



amfAR™

MAKING AIDS HISTORY

INNOVATIONS

MARCH 2017

2016 HIV Cure Summit

Researchers gear up
for clinical studies

Also Inside:

New amfAR Grants
Support Young
Scientists

Infographic: The World
Without PEPFAR

Harm Reduction Amid
Heroin Crisis

MARCH 2017

The biannual newsletter of amfAR,
The Foundation for AIDS Research

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Accountability



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HIV Cure Summit 2016

Researchers gear up for clinical studies

Scientists from the amfAR Institute for HIV Cure Research delivered a World AIDS Day community update on their progress.

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Kevin Robert Frost (Photo: Kevin Tachman)

(Clinical) Trials and Tribulations

For many people living with HIV, 2017 brings a great deal of uncertainty and anxiety. Those who have gained access to health insurance through the Affordable Care Act risk losing coverage if the Act is defunded or repealed. The future of Medicaid and Medicare is also uncertain. And what will become of federal programs such as Ryan White, the AIDS Drug Assistance Program, and Housing Opportunities for Persons with AIDS, on which so many rely for their lifesaving medications, housing, and other essential services?

Through our Public Policy Office and with our allies in Washington, we will do everything in our power to ensure that these critically important programs endure.

As a research organization, we're particularly concerned about the fate of AIDS research supported by the National Institutes of Health (NIH). The NIH is an indispensable driver of AIDS research, but there are many in Congress who would choose to slash that budget in favor of other "more deserving" diseases.

As a counterweight to all this uncertainty, amfAR remains steadfast in its pursuit of evidence-based solutions to HIV/AIDS and its search for a cure. Indeed, as the new year gets underway, there is much to be optimistic about.

Researchers—many of them supported by amfAR—are making headway on a range of cure-focused strategies. These include development of latency-reversing agents, immunotherapy, cell and gene therapy, therapeutic vaccines, and the use of broadly neutralizing antibodies.

At the amfAR Institute for HIV Cure Research, now in its second year, a series of clinical studies will begin in 2017 to test a number of potentially curative interventions (see page 11). And a consortium of European investigators, also supported by amfAR, is following a number of patients in its quest to replicate the only known case of an HIV cure to date: the "Berlin patient."

All of this work—and the optimism it engenders—is made possible by the support of amfAR's generous donors in the U.S. and around the world. We thank you all and, whatever else may transpire in 2017, amfAR will continue to lead the effort to develop a cure for HIV.

Harm Reduction Gains Momentum Amid Heroin Crisis

A spate of heroin overdose deaths, particularly in white, rural, and destitute communities, has increased support for harm reduction programs to combat what is increasingly being viewed as a public health crisis.

From short-term statewide action to funding by major cities to study the issue, public health officials perceive a shift in attitudes over the past 18 months.

HIV diagnoses among drug users fell by 63% between 2005 and 2014. However, the current opioid epidemic could reverse those gains.

"We are experiencing rising deaths from opioids, people switching from painkillers to heroin," said William McColl, AIDS United's director of health policy. "It's a sad commentary on our society, but it's really hard for people to ignore. All of a sudden it's happening with a lot higher visibility."

HIV transmission among injection drug users is also a concern. In 2015, Scott County, IN, 30 miles north of Louisville, KY, experienced a drug-fueled HIV outbreak, prompting former Indiana governor and incoming Vice President Mike Pence to allow a short-term syringe exchange program and provision of the anti-overdose drug naloxone to help curb escalating overdose deaths.

Studies show that syringe services programs (SSPs), which provide sterile needles while disposing of used ones, reduce the transmission of HIV and other blood-borne diseases without increasing drug use.

Nationally, HIV transmission among injection drug users is on the decline. The Centers for Disease Control and Prevention recently reported that HIV diagnoses among drug users fell by 63% between 2005 and 2014. However, the current opioid epidemic could reverse those gains.

Dr. Marion Riedel, associate professor of professional practice at the Columbia University School of Social Work, argues that syringe programs should be supplemented by supervised injection facilities (SIFs) to provide a multitude of services.

SIFs provide a safe and hygienic place where people can inject pre-obtained drugs under clinical supervision and also receive health care,

counseling, and referrals to health and social services. They have been shown to reduce overdose deaths and the transmission of HIV

and viral hepatitis infections, while increasing access to drug treatment and other health care.

Nearly 100 such facilities exist in 10 countries, including Switzerland, Germany, Denmark, and Greece. Insite in Vancouver, Canada, became North America's first legal SIF when it opened in 2003. In January, Seattle officials approved two SIFs, the first of their kind in the U.S. Both sites will be aimed toward homeless drug users, with the goal of providing health services and ultimately drug treatment, the *Washington Post* reported.

"Most of the syringe exchange programs have food pantries, showers, access to counseling," Riedel said. "If you are going to give them five syringes, what better place to shoot up? Those organizations have also already fought the community resistance to syringe exchange."

In February 2016, the mayor of Ithaca, NY, Svante Myrick, proposed the first SIF in the U.S. The proposal followed more than a dozen heroin overdoses in a week and a half in 2014 — three fatal — in the town of 30,000, according to *The New York Times*. In September, the New York City Council agreed to fund a \$100,000 study on the pros and cons of SIFs.

Despite overwhelming support — 30 organizations have endorsed SIFs in New York City — the idea faces challenges. *The New York Times* quoted a New York state legislator labeling Myrick's proposal "preposterous" and "asinine" and a Cornell law professor who said it would be a "government-run heroin shooting gallery."

Still, some feel the growing acceptance of SSPs will eventually extend to SIFs. "SSPs were resisted even in the public health community when first presented," Dr. Miriam Boeri, associate professor of sociology at Bentley University in Waltham, MA, said in an email.

"The U.S. was one of the late adopters and we suffered due to this. Even today, there are many politicians who resist this response and only the recent opioid epidemic is tearing down this resistance."



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Vigilance Needed to Sustain Global Fight Against HIV

New amfAR report argues that a cure alone won't end the epidemic

While there is great hope that a cure for HIV will be discovered in the not-too-distant future, such a development by itself will not automatically spell an end to the epidemic.

Using tuberculosis (TB) and malaria as examples, a new amfAR report shows how global efforts to eradicate widespread diseases can fail even when effective cures are available. Despite TB and malaria being preventable and curable, almost two million people continue to die every year from these diseases.

