions through an open discussion format.

- To address the regulatory implications facing clinical trial design as it pertains to treatment interruptions and use of remission as an endpoint, inclusion of specific
populations, the ethical challenges of gene therapy and discuss the ethical considerations and community engagement in the conduct of HIV Cure research.

- To produce recommendations that help address the regulatory, ethical and community engagement hurdles around clinical trial design for HIV cure oriented studies

**Organization**

**Conference Planning Committee**

For the organization of this conference, the Forum convened a planning committee comprised of experienced individuals in the field of HIV cure, some of whom have collaborated with the Forum in other HIV related projects, including the HIV cure project in 2013-2014. The planning committee’s task was to propose timely topics, design the agenda and suggest speakers and panelists for each session. The planning committee continues to contribute with the production of the meeting report, position papers and manuscripts.

Members of the committee are:

- **Adaora Adimora**, MD, is a Professor of Medicine at the University of North Carolina School of Medicine and a research in the areas of HIV in women and minorities.

- **Moises Agosto**, is the Director of Treatment, Education, Adherence and Mobilization at the National Minority AIDS Council and longtime HIV/AIDS activist and advocate.

- **Jintanat Ananworanich**, MD, PhD, serves as the Associate Director for Therapeutics Research at the Military HIV Research Program.

- **Paula Cannon**, PhD, is a Professor in the Department of Molecular Microbiology and Immunology at the University of Southern California’s Keck School of Medicine.

- **Lynda Dee**, JD, is the President of AIDS Action Baltimore, a non-profit dedicated to HIV treatment and prevention education, patient services as well as drug development and access advocacy.

- **Dazon Diallo Dixon**, MPH, DHL is a Founder and President of SisterLove, Inc., a women’s HIV/AIDS organization and advocate for women’s human rights and reproductive justice.
• **David Evans** is the Director of Research Advocacy at Project Inform and an HIV treatment advocate and educator.

• **Nir Eyal**, DPhil, is an Associate Professor in Global Health and Social Medicine (Medical Ethics) at the Harvard Medical School.

• **Pedro Goicochea**, MSc, MA, is a Senior Research Associate at the Forum for Collaborative Research.

• **Richard Jefferys** is the Science, Vaccines and Cure Project Coordinator at the Treatment Action Group, he also publishes on HIV treatment interruption research, pathogenesis and immunology of HIV infection.

• **Rowena Johnston**, PhD, is the Vice President and Director of Research at the Foundation for AIDS Research and directs the amfAR Research Consortium on HIV Eradication.

• **Veronica Miller**, PhD, is the Executive Director of the Forum for Collaborative Research and Senior Researcher & Lecturer at University of California, Berkeley.

• **Jeffrey Murray**, MD, MPH, is the Deputy Director of the Division of Antiviral Products at the US-FDA.

• **Deborah Persaud**, MD, is a professor of pediatrics at the Johns Hopkins University School of Medicine and directs the pediatric infectious diseases fellowship program at the Johns Hopkins Children’s Center.

• **Kenneth Taymor**, JD, is the Deputy Director of the Forum for Collaborative Research and the Executive Director of the Center to Advance Science and Policy at UC Berkeley School of Public Health.

**Conference Sponsors**

The conference was made possible thanks to financial contributions from the US National Institutes of Health through Grant 1R13AI136713-01 awarded to the Forum for Collaborative Research; and grant U19 AI096113 as a supplement through University of North Carolina, Chapel Hill; the American Foundation for AIDS Research (amfAR), Treatment Action Group and Project Inform. Additional support came from the HIV Forum sponsors Abbott, Gilead Sciences Inc., Merck and Roche.
Registration and Participation

Registration for the conference opened on December 1st, 2017 and was opened until January 25th, 2018. During this period 184 people registered to the conference, and 126 attended in person.

We offered 25 full domestic scholarships to participate in-person in the conference and received 18 applications. All applicants were awarded a scholarship including four international participants from Argentina, Georgia, Puerto Rico and Thailand.

There were 37 presenters and panelists including the Director of the Office of AIDS Research (OAR) and the Deputy Director of the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID).

The conference was very well attended by Federal Government representatives (41.3%), members of the academia (28.7%), industry representatives (13.2%) and community representatives or members of advocacy organization (10.8%). (See Figure 1)

![Figure 1: Participants by Type of Organization](image)

A great proportion of attendees were from the United States (95.2%), however, there were participants from Argentina (1), France (1), Georgia (1), Mexico (1), Puerto Rico (1), South Africa (1), Spain (1) and Thailand (1).
There were 62 people participating remotely. Of those participating remotely, 53 were from the US and nine from other countries; Spain (3), Thailand (1), Wales (2) and Germany (1). Twenty-three of remote participants were from industry, 15 from the US-FDA/NIH, 8 from academic institutions and 16 from other organizations.

**Agenda**

The agenda was organized in eight (8) sessions and five (5) panels that included topics on treatment interruption and remission as an endpoint; population specific issues in HIV cure research (women and children); combination treatment approaches to HIV cure and gene therapy approach to HIV cure. (See Appendix 1)

**Conference Evaluation**

An on-line conference evaluation survey was designed and distributed on January 29th, 2018 and was closed on March 2nd, 2018. The survey consisted of 30 questions inquiring about a) motivation to participate in the conference, b) evaluation of each of the conference sessions, c) the overall conference evaluation, and d) the logistics of conference organization. Additionally, we enquired about suggestions regarding next steps for the HIV Forum’s HIV Cure Project. For a complete copy of the survey, see Appendix 2.

