

International AIDS Society
"Towards an HIV Cure":
Global Scientific Strategy
2011-2012
Concept Note

Introduction

As Professor Françoise Barré-Sinoussi, International AIDS Society (IAS) President-elect and 2008 Nobel Laureate for Medicine, noted at the 5th IAS Conference in Cape Town, South Africa, in July 2009, *"There is a strong need for continued investments in basic science research in order to increase our understanding of the mechanisms of HIV persistence and elaborate better and more affordable treatment options."*

Scientific research has led to remarkable discoveries since HIV was first identified thirty years ago. Today, individuals living with HIV can expect to live a relatively normal lifespan provided they are both diagnosed and treated early enough and if they comply with life-long adherence to antiretroviral drug regimens. However, combination therapy—even when given for decades—is not curative, as HIV persists even in efficiently treated patients.

Combination antiretroviral treatment has radically changed the face of HIV infection, from a lethal disease into a chronic condition. Nevertheless, antiretroviral regimens are indeed costly and tiring for patients. Side-effects associated with years of ARV use can be severe while meticulous life-long adherence to ART is essential for the success of treatment, in particular to avoid the emergence of a resistant virus.

Moreover, there is an emerging consensus that persistent HIV infection is harmful even for treated patients who sustain undetectable viral load. The subsequent inflammation and

chronic immune activation contributes to increased risks of cardiovascular disease, cancer and accelerated aging in patients living with HIV. Thus, even in successfully treated patients, normal life expectancy is not fully restored.

In addition to the individual benefits, recent scientific evidence has brought concrete proof that optimal ART can prevent HIV transmission at the population level through viral suppression in HIV infected patients. Therefore, finding novel therapeutic options in which patients would discontinue ART, and HIV would remain permanently undetectable should also have additional public health benefits by reducing HIV incidence.

Within the next decade, most of the 34 million people currently living with HIV will, according to the current eligibility criteria of $<350\text{CD4}$ cell count, require treatment; the total number of people eligible for treatment continues to expand.

Given the current economic situation the life-long sustainability of treatment roll-out is threatened. The need for investment in short-course and more effective treatment strategies is critical to achieve at least long-term remission of patients. It is a humanitarian imperative both in terms of the individual and public health benefits it would give, as well as an opportunity to potentially avoid the long term cumulative costs of ART.

The IAS, with the support of the National Institutes of Health, the French Agence Nationale de Recherche sur le SIDA, the Austrian Federal Ministry of Science and Research, Sidaction, and the Treatment Action Group, organized a workshop on HIV Reservoirs in conjunction with the XVIII International AIDS Conference (AIDS 2010) in Vienna, Austria. Following the success of the workshop and in light of the resurgence of interest and optimism on prospects of a cure for HIV - either a sterilizing one or a functional one - the IAS has engaged in dialogue with a number of stakeholders in the field (researchers, activists, industry, funders). With the support of its partners, the IAS is committed to seizing the momentum and demonstrating leadership in advocating for increased investment in HIV cure research and more concerted efforts to advance the science. The IAS has undertaken to guide the development of a Global Scientific Strategy, "Towards an HIV Cure", with the expectation that it will contribute to the establishment of an international research

alliance and/or expansion and global collaboration of existing consortia towards an HIV cure. In line with the IAS strategy 2010-2014, the IAS Governing Council prioritized an HIV cure as one of its four key policy areas during its November 2010 retreat. The IAS Governing Council has reaffirmed that HIV Cure is a priority for 2012.

Global Scientific Strategy, "Towards an HIV Cure"

The foundation of this Global Scientific Strategy will be consensus on the state of the art in HIV cure research by leading scientists in the field. The strategy will contribute to maximizing resources and strategic investment in the most promising strategies in search of a sterilizing or a functional cure.

It is foreseen that the IAS HIV Cure initiative will consist of five steps. Three of these relate directly to the development of a scientific strategy. The three are:

- Development of a draft Global Scientific Strategy by an international researchers' working group, comprising basic scientists and clinicians in cooperation with a stakeholders' advisory board
- Consultations on the draft strategy with scientists from various disciplines (non-HIV), patient organizations, industry, international organizations, and regulatory and research funding agencies.
- A symposium to launch the strategy in conjunction with AIDS 2012.

The first two steps were completed in 2011. Lessons learned from these two phases have led the IAS and the "Towards an HIV Cure" Advisory Board to plan the next steps needed for the roll-out of the scientific strategy. These include the following activities:

- Carry out more research on ethical issues linked to HIV cure research and cost-effectiveness of HIV cure strategies.
- Facilitate information and research data exchange on HIV cure.
- Stimulate innovative public-private research collaboration efforts.
- Develop policy & advocacy activities aimed at fostering research "Towards an HIV Cure".