"Our experience with TB and malaria shows us that the development of effective medical interventions—even cures—is only one step in the control of disease," said Alana Sharp, a policy associate at amfAR and the primary author of the report.

Elimination of both TB and malaria has been hampered by lack of timely and accurate diagnosis, drug resistance, and insufficient research and development. These factors predict similar challenges to eradicating HIV, even in the event of a cure.

Until a cure for HIV is available and accessible, the report, titled *How Cures Can Fail*, recommends



the following strategies to prevent new infections and keep people on treatment:

- ◆ **Increase support for implementation research to ensure engagement along the care continuum.** Evidence-driven, patient-centered, and cost-effective methods must be developed to dramatically improve rates of diagnosis and retention in care.
- ◆ **Increase research and development funding aimed at developing new treatments and diagnostic technologies.** Research must continue to find new pharmaceutical treatments

and to develop technologies to identify HIV immediately after infection and to test for drug resistance at diagnosis.

- ◆ **Sustain political commitment to HIV.** Achieving an end of HIV will require continuing political and financial commitment from donor governments, multilateral and philanthropic organizations, and pharmaceutical organizations, and HIV programming must be integrated within existing national health programs.

To read the full report, visit <http://bit.ly/HowCuresFail>

Advocating More Effective Engagement in HIV Care

A new amfAR report recommends several measures that health plans and health care purchasers, including Medicaid and Medicare programs and private insurers, should take to help end the HIV epidemic in the U.S.

Curbing the HIV Epidemic by Supporting Effective Engagement in HIV Care: Recommendations for Health Plans and Health Care Purchasers outlines actionable and meaningful steps to improve health outcomes, reduce unnecessary spending, and contribute to the development of more tightly integrated systems of care.

In recent years, the percentage of HIV-positive Americans who know their status has risen to record levels. However, according to the Centers for Disease Control and Prevention,

almost half of those diagnosed in the U.S. are not receiving regular HIV care. Moreover, while more people with HIV in the U.S. are on antiretroviral treatment, only 30% have the virus under control.

"Our research team members each brought very different expertise and we interviewed a broad range of leading clinicians and researchers," said Jeffrey Crowley, Distinguished Scholar at the O'Neill Institute for National and Global Health Law at Georgetown Law and lead author of the report. "Our goal was to distill a lot of ideas into high priority actionable steps for health plans and purchasers."

The researchers urged health plans and health care purchasers to consider taking action within

three primary domains: 1) better monitoring of engagement in HIV care; 2) intervening to support continuous and sustained engagement in care and HIV viral suppression; and 3) supporting policy changes at all levels of government to strengthen engagement in HIV care.

"We hope that this report shows health plans and major health care purchasers that they can take a small number of strategic steps to provide better care to their members that will help us achieve critical national goals," said Greg Millett, vice president and director of public policy at amfAR.

To read the full report, visit www.amfar.org/Effective-Engagement/

The World Without PEPFAR

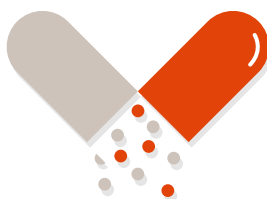
Launched in 2003 under President George W. Bush, the President's Emergency Plan for AIDS Relief (PEPFAR) made billions of dollars available for HIV programs in developing countries. At the time, global investment in HIV programs was practically nonexistent. In most African countries,

medication was expensive and unavailable. And few had the infrastructure necessary to deliver treatment programs. **As our infographic shows, the world would be a remarkably different place *without* PEPFAR, which fundamentally altered the course of the global HIV/AIDS epidemic.**

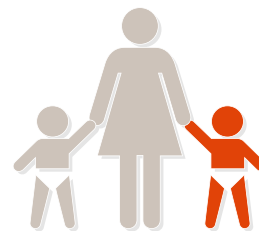
INDIVIDUAL OUTCOMES



More than **13 million** more people die of AIDS-related causes, and life expectancy declines to **less than 40 years** in the hardest hit countries in sub-Saharan Africa



11.5 million fewer people have access to treatment. Limited access to treatment undermines testing efforts

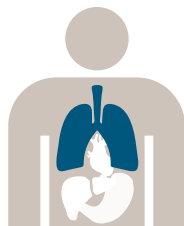


Prevention of mother-to-child transmission programs are never properly scaled up. **50% of children** born with HIV and left untreated **die** before their 2nd birthday

INFRASTRUCTURE OUTCOMES



Without the economies of scale realized by PEPFAR, the price of drugs and diagnostic tests **is not significantly reduced**



HIV treatment is one of the best interventions for preventing new TB infections; without HIV programs scaled up through PEPFAR, **TB rates skyrocket**



Public health systems are at **breaking point** trying to provide palliative care and treat opportunistic infections in the absence of antiretroviral therapy

STABILITY & CREDIBILITY OUTCOMES



Unable to sustainably develop human capital or to attract critical foreign investment, many African economies face a **catastrophic downward spiral**



U.S. credibility as a leader on global health and human rights is **permanently diminished** for its failure to address the **global health crisis** of the century



Political instability in sub-Saharan African nations grows significantly, **increasing the likelihood of conflicts** affecting U.S. security interests

Can Cancer Treatments Pave the Way to a Cure for HIV?

An interview with Professor Sharon Lewin

Professor Sharon Lewin is director of the Peter Doherty Institute for Infection and Immunity at the University of Melbourne, where she leads a multidisciplinary research team focusing on HIV persistence and eradication. An amfAR grantee, Dr. Lewin spoke with amfAR Vice President and Director of Research Dr. Rowena Johnston.

Johnston: In 2015, you received a four-year amfAR Impact grant to test cancer drugs in HIV. What do you hope to achieve?

Lewin: Immune checkpoints are proteins that keep T cells nonfunctioning. If you block those immune checkpoint proteins, the immune system can rev up again and start to recognize cancer, and we hope could recognize HIV. The grant will let us study immune checkpoint blockers in combinations. In previous skin cancer studies, the use of two blockers was more likely to increase the immune response to infected cells. We think this could be key in a cure for HIV as well.

Johnston: What kind of cancers are currently being treated by these drugs? How could the drugs be used to potentially cure HIV?

Lewin: The drugs have been licensed for the treatment of melanoma and lung cancer, and are being investigated in solid organ tumors and even blood tumors.