The survey was distributed to the 167 conference attendees on January 29th, 2018 and reminders were sent on February 5th, 12th, 19th and 26th. Seventy-six (45.5%) persons replied to the survey. The distribution of the respondent by type of organization reflects the overall participation and is described on the following figure:
Motivation to Participate in the Conference

For less than half of participants (47.4%) this was the first time attending an event organized by the Forum for Collaborative Research. The reasons most frequently mentioned to attend the conference were the “opportunity to hear the regulatory perspective of HIV cure” (81.58%) and the “opportunity to hear the latest developments in the field (63.16%). (See Figure 2)
Figure 3: Motivation to Participate in the Conference

Evaluation of the Conference Sessions

The conference consisted of eight sessions and five panels with extensive time for active discussions. Each session was evaluated through the survey.

Setting the Stage

The first session consisted of six panelists who expressed their expectations on the conduct and outcomes of the conference from different perspectives: ethical, regulatory, community, academia and advocacy.

A great proportion of survey respondents agreed and strongly agreed that the panelists’ perspectives were relevant to the regulatory discussions (85.3%) and that the session was a valuable component of the HIV cure discussions (84.8%). Finally, 87.7% agreed that the time allotted to this session (20 minutes) was appropriate in length. Very few mentioned that the
session was too short (9.2%) and only 2 respondents (3%) mentioned that the session was too long.

PANELS I-IV: Perceptions of the Relevance of the Topics and Time

Survey respondents agreed and strongly agreed that the panel topics contributed to the understanding of the regulatory implications and that they were a valuable component of the HIV cure discussion agenda. Time allotted to the panels was considered appropriate. (see Figure 4).

![Evaluation of Panel Sessions (%)](image)

- This panel contributed to my understanding of the regulatory implications of the topic in discussion (Agree/Strongly agree)
- I plan to apply knowledge gained from this panel to my work and/or practice (Agree/Strongly agree)
- This panel was a valuable component of HIV cure research discussion (Agree/Strongly agree)
- Time allotted to discussion was adequate

**Figure 4: Degree of Agreement on Panel Evaluation**
- PANEL I: Treatment Interruption and Remission as an Endpoint
- PANEL II: Population-Specific Issues in HIV Cure Research – Women
- PANEL III: Population-Specific Issues in HIV Cure Research – Children
- PANEL IV: Combination Treatment Approaches
- PANEL V: Gene Therapy

**Perceptions of Conference Achievements**

The conference Regulation of Clinical Research Related to HIV Cure was perceived as a forum that facilitated the formulation of questions, the interactions and potential collaboration with individuals and organizations, that presented information valuable for the participants’ work presently and in the future. (See Figure 5)
Overall, the conference experience was considered either good or excellent by a majority of respondents (94%). Events communications in terms of frequency and content were considered “excellent” by more than half of respondents (57%). The registration process was reported as either good or excellent (94%) and the event venue, room set up and audiovisual equipment were perceived good/excellent by more than 50% of respondents.

Some opinions/suggestions/recommendations on the organization of the conference collected from the open-ended questions of the evaluation could be divided into three categories; a) organization, b) technical aspects, and c) opinions/perceptions and others.

**Organization**

Respondents to the evaluation considered that the panels could incorporate more men and women of color and “more diversity” that reflects the epidemic and communities that would be the focus of HIV cure research participation. On the other hand, it is also acknowledged that the panels their composition and the diversity of the panelists and the inclusion of
community representatives in every panel should serve as a “model for other conferences where activists have an active role”. One respondent mentioned that having seven panelists in one panel was too many, suggesting that a panel of five suffices.

Panels were good in length, it would have been good that moderators provided a summary of recommendations/next steps at the end of the panel session. There is one mention that the one-day meeting turned out to be too short for the topics that were being treated.

It was also mentioned that panelists/presenters should have been coached more beforehand and have preparatory meetings (calls) prior to the conference in preparation for their presentations so that to have a list of questions to address during their interventions. A couple of panels went off topic and

More audience discussion should have taken place on the IMPAACT P1115 trial session.

A better balanced was suggested on the inclusion of ethicists in the panels. For one of the panels, the inclusion of two ethicists was “too much” and the philosophical discussion turned out to be long.

Technical aspects of the conference

Technical aspects include the audiovisual equipment and webcast streaming for remote participants. We used ZOOM as a conference call service provider and contracted with a webcast services provider. We contracted with the Bethesda Marriott Hotel to provide audiovisual equipment and support for the conference.

Comments on these aspects included to have additional camera angles on the webcast; ZOOM did not show the slides (although there were no slides for presentations except a few) and that the quality of the audio and the video were “excellent” and that the webcast was very well done. One person reported that he/she had problems with the audio during the morning session.

Opinions/perceptions and others

In general, opinions on the conference were very positive, people reported that the topics were very well selected panel format was refreshing and that the discussions were useful and an opportunity where a lot was learned, ample time for networking.

Other suggestions and opinions included to continue engaging stakeholders in more frequent discussions through the organization of working groups that frequently meet over conference call or in person.

Topics for further Discussions
Few respondents to the conference evaluation proposed topics to be considered as part of the HIV cure project:

- Third party risk in treatment interruption (TI) studies
- Better monitoring and evaluation of analytical treatment interruption (ATI)
- Uniformity in HIV cure language
- Inclusion of women/trans women in HIV cure research
- Inclusion of adolescents
- Assessment of risks and benefits and informed consent
- Best surrogate marker for FDA in studies with and without interruption
- Minimal standard measurement for cure
- Persons of color in HIV cure research
- HIV cure science/research literacy and dissemination
- Additional safety criteria for treatment interruption studies
- Creation of new community engagement models for HIV cure research
- Clarification of IND process
- Combination of pharmacological interventions with alternative medicine approaches
- Clinical trial design approaches for registered and non-registered products
- Combination strategies and how they will be regulated

**Conclusion**

Q30 Please add any additional comments or suggestions:

*Science Excellent GREAT Job*