Step 1 - Develop the Global Scientific Strategy, "Towards an HIV Cure"

The IAS is establishing an International Working Group to develop the Global Scientific Strategy. It will provide strategic analysis of the state of research in the area of HIV persistence and eradication to develop recommendations for future studies and to promote international and cross-disciplinary research cooperation.

The International Working Group will be co-chaired by the IAS President-elect, Professor Françoise Barré-Sinoussi, and Professor Steven Deeks from the University of California, San Francisco (UCSF).

The International Working Group will consist of a group of researchers from a diverse range of research institutions and areas of work (genetics, molecular biology, immunology, animal modelling, medical virology, clinical science).

In order to ensure that key partners, including major institutions, funders, regulators and advocates of HIV cure research, are engaged and informed throughout the process, the IAS will create an advisory board. The input of the advisory board will be sought at each step of the process and it will provide strategic advice to the IAS during the consultation phase and will be strongly involved. Advisory group members will also play an essential role in the launch of the strategy and in ensuring that it is implemented.

Dr. Jack Whitescarver, Director of the Office of AIDS Research at the National Institutes of Health, who played a pivotal role in the Vienna workshop "Towards an HIV Cure", will co-chair the advisory board together with the IAS President-elect.

The advisory board will consist of selected leaders from research institutions active in the field of HIV reservoirs and persistence, community representatives, international organizations and researchers from low- and middle-income countries.

Outcomes/deliverables for Step 1

The IAS has completed the following deliverables:

- Set up an International Working Group to develop the Global Scientific Strategy, “Towards an HIV Cure”. Ensure that all fields of scientific expertise and all scientific strategies addressing HIV persistence are represented in the group
- Set up an advisory board with representatives from key organizations involved in HIV cure research
- Convene and facilitate working group meetings and teleconferences to review the scientific evidence, define the outline of the strategy, and provide feedback on the draft
- Convene and facilitate advisory board meetings and teleconferences to provide input on the initial steps of the process and draft strategy
- Draft the Global Scientific Strategy, “Towards an HIV Cure”.

Step 2 - Consult Stakeholders Involved in HIV Research on the Strategy

The draft strategy was circulated widely to stakeholders involved in the HIV/AIDS response in the second half of 2011 to solicit their input and perspectives. The consultations were held through face-to-face meetings and online surveys, as well as key informant interviews.

Scientists from various disciplines (non-HIV), research funders, patient representatives, regulatory agencies, international organizations and pharmaceutical companies were consulted.

To reach a broad array of researchers and other stakeholder’s, the consultations were organized in coordination with a number of partners such as the European AIDS Treatment Group, the European AIDS Clinical Society, the Treatment Action Group, the Australasian Society for HIV Medicine, the U.S. National Alliance of State and Territorial AIDS Directors.

These consultations have enabled the IAS to learn from stakeholder’s what the priorities in HIV cure research are for them and also raise interest for HIV cure among the stakeholders. Conclusions are compiled in a consultations’ summary report. Those consultations have confirmed that momentum for collaborative research in HIV cure is growing.

Outcomes/deliverables for Step 2

The IAS has:

- Planned a comprehensive and inclusive consultation process on the draft Global Scientific Strategy, "Towards an HIV Cure", to ensure that the perspectives of all relevant stakeholders (HIV researchers and scientists from other fields, research funders, patient representatives, international organizations, regulatory agencies and pharmaceutical companies) are taken into consideration
- Convened and facilitated multi-stakeholder consultation meetings and teleconferences
- Prepared an exhaustive report on the consultations as well as a summary report.
- Revised the strategy based on the feedback and input from consultations.

Step 3 -Research and Policy Activities leading-up to the release of the Global Scientific Strategy

Based on discussions held at the stakeholder's consultations, the IAS decided to add one more step to the design of the scientific strategy before its release. Ethical issues were highlighted as one crucial area of the global scientific strategy that needed further development. This is why the IAS will create a Special Working Group on Ethics to develop specific recommendations on these issues. The tasks of the group will be to write short recommendations to include in the scientific strategy itself and to prepare a detailed appendix to the scientific strategy which outlines all ethical considerations for humans and Non-Human Primates.

The IAS and the Advisory Board also decided that it would be important to complement the biomedical scientific strategy by a policy paper to help engage with non-researchers. This policy paper will highlight the expected benefits of HIV cure and important measures to be taken for the roll-out of the strategy. To support the development of this policy paper, the IAS will create a Special Working Group on Cost-Effectiveness to estimate the costs and public health benefits of different cure strategies.

The work of this group will feed in to the development of the policy paper on HIV Cure which will be circulated widely to donors and policy makers. Parallel to this, the IAS will design an advocacy and communications strategy to pave the way for the roll-out of the scientific strategy outside of expert circles. The IAS welcomes collaboration with other groups and the inclusion of consortiums to contribute to research and policy activities.