There are many overlaps in HIV and cancer research. In cancer you're going after these few cells that are left so the cancer won't come back and in HIV you're trying to reach the few persistent cells that are latently infected. In both there is inflammation, which dampens an effective immune response, and in both you want to remove the target as well as boost the immune system response. In HIV, the target is latently infected cells; in cancer, it is malignant cells.

“There’s a shift now into developing and focusing on long-term immune control, not just attacking the reservoir.”

Johnston: What do you consider to be the most exciting cure possibilities on the horizon?

Lewin: There are many interesting proposals for gene therapy and some very good animal models to test them. There's a shift now into developing and focusing on long-term immune control, not just attacking the reservoir and reducing how much virus persists. These strategies may involve vaccinations or immunomodulation,

including immune checkpoint blockers. I think we will be hearing more about combination studies.

Johnston: If there was one question that cure researchers need to answer right now to move the field forward, what would that be?

Lewin: I would say understanding viral rebound. It is assumed that it's coming from latently infected cells, or from persistent productively infected cells sitting in lymph nodes, or from cells other than T cells. We must understand where the virus comes from that rebounds.

Johnston: How optimistic are you that we're going to develop a cure or the scientific basis of a cure in five years?

Lewin: I'm pretty optimistic that we'll find a way to keep more people in long-term remission, meaning that their virus is kept at low levels without antiretroviral therapy. Most likely those will be people who are treated very early, or potentially babies born with HIV. The real challenge will be finding an intervention that can be translated to the many people diagnosed with HIV after living with the virus for years. But I think we're going to get somewhere in five years.

To read the full interview with Professor Lewin, visit www.amfar.org/pave-the-way/



Dr. Sharon Lewin (third from left) speaks at the Towards an HIV Cure Symposium at the 21st International AIDS Conference in Durban, South Africa, July 2016.

What to Look for in Assessing HIV Cure Stories in the Media

From time to time, stories appear in the media about possible cases of an HIV cure. How should readers assess stories like these? What should they look for?

The key thing to remember is that it's currently impossible to know whether someone has been cured until they have been off antiretroviral therapy (ART) for a substantial period of time – at least a couple of years. Some researchers have proposed that five years is the more appropriate cut-off, at which point there is a 50% chance that the person is truly cured.

Another thing to remember is that if an HIV-positive person is taking medications consistently and correctly, it is likely that their viral load will reach an undetectable level. Most of the time, more advanced tests, normally used only in scientific studies, can find the virus in the blood.



And even if the most sensitive tests showed no evidence of virus in the blood, reservoirs of persistent virus are also present in tissue in certain parts of the body, and these pockets of virus may be much more difficult to detect.

A credible report of the possibility of a cure almost certainly will mention attempts to measure the HIV reservoir that persists while

people are taking ART. This is one of the greatest challenges in HIV research. Many of the approaches being studied involve measuring the level of HIV DNA in a person, but we know that this does not tell us definitively whether someone has been cured.

Ideally, scientists would be able to measure something in the blood or tissues that indicates whether a patient is cured, without having to take the patient off ART. In 2016, amfAR awarded a grant to a team of researchers who are conducting a study aimed at discovering such a measure. The researchers will look for indicators in the blood and tissues that predict a longer delay to rebound. If successful, researchers could finally have a tool for gauging the success of potential cure interventions.

It's currently impossible to know whether someone has been cured until they have been off antiretroviral therapy (ART) for a substantial period of time.

amfAR Awards New Grants to Support Young Scientists

In October, amfAR announced the 2016 recipients of the Mathilde Krim Fellowships in Basic Biomedical Research, an annual research initiative that supports bright young scientists exploring innovative solutions to HIV/AIDS.

The six Krim Fellows — Amy Chung, Ph.D., of the University of Melbourne, Australia; Daniela Fera, Ph.D., of Boston Children's Hospital; Marit van Gils, Ph.D., of Academic Medical Center of the University of Amsterdam, the Netherlands; Judd Hultquist, Ph.D., and Anand Pai, Ph.D., of the J. David Gladstone Institute in San Francisco; and Daniel Rosenbloom, Ph.D., of Columbia University — were each awarded approximately \$150,000 over two years.

The fellows will pursue a range of approaches to the development of a vaccine and a cure for HIV.

"This is an exceptionally talented group of young investigators," said amfAR CEO Kevin Robert Frost. "At a time when research funding for young scientists is flatlining, we're delighted to be able to support and advance the fresh and imaginative ideas they bring to the table."

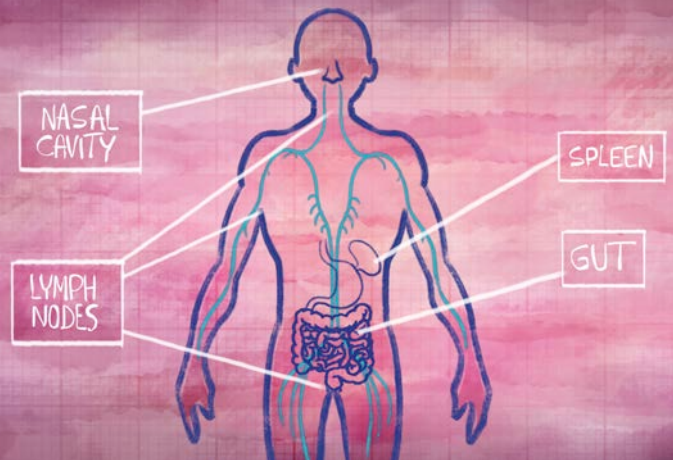
amfAR Vice President and Director of Research Dr. Rowena Johnston added: "Their varied backgrounds and collective talents are sure to invigorate the field of AIDS research, and I've no doubt each will make important contributions to the field as their careers evolve."



Since 2008, the Krim Fellowships, named in honor of amfAR's Founding Chairman Dr. Mathilde Krim, have provided more than \$7.4 million to young researchers.



HOW do these viruses
become latent
when most other viruses are
actively replicating?