Outcomes/deliverables for Step 3

The IAS will:

- Set up a Special Working Group on Ethical guidance for HIV Cure studies
- Set up a Working Group on Cost-Effectiveness of HIV cure strategies
- Convene and facilitate working group meetings for both of these groups. Develop terms of reference for both groups.
- Create a policy paper “Towards an HIV Cure” and disseminate it.
- Design a communications strategy and ensure its implementation in the lead up to the pre-conference symposium, at AIDS 2012 and in the roll-out after the release of the strategy.

Step 4 - Release the Strategy

The strategy, “Towards an HIV Cure”, will be launched at a scientific symposium organized in advance of AIDS 2012 in Washington, D.C. The symposium will be structured in line with the scientific priorities defined in the Global Scientific Strategy. It will include invited speakers, presentations of abstracts and a scholarship programme. The IAS will invite submissions of abstracts on the various priority areas identified in the strategy. At AIDS 2012, sessions will be organized to report on the highlights of the symposium.

In order to plan the symposium, the IAS created a Programme Committee. The role of the committee is to decide on the structure of the symposium, choose the invited overview speakers, and disseminate the call for abstracts and to select abstracts and scholarships.

The Global Scientific Strategy will also be disseminated within the scientific community using IAS platforms, such as the International AIDS Conference, IAS membership (16,000 members in 196 countries) and other meetings.

The strategy will be made available for endorsement to all stakeholders in the global HIV and AIDS response.

Outcomes/deliverables for Step 4

The IAS will:

- Set up a Programme Committee to plan for the pre-conference symposium, including abstract scoring and selection. Convene and facilitate programme committee meetings and teleconferences to discuss tasks related to the pre-conference symposium.
- In advance of AIDS 2012, organize an invitation-only symposium of up to 300 participants from a wide range of laboratories and institutions throughout the world. This symposium will be attended by senior, mid-career and junior scientists, and will include a number of clinical researchers, scientific journalists, research funding administrators and community representatives. The aim of this symposium will be to:
 - a. Launch the Global Scientific Strategy, "Towards an HIV Cure"
 - b. Present state-of-the-art basic science research on the scientific priorities identified in the strategy
 - c. Accelerate research on viral reservoirs as the way towards achieving a cure for HIV infection
 - d. Provide an opportunity for scientists who are working on HIV cure to share ideas, debate, and network among their peers.
- Propose and develop sessions and events at AIDS 2012 to present the Global Scientific Strategy "Towards an HIV Cure", and report on the highlights of the symposium in order to re-engage the broader HIV community in basic science.
 - a. Organize the launch of the Global Scientific Strategy before and at AIDS 2012 (press conference, social event/reception)
 - b. Present the scientific recommendations of the strategy at AIDS 2012

- Publicize and disseminate the Global Scientific Strategy through publication in scientific journals in conjunction with AIDS 2012, and also through communication and advocacy efforts by the IAS. These efforts will include: additional publications; media outreach; and specific activities during international and regional conferences.

Step 5 - Roll-out of the Global Scientific Strategy

The IAS and the Advisory Board “Towards an HIV Cure” intend to monitor the roll-out of the scientific strategy by continuing to build international research alliances and contributing to the expansion of existing consortiums in order to work collaboratively and in an orchestrated manner on the priorities defined in the strategic plan - to accelerate scientific advancement in this field.

Firstly, to facilitate the roll-out of the scientific strategy, an international information exchange database on HIV cure will be created. The database will be an online registry which will gather information on research funding, pre-clinical and clinical trials, research results - both positive and negative, assays, reagents used and contact person.

Secondly, the IAS will design and implement a multi-year funding coordination plan, together with research funding agencies, philanthropic organizations, businesses, scientific and medical communities, people living with HIV, and others globally. The synergies between this field and others (immunology, cancer) will be highlighted and gap analysis used to identify underfunded areas. This funding coordination will include the organization of regular funder’s meetings.

Thirdly, the IAS will design an industry outreach plan, involving the creation of an industry collaboration group. The mandate of the group will focus on intellectual property issues and include provision of drugs for pre-clinical and clinical studies, creation of an open collaborative platform, and assay development and standardization.

Other components of the IAS project include working on collaborative efforts to expand a study on the psycho-social aspects of an HIV Cure, currently being developed in the Netherlands.