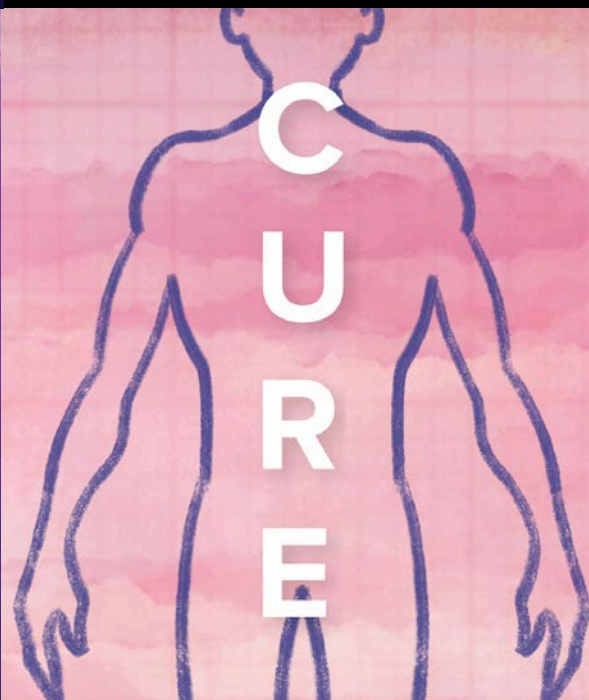


amfAR's Roadmap to a Cure

amfAR has teamed up with an animation studio to create a series of short educational videos to explain the challenges of curing HIV and outline the four key components of our roadmap to a cure. The videos were screened for the first time at the 2016 World AIDS Day HIV Cure Summit on December 1 and are available at www.curecountdown.org/challenges/.

CD4
TCELL

HIV



2016 HIV Cure Summit

Exactly 12 months since amfAR established its Institute for HIV Cure Research, Institute researchers reported on their progress at the 2016 World AIDS Day HIV Cure Summit, December 1. The Summit was held at the University of California, San Francisco, where the Institute is based.

“I’d like to thank our entire San Francisco community and especially the people living with HIV that are here with us today,” said Institute Director Dr. Paul Volberding, a professor of medicine at UCSF and a pioneering HIV/AIDS physician and researcher, in his opening remarks. “Because we want to move as quickly as possible towards a cure, our involvement with the community is especially important.”



amfAR CEO Kevin Robert Frost (right) moderates the panel discussion.

Counting Down to a Cure for AIDS

To accelerate the pace of HIV cure research, amfAR launched a \$100 million Countdown to a Cure for AIDS initiative in 2014. The goal of the Countdown is to develop the scientific basis of a cure by the end of 2020.

To date, amfAR has awarded 36 grants totaling \$35,882,927 through the Countdown, supporting research conducted by 151 scientists working at 55 institutions in 10 countries.

The centerpiece of the Countdown is the amfAR Institute for HIV Cure Research, established at the beginning of 2016 with a five-year \$20 million grant to the University of California, San Francisco.

The remaining \$80 million will support a grant-making strategy to advance a wide range of scientific approaches to an HIV cure at leading academic institutions in the U.S. and around the world.

A Cornerstone of HIV Cure Research

“The Institute forms the cornerstone of our cure research efforts,” said amfAR CEO Kevin Robert Frost. “We’ve made a commitment to invest \$100 million in cure research over the next five years and in the first year alone we’ve already committed close to \$40 million to this effort. The Institute represents about \$20 million of that.”

The summit was organized around the four research modules that form the structure of the amfAR Institute and that each relate to the HIV reservoir, the principal barrier to a cure: **Chart**, **Understand**, **Record**, and **Eradicate**.

Dr. Peter Hunt reported on the efforts of his team to chart, or pinpoint, the precise locations of the reservoir. Dr. Hunt’s team is the first to have generated data showing the different cell types that are expressing virus in tissues. In an effort to identify signatures of latently infected cells in tissues, the researchers are using a kind of “facial recognition software for the HIV reservoir.” This sophisticated technology – CyTOF – uses 38 markers to form a

multidimensional description of the cells’ surface.

“Shock and Kill”

Dr. Warner Greene leads the “Understand” module, which is focused on a cure strategy called “shock and kill.” His team is working to identify agents that can effectively “shock” the virus out of hiding so that it can be killed by the immune system or interventions such as a therapeutic vaccine or broadly neutralizing antibodies.

Dr. Greene’s primary focus is on stimulators of the body’s innate immune response called toll-like receptors. “These are the first line of defense,” he said. “What we’re trying to do is to stimulate that response because it magically influences the adaptive immune response – the antibody production and CTL (cytotoxic T cells, also known as CD8+ cells) formation. Stimulating these receptors is like the adjuvant that makes vaccines more potent. Maybe if we combine a toll-like receptor agonist with a vaccine, we can make the vaccine more potent, and ideally the toll-like receptor will also act as a shocking agent and make the cells visible for a more efficient attack by the vaccine.”

Cure-Focused Clinical Studies Move Forward

As they explained at the Cure Summit, researchers at the amfAR Institute for HIV Cure Research are pursuing a shock-and-kill approach to curing HIV and will undertake a number of clinical studies in 2017.

The shock in shock and kill aims to restart viral replication – in other words, to reverse latency – using a variety of so-called latency reversing agents (LRAs). The researchers are testing several different classes of LRAs, alone and in combination. These include HDAC inhibitors (e.g., vorinostat, panobinostat), PKC agonists such as kansui, and agents identified empirically with amfAR funding, including a drug approved to treat alcoholism (disulfiram) and an estrogen blocker (tamoxifen).

Once viral replication has been restarted, interventions will be required to kill the virus-producing cells. Institute researchers aim to test whether the immune system can kill infected cells by: using various vaccines; blocking the signals that indicate immune exhaustion; and reducing inflammation that helps reservoirs persist.

In some clinical studies, these approaches will be combined in the form of TLR (toll-like receptor) agonists, which have shown the potential to both shock the virus out of its latent state and kill infected cells.

Finally, to measure the impact of these approaches on reducing the size of the reservoir, research teams will use a series of diagnostic technologies employing PET scanning and will undertake what's called an analytic treatment interruption (ATI) study. In the latter study, Institute researchers will collaborate with Dr. Timothy Schacker of the University of Minnesota to try to find indicators in the blood and tissue that can ultimately predict the likelihood that remission or a cure has been achieved.

“These are potentially very exciting developments,” said Dr. Rowena Johnston, amfAR’s vice president and director of research. “These studies will provide us with a trove of invaluable information about the effectiveness of these interventions and the direction further cure-focused research should take.”

STUDY	APPROACH
SHOCK	
Tamoxifen/vorinostat	Latency-reversing agent
Kansui (ingenol)	Latency-reversing agent
Disulfiram/vorinostat	Latency-reversing agent
KILL	
Inovio DNA vaccine (with or without pembrolizumab)	Vaccine
HIVcons vaccine (ChAd/MVA mosaic)	Vaccine
CMV vaccine	Vaccine
Pembrolizumab (anti-PD-1)	Immune checkpoint blocker
Nivolumab (anti-PD-1) with or without ipilimumab (anti-CTLA4)	Immune checkpoint blocker
Canakinumab (IL1-beta inhibitor)	Anti-inflammatory
Sirolimus (mTOR inhibitor)	Anti-inflammatory
Everolimus (mTOR inhibitor)	Anti-inflammatory
Methotrexate	Anti-inflammatory
Ruxolitinib (JAK1/2 inhibitor)	Anti-inflammatory
SHOCK-AND-KILL COMBINATION	
GS9620 (TLR7 agonist)	TLR agonists
TLR9 agonist (MGN1703) with bNAbs (3BNC117 and 10-1074)	TLR agonists
QUANTIFYING THE EFFECTS OF SHOCK-AND-KILL INTERVENTIONS	
Analytic treatment interruption (ATI)	Diagnostics
VRC01 labeling	Diagnostics
Raltegravir labeling	Diagnostics
Envelope-specific tracers	Diagnostics

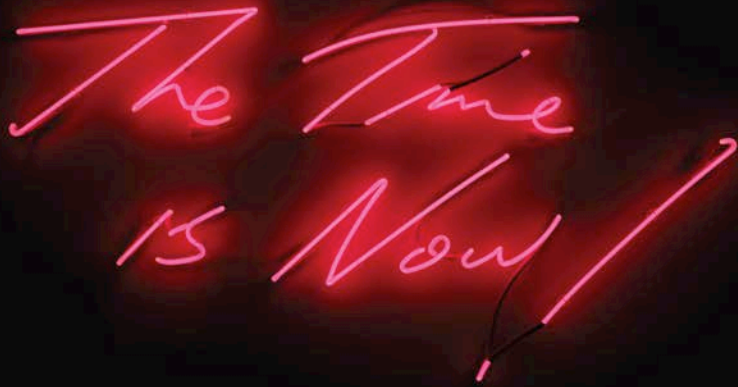
Dr. Satish Pillai and his team are charged with recording, or measuring, the size of the persistent HIV reservoir. Dr. Pillai and his colleagues are developing highly sensitive tools that are more effective at identifying tiny amounts of residual virus, since as few as ten in a million cells may be infected in a person on antiretroviral therapy.

Testing Cure Interventions

Dr. Steven Deeks, who leads the “Eradicate” module, aims to take the experimental interventions developed by Institute researchers and test them in clinical trials (see above). “My job for the past year has been to help develop an infrastructure and get all the protocols in place to begin to do studies in people,” he said.

“We’ve done that. And now we’re set to start doing clinical studies of some of the ideas that are coming out of the Institute.”

The researchers’ presentations and a webcast of the 2016 HIV Cure Summit can be viewed at www.curecountdown.org.



1980s Classics Updated in Compilation Album to Benefit amfAR



A collection of 1980s classic hits has been reimagined by contemporary artists for *The Time Is Now*, a 14-track compilation album created to benefit amfAR.

The album features a soulful rendition of Michael Jackson's "Billie Jean" by singer-songwriter Aloe Blacc and a rendition of New Order's "Bizarre Love Triangle" by Sugar for Sugar, Scarlett Johansson's band with Julia Haltigan, Holly Miranda, and Kendra Morris.

The band Lower Dens provides their updated version of Hall & Oates' "Maneater," while the pop rock group DNCE puts its stamp on Tina Turner's "What's Love Got to Do With It." Dita Von Teese and Sebastien Tellier revamp "Do You Really Want to Hurt Me" by Culture Club and

the songwriting duo Marian Hill performs Whitney Houston's "I Wanna Dance With Somebody (Who Loves Me)."

The artwork for the album cover was designed exclusively for amfAR by iconic British artist Tracey Emin.

The Time Is Now is the brainchild and labor of love of executive producers Michaelangelo L'Acqua, internationally acclaimed music curator, Andy Boose, longtime producer of many of amfAR's events, and Peter Bittenbender, CEO of Mass Appeal.

"Music ... was a source of inspiration and solace with the advent of HIV/AIDS," L'Acqua said. "This album is a tribute to that extraordinary time."

Throughout its history, amfAR has enjoyed the steadfast and generous support of the music industry. In 1985, Dionne Warwick, Elton John, Gladys Knight, and Stevie Wonder recorded a collaborative rendition of the song, "That's What Friends Are For," raising millions for AIDS research.

"*The Time Is Now* is a great example of our longstanding relationship with the music industry, and we are deeply grateful to the artists who graciously donated their time and talents to the making of this album," said amfAR CEO Kevin Robert Frost.

The Time Is Now was released in October by Mass Appeal and Republic Records.



Left to right Aloe Blacc, Jana Hunter of Lower Dens, Theophilus London, Sabina Sciubba of Brazilian Girls, Dita Von Teese (Photos: Getty Images and amfAR).

Climbing Mountains for Magnolia

15-year-old raises \$5,000 for amfAR with 100-mile hike through Alps



Will and his sister Maggie

Fifteen-year-old Will always wanted to hike across the Alps. And with a 3-year-old sister born with HIV, he wanted to raise awareness of the virus too. Will combined his desires over the summer, when he trekked 100 miles over eight days from Oberstdorf, Germany, to Merano, Italy. The hike raised \$5,000 for amfAR's life-saving research programs.

Will's sister, Magnolia, or Maggie as she is affectionately known, was adopted at birth. She was diagnosed with HIV when she was four months old after coming down with a rare form of pneumonia. Her birth mother had contracted the virus late in pregnancy. Since her diagnosis, Magnolia has been on antiretroviral therapy.

“Modern medicine literally saved Maggie’s life,” Will said. “And although we are grateful for modern day treatments, our ultimate goal is to find a cure.”

“My family has done a lot of research on HIV/AIDS since Magnolia was diagnosed,” said Will, who lives in Washington, DC. “We were particularly interested in amfAR because of the launch of the amfAR Institute for HIV Cure Research and the unprecedented investments in HIV research in an effort to find a cure.”

“One of the challenges for our family is having to give her the oral meds twice a day, but so far she is quite accepting of them,” said Maggie’s mother, Kelly. “She goes to the HIV clinic once a quarter for an exam and blood work. The hardest part is the blood draw, which Maggie hates. She is very afraid. It is difficult on all of us to see her so confused and upset.”