Outcomes/deliverables for Step 5

The IAS will:

- Expand the International Scientific Working Group and its mandate to include the yearly review of progress made towards the implementation of scientific recommendations.
- Develop the information exchange database to enable comparison, cooperation and standardization across HIV cure research.
 - Set-up a Working Group to design the database
 - Develop an online version of the database
 - In cooperation with partners, keep it up-to-date regularly.
- Collaborate with the advisory board members and donor organizations to coordinate research funding based on the scientific strategy, with the aim of bringing more funding to this area. This will include:
 - Contacting potential donors to encourage them to fund this area of research.
 - Convening yearly funder's meeting.
 - Yearly mapping of funding (included in database).
 - Advocate for increased resources for HIV cure research.
 - Stimulate coordination of existing calls and development of joint calls.
- Design an industry outreach plan including:
 - Set-up an industry collaboration group
 - Develop terms of reference and the group mandate
- Convene and facilitate meetings between industry representatives, academics and regulators to discuss opportunities for collaboration and design cooperation tools.
- Include the study on psycho-social aspects of an HIV Cure in the pre-conference symposium programme. To aid the expansion of the study, the IAS will convene meetings to discuss its scope and methodology, and facilitate collaboration with key experts.

Timeline:

Date	Activity	Who/Where
5 November 2010	Start up: core scientific group conference call; discussion of the nomination process for International Working Group members; and fundraising	Core group members with IAS Secretariat
January - February 2011	Selection and invitation of the International Working Group members and advisory board members	IAS, with support from core group members
January - February 2011	Preparation of the first working group meeting: brainstorming on recommendations and definition of the Global Scientific Strategy outline Recruitment of a consultant	Core group members and IAS
26 February 2011 (CROI)	International Working Group and advisory board meetings and discussion on preliminary recommendations Sub-group meetings: first draft of the Global Scientific Strategy will be prepared following these meetings	International Working Group and advisory board members and IAS, in Boston.
21 July 2011	International Working Group and advisory board meetings to review the draft Global Scientific Strategy sub-group meetings Second draft of the Global Scientific Strategy will be prepared following this meeting	At IAS 2011 in Rome
July - December 2011	Consultations on the draft Global Scientific Strategy (in person, online)	IAS, with support from International Working Group and advisory board members at: IAS 2011; regional conferences; and other meetings

7 December 2011	<p>International Working Group and advisory board meetings to review the revised draft Global Scientific Strategy and feedback from consultations</p> <p>Planning of the launch symposium (invited presentations)</p>	<p>International Working Group members and advisory board members with IAS, in conjunction with the St Martin Workshop on HIV Persistence</p>
January - February 2012	<p>Finalizing the Global Scientific Strategy and calling for abstracts for the launch symposia.</p>	<p>IAS, with support from the International Working Group and Advisory Board</p>
7 March 2012 (CROI: 5-8 March)	<p>Industry outreach plan development - meeting with industry representatives and working group members</p>	<p>Industry representatives, working group members and IAS; at CROI, Seattle</p>
2 April 2012	<p>Advisory board meeting to complete release and roll-out planning.</p> <p>Start implementation of funding coordination plan and dissemination of policy paper.</p> <p>Ethics and cost-effectiveness working group meetings and discussion on preliminary recommendations.</p>	<p>Advisory board members, and working group members for ethics and cost-effectiveness with IAS, in conjunction with the CCC meeting in DC</p>
May - July 2012	<p>Project Planning for the Online Information Exchange Database.</p> <p>Meeting to discuss the scope and objectives of the psycho-social study.</p>	<p>IAS with support from Advisory Board, and researchers</p>
19, 20 and 21 July 2012	<p>Global Scientific Strategy launch at pre-conference symposia, and other dissemination activities.</p> <p>Working group and advisory board</p>	<p>At AIDS 2012 in Washington, D.C.</p>

<p>24 July 2012</p> <p>August - October 2012</p> <p>Autumn 2012</p> <p>Autumn 2012</p> <p>1 January 2013</p> <p>Spring 2013</p> <p>2013</p>	meetings to follow-up on roll-out.	
	Industry Outreach Plan: Terms of Reference and the Group Mandate completed via email and TC.	Industry Collaboration Group in DC during AIDS 2012
	Technical Development of the Online Information Exchange Database. Work with board members IT services to create automatic feeds to link websites.	IAS, with support from board members and their IT departments
	Content Development of the Online Information Exchange Database. Select 2 advisors per major theme to review and select information. Publication of recommendations from Ethics Working Group and edition of Policy Paper including cost-effectiveness analysis.	Online. IAS with support from scientific working group, advisory board and selected advisors
	First Funder's Coordination Meeting - Presentation of the Scientific Strategy	TBD
	Launch of the Online Information Exchange Database	IAS
	Review of the Scientific Recommendations from the Scientific Strategy	Scientific Working Group
	Second donor's coordination meeting and publication of the first Global Scientific Strategy Progress Report.	IAS with support from the scientific working group and advisory board.