Will in the Alps

Maggie is in preschool, is strong and healthy and has an undetectable viral load. Will and his mother describe her as beautiful, happy, and courageous.

“Modern medicine literally saved Maggie’s life,” Will said. “And although we are grateful for modern day treatments, our ultimate goal is to find a cure.”

Transwomen in Peru Engage in amfAR-Funded Research

More than 100 transgender women (transwomen) in Lima, Peru, have joined an amfAR-funded study that aims to determine if combining HIV prevention and treatment with gender-affirming medical care will help these women access health services and remain in care.

Transwomen have the highest prevalence of HIV in Peru—30 percent in Lima, according to one study—yet the least access to services.

“Stigma and discrimination are powerful barriers that prevent transwomen from participating in society,” said principal investigator Dr. Javier Lama of Asociación Civil Impacta Salud y Educación (IMPACTA), a nonprofit that conducts HIV/AIDS research. “The staff of most public clinics are unfriendly toward these women and often have no idea about their unique medical needs.”

Many transwomen use female hormones to feminize their appearance and affirm their gender. In Peru, they often must resort to using black market hormones, which can pose significant health risks.

IMPACTA and its research partners—the Boston-based Fenway Institute and EPICENTRO, Lima’s only community-based organization providing support and health services to transwomen and men who have sex with men (MSM)—have developed an innovative model that combines feminizing hormone therapy with essential HIV services.



Transwomen members of Feminas House in Lima participate in a health seminar on the effects of hormone therapy led by Dr. Alex Gonzalez, medical director of Fenway Health in Boston.

The project, known as *Feminas*, relies heavily on a transgender women’s task force of community leaders, health outreach workers, and activists, to help guide the research team. The task force also raises awareness of the program and provides ongoing input from Lima’s trans communities.

“We tried to ensure that transwomen played a central role in the project,” said study coordinator Leyla Huerta, herself a transwoman and longtime trans activist. She added that the task force has been instrumental on many levels, including helping to open a safe space for transwomen (*Feminas House*) and building recognition of *Feminas* in their local communities.

“During this first year, the girls have been able to find a space where they can be themselves and where they are made to feel valued and part of this important work,” she said.

Over the past few years there has been a growing interest in community-based participatory research—doing research *with* a community rather than *on* it, said co-investigator Dr. Kenneth Mayer, medical research director of the Fenway Institute.

Earlier HIV research in Peru focused mainly on MSM; transwomen were

often overlooked. “A program that makes it clear that we want their involvement—and that we are not going to do anything without their input—is essential because there is a long legacy of mistrust,” Mayer said. “If they are going to engage, they really have to feel that they have a voice and a stake in the process.”

Such a collaboration builds trust, said co-investigator Dr. Sari Reisner, an affiliated research scientist at the Fenway Institute. “It has not only a greater chance of success, it helps the community feel empowered and want to participate.”

And transwomen especially need that empowerment, Huerta said. From an early age, they are ostracized, she said. “By rebuilding that confidence, that sense of ‘you are important, you are part of this, you too can get to where we are,’ we’ve begun to enable each of them to move forward,” Huerta said. “I think that’s fundamental—being able to rely on our experience and creating solutions that move us forward.”

Advocacy efforts have produced encouraging results: the Peruvian Ministry of Health has recently approved the first-ever policy to provide integrated care for transwomen within government health centers that includes feminizing hormone therapy to facilitate access to HIV and other treatment services.



Feminas study coordinator Leyla Huerta

Cervical Cancer in Asia: A Deadly but Preventable Epidemic

amfAR/Treat Asia report advocates expanded access to HPV vaccines

Annually, more than 500,000 women develop cervical cancer and 270,000 die from the disease. In Southeast Asia, it is the second most common cancer in women, with roughly 175,000 diagnoses annually. Virtually all cervical cancer is caused by the human papillomavirus (HPV).

HIV and HPV are dual epidemics that fuel each other in a deadly vicious circle: people living with HIV are at higher risk of contracting HPV and developing HPV-associated cancers, while infection with HPV increases susceptibility to HIV.

Since 2008, three highly effective HPV vaccines have been developed and approved in more than 100 countries. These vaccines provide population-level protection against cervical cancer not possible through screening alone.

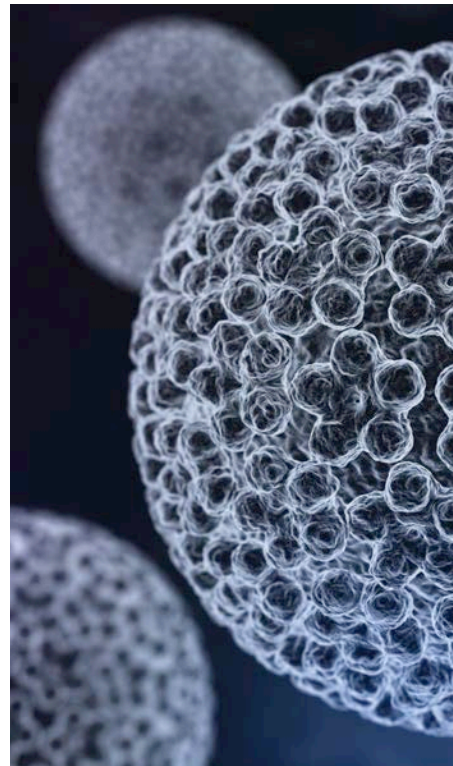
In spite of the vaccines' effectiveness, a new report from amfAR and its TREAT Asia program documents the slow uptake of HPV vaccination in Southeast Asia.

"Despite the proven effectiveness of HPV vaccines and the high burden of HPV-associated illnesses and mortality, many in the region who could benefit from the vaccines still do not receive them," said Jennifer Sherwood, a policy associate at amfAR and a primary author of the report.

The report recommends eligible countries apply for financial support from Gavi, the Vaccine Alliance. It also outlines steps countries can take to increase vaccination rates, such as including vaccinations in cancer prevention programs and offering them through school-based or community programs.

"By developing collaborative funding arrangements and innovative delivery strategies, regional public health programs can prevent cervical cancer," said Dr. Annette Sohn, director of TREAT Asia. "This is particularly important for women living with HIV."

Read the full report, Cervical Cancer, Human Papillomavirus (HPV), and HPV Vaccines in Southeast Asia, at <http://bit.ly/HPVBrief>



Helping Young People Transition to Adult Care

Transitioning through adolescence into adulthood can be difficult for most children, and even more so for those living with HIV, who face serious consequences if they stop taking their antiretroviral medicines.

There are 190,000 HIV-positive children under the age of 15 in Asia who will be making this transition over the coming years, and health care workers face major challenges in bridging the gap between pediatric and adult HIV care.

"Adolescent transition is a growing concern for TREAT Asia and our research network," said Dr. Annette Sohn, director of TREAT Asia. "This is a period of intense social, emotional, and mental development. We need more tools for young people, families,

and health care providers to better facilitate this process."

As part of its efforts, TREAT Asia has provided a grant to the Children and Youth Program

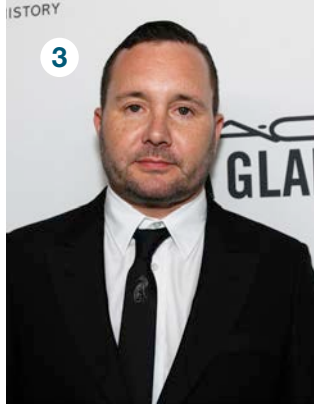
of SEARCH (South East Asia Research Collaboration on HIV) at the Thai Red Cross AIDS Research Centre in Bangkok to implement a transition model. The program currently cares for 210 youth living with HIV, most of whom were infected at birth.

The project involves volunteer youth leaders who are developing a curriculum that focuses on issues such as moving to adult care, treatment, communication, stigma, and coping with negative emotions. They are also doing peer counseling and outreach.

TREAT Asia is working with the Children and Youth Program to develop and adapt resource materials for network sites across the region.



SEARCH adolescent transition project staff work with clinical and community partners to develop their curriculum.



Inspiration Gala New York

amfAR honored Naomi Campbell and Louis Vuitton Men's Artistic Director, Kim Jones, with the Award of Inspiration at the seventh annual Inspiration Gala New York on June 9. Longtime amfAR supporter Whoopi Goldberg emceed the black-tie event, which included a live auction of luxury items, gala dinner, and a dazzling menswear runway show. Chart-topping singer/songwriter Zayn Malik presented the award to Jones while Wendy Williams bestowed the award on Campbell. The event, which raised \$1.2 million for amfAR, featured rousing musical performances by Jason Derulo and Nico & Vinz.

Special thanks: Harry Winston, M•A•C Viva Glam, The Points Guy, Moët Hennessy, Windows, Reca Group, and Delta Air Lines



@mrkimjones: Thanks @amfar for the honour ... Very kind thank you and thanks to all the people who came to support X



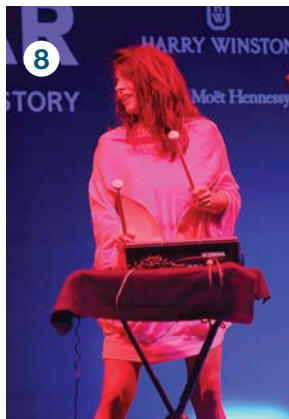
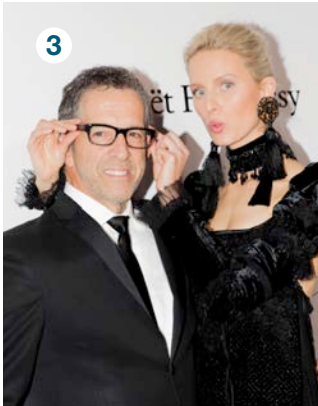
HARRY WINSTON

amfAR
MAKING AIDS HISTORY

COUNTDOWN TO A CURE TIMEPIECE

Twenty percent of the retail sales price will be donated to amfAR's efforts to develop the scientific basis of a cure for HIV by 2020.

1. Zayn Malik 2. Whoopi Goldberg 3. Honoree Kim Jones 4. amfAR CEO Kevin Robert Frost and Dwyane Wade 5. Gabrielle Union and honoree Naomi Campbell 6. UNAIDS Executive Director Michel Sidibé and amfAR Trustee Regan Hofmann 7. Jason Derulo had the crowd on their feet with a set of his biggest hits, including "Trumpets," "Wiggle," "Talk Dirty," and "Want to Want Me." 8. Nico & Vinz performed their smash hit "Am I Wrong." (Photos: amfAR and Kevin Tachman)



amfAR Milano

Heather Graham, Adriana Lima, Karolina Kurkova, amfAR Chairman Kenneth Cole, and many others joined the Italian fashion community at the eighth annual amfAR Milano gala on September 24. Held in conjunction with Milan Fashion Week, the spectacular evening featured live performances by Charli XCX and Brazilian Girls. Michelin star chef and host of *MasterChef Italia* Carlo Cracco presented entrepreneur Lapo Elkann with the Award of Courage for his personal commitment to ending the global AIDS epidemic. The gala raised nearly \$2 million for the Foundation, a record amount for amfAR Milano.

Special thanks: Harry Winston, Moët Hennessy, Delta Air Lines



amfAR Paris

Nearly 200 guests, including Adrien Brody, Naomi Campbell, Jennifer Garner, and amfAR CEO Kevin Robert Frost, gathered for an intimate black-tie dinner and auction to benefit amfAR at The Peninsula Paris on July 3. Grammy-nominated chanteuse Ute Lemper closed the evening with an unforgettable live performance.

Donatella Versace, Naomi Campbell, Adrien Brody, and Jennifer Garner (Photo: Ryan Emberley)

1. Heather Graham 2. Victoria's Secret Angels Adriana Lima and Sara Sampaio introduced two tickets to the most anticipated fashion event of the year, the 2016 Victoria's Secret Fashion Show. 3. amfAR Chairman Kenneth Cole and Karolina Kurkova 4. amfAR Global Fundraising Chairman Milutin Gatsby and honoree Lapo Elkann 5. generationCURE Ambassador Chiara Ferragni 6. Dita Von Teese presented Marilyn Monroe in Los Angeles, a 1961 photograph by Douglas Kirkland featuring the actress, model, singer, and icon naked in bed. 7. Charli XCX started a dance party with an explosive set of her top hits, including "Boom Clap," "I Love It," and "Break the Rules." 8. Brazilian Girls, a band featured on "The Time is Now!" compilation album to benefit amfAR, performed "Whip It," originally by Devo, "Wolkentanz," and "Let's Make Love." (Photos: Kevin Tachman, Getty Images, amfAR)



Inspiration Gala Los Angeles

Jeffrey Katzenberg and Charlize Theron were honored at the seventh annual Inspiration Gala Los Angeles on October 27 for their exceptional contributions to the fight against AIDS. Chelsea Handler presented the amfAR Award of Inspiration to Theron while Barry Diller bestowed the award on Katzenberg. Heidi Klum, Jon Hamm, Dita Von Teese, Jane Lynch, Lea Michele, Cheyenne Jackson, Victoria Justice, and amfAR Chairman Kenneth Cole were among those in attendance at the gala, which raised over \$2 million for amfAR. The evening ended with an explosive performance by Jason Derulo.

Special thanks: Harry Winston, M•A•C Viva Glam, Cadillac, Moët Hennessy, MILK, Delta Air Lines

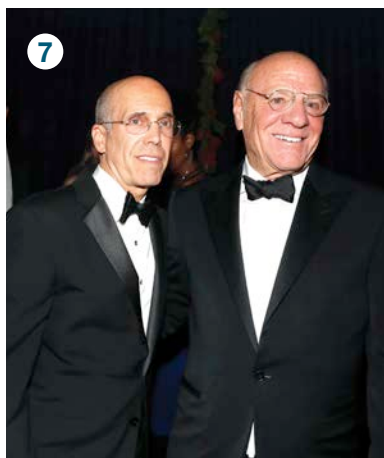


Bloomingdale's Fashionable Fundraiser

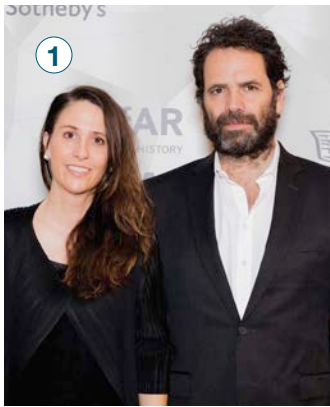
In August, Bloomingdale's made a \$75,000 donation to amfAR as part of its five-day annual Fashionable Fundraiser, a national campaign celebrating fashion and fitness. Bloomingdale's has been an amfAR supporter since 1986.

(Photo: amfAR)

@CharlizeAfrica: Thank you @amfAR for honoring me and my work with @CTAOP tonight. I'm more motivated than ever! #amfARInspiration #genendit



1. Jon Hamm 2. Lea Michele and Heidi Klum 3. amfAR Chairman Kenneth Cole, amfAR Trustee Jay Ellis, Nina Senicar, and amfAR Trustee T. Ryan Greenawalt 4. Jason Derulo ended the evening with an electrifying performance of his top hits, including "Whatcha Say," "Wiggle," "Talk Dirty," and "Want To Want Me." 5. Chelsea Handler and honoree Charlize Theron 6. Cheyenne Jackson and Jane Lynch performed Aladdin's "A Whole New World" as part of a Disney-themed tribute to honoree Jeffrey Katzenberg. 7. Honoree Jeffrey Katzenberg and Barry Diller (Photos: amfAR and Kevin Tachman)



TWO x TWO for AIDS and Art

Cindy and Howard Rachofsky hosted the 18th annual TWO X TWO for AIDS and Art dinner and art auction on October 22, raising \$7.5 million for amfAR and the Dallas Museum of Art. Actor Teddy Sears emceed the sold-out black-tie gala, which featured an electrifying performance by Ricky Martin. During the live auction, "Untitled" by Laura Owens, recipient of amfAR's 2016 Award of Excellence for Artistic Contributions to the Fight Against AIDS, sold for \$1.2 million.

Special thanks: Harry Winston, Cadillac, TODD Events, Dom Pérignon, Belvedere Vodka

1. Honoree Laura Owens with her gallery manager
2. Prabal Gurung and Nancy C. Rogers 3. Ricky Martin performed some of his biggest hits, including "Livin' La Vida Loca" and "Shake Your Bon-Bon." 4. Howard Rachofsky, Cindy Rachofsky, and John Benjamin Hickey. Cindy and Howard Rachofsky hosted the event at their Richard Meier-designed home. 5. Zoe Saldana 6. Howard Rachofsky and Jamie Niven 7. Teddy Sears, Eneuri Acosta, and Milissa Sears (Photos: Kevin Tachman)



generationCURE Holiday Party

Nearly 300 young professionals joined amfAR CEO Kevin Robert Frost, amfAR Chairman Kenneth Cole, and amfAR Trustee Jay Ellis at the third annual generationCURE holiday party on December 7 at the Cadillac House in New York City. Samantha Ronson and Jilly Hendrix DJed the event, which raised more than \$118,000 for HIV cure research.

Simone Missick, Yvonne Orji, Naturi Naughton, Serayah, and Mia Jordon (Photo: Getty Images)

Dallas is the place for love and that's mine. Always and forever @zoesaldana xPG.@amfar #twoxtwo by @kevintachman #prabaldoesdallas



@prabalgurung

SINCE *Kiehl's* 1851



"We're thrilled to continue to honor Kiehl's heritage of supporting HIV/AIDS awareness organizations by giving back to amfAR through initiatives like LifeRide. Throughout the history of LifeRide for amfAR, we've ridden 11,000 miles, raised more than \$1.6 million and funded eight cure-related grants, and we'll continue riding until we find a cure."

- Chris Salgado, President, Kiehl's USA

Kiehl's Since 1851, a New York-based skin and hair care brand, has been a staunch supporter of amfAR, The Foundation for AIDS Research, for two decades. In 2009, Kiehl's created several limited-edition products to benefit amfAR's innovative HIV/AIDS research programs. The following year, the company launched the Kiehl's LifeRide for amfAR, an annual motorcycle ride through major U.S. cities that includes high-profile events at Kiehl's stores to raise awareness about amfAR and the fight against AIDS. Kiehl's has raised more than \$1.6 million for amfAR.

Because of supporters like Kiehl's, amfAR is able to continue funding efforts to eradicate HIV/AIDS, and for that, the Foundation is profoundly grateful.

Upcoming Events

- | | |
|----------|--|
| March 25 | amfAR Gala Hong Kong
Hong Kong |
| April 27 | amfAR Gala São Paulo
São Paulo, Brazil |
| May 25 | amfAR Gala Cannes
Cap d'Antibes, France |

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