



Initiative for Medicines
Access & Knowledge

2016

Annual Report

ACRONYMS

A2M	ACCESS TO MEDICINES
ABC	ABACAVIR SULFATE (ZIAGEN®)
ARV	ANTIRETROVIRAL
DAC	DACLATASVIR (DAKLINZA®)
DNP+	DELHI NETWORK OF POSITIVE PEOPLE (INDIA)
EPO	EUROPEAN PATENT OFFICE
ETR	ETRAVIRINE (INTELENCE®)
HCV	HEPATITIS C VIRUS
HPV	HUMAN PAPILLOMAVIRUS
I-MAK	INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE
LED	LEDIPASVIR (WITH SOFOSBUVIR IN HARVONI®)
LMICS	LOW- AND MIDDLE-INCOME COUNTRIES
LPV/R	LOPINAVIR/RITONAVIR (KALETRA®)
MICS	MIDDLE-INCOME COUNTRIES
NVP	NEVIRAPINE HEMIHYDRATE (VIRAMUNE®)
OSF	OPEN SOCIETY FOUNDATION
RAL	RALTEGRAVIR (ISENTRESS®)
SOF	SOFOBUVIR (SOVALDI®)
TB	TUBERCULOSIS
TDF	TENOFOVIR DISOPROXIL FUMARATE (VIREAD®)
TDF/FTC/EFV	EFVIRENZ / EMTRICITABINE / TENOFOVIR (ATRIPLA®)
VEL	VELPATASVIR (WITH SOFOSBUVIR IN EPCLUSA®)

I-MAK IS A NON-PROFIT ORGANIZATION OF LAWYERS AND SCIENTISTS REPRESENTING THE RIGHTS OF LOW-INCOME PATIENTS WORLDWIDE. WE BELIEVE ALL PEOPLE HAVE THE RIGHT TO ACCESS AFFORDABLE, LIFE-SAVING MEDICINES FOR HIV/AIDS AND OTHER DISEASES. WE BELIEVE THE PATENT SYSTEM IS BROKEN AND DISPROPORTIONATELY REPRESENTS PRIVATE INTERESTS OVER PATIENT RIGHTS. OUR MISSION IS TO CHANGE THIS.

LETTER FROM THE FOUNDERS

2016 marks the ten year anniversary of I-MAK's founding. When we first dreamed about starting an organization to fight unjustified patents that stood in the way of life saving medicines over a kitchen table in India, we had no idea that it would take us to where we are today - working in 49 countries, participating in a global debate on access to medicines, and achieving real impact such as actual cost savings of **\$695M per year on lifesaving HIV treatments in four countries**.



Our tenth year was one of tremendous growth and reflection:

- In 2006 I-MAK began working on one disease in one country. Today the organization has expanded its work to **20 therapies for eight diseases in 49 countries**.
- We provided real-time support to partners in the wake of major cases they were mounting to ensure all people get the medicines they need (see [2016 Update](#)).
- Between 2013 and 2016, **I-MAK tripled its revenue** (See [Organizational Health](#)), surpassing a million dollars in revenue from new and existing donors. To absorb this growth, we spent a lot of time and resources this year developing infrastructure and systems.
- We focused on **increasing the visibility of IMAK**, and built a brand that is now recognized worldwide. We placed two high-profile op-eds (See [I-MAK in the Media](#)).
- While we grew and expanded, we **held true to our values and underwent a process to define I-MAK's principles** so we are tied to them as we continue to grow.
- Reflected on the organization's history and growth, and **invested in executive leadership and systems to absorb future growth**.

In the midst of this expansion, we reflected upon where the field of access to medicines is headed, I-MAK's niche within that field, and how the organization should evolve over the next ten years. We realized that we have spent the last ten years focusing and gathering evidence on the problem - unjustified patents that block access to affordable medicines for medicines - and want to spend the next ten years focusing on solutions.

Armed with our evidence and experience, we see I-MAK's role going forward as developing new solutions, leveraging our decade of work of conducting patent oppositions as a platform. We are now **evolving our strategy to spend the next decade designing and advocating for evidence-based, systemic solutions to effect even greater change**, and are excited for the new challenges and opportunities that lay ahead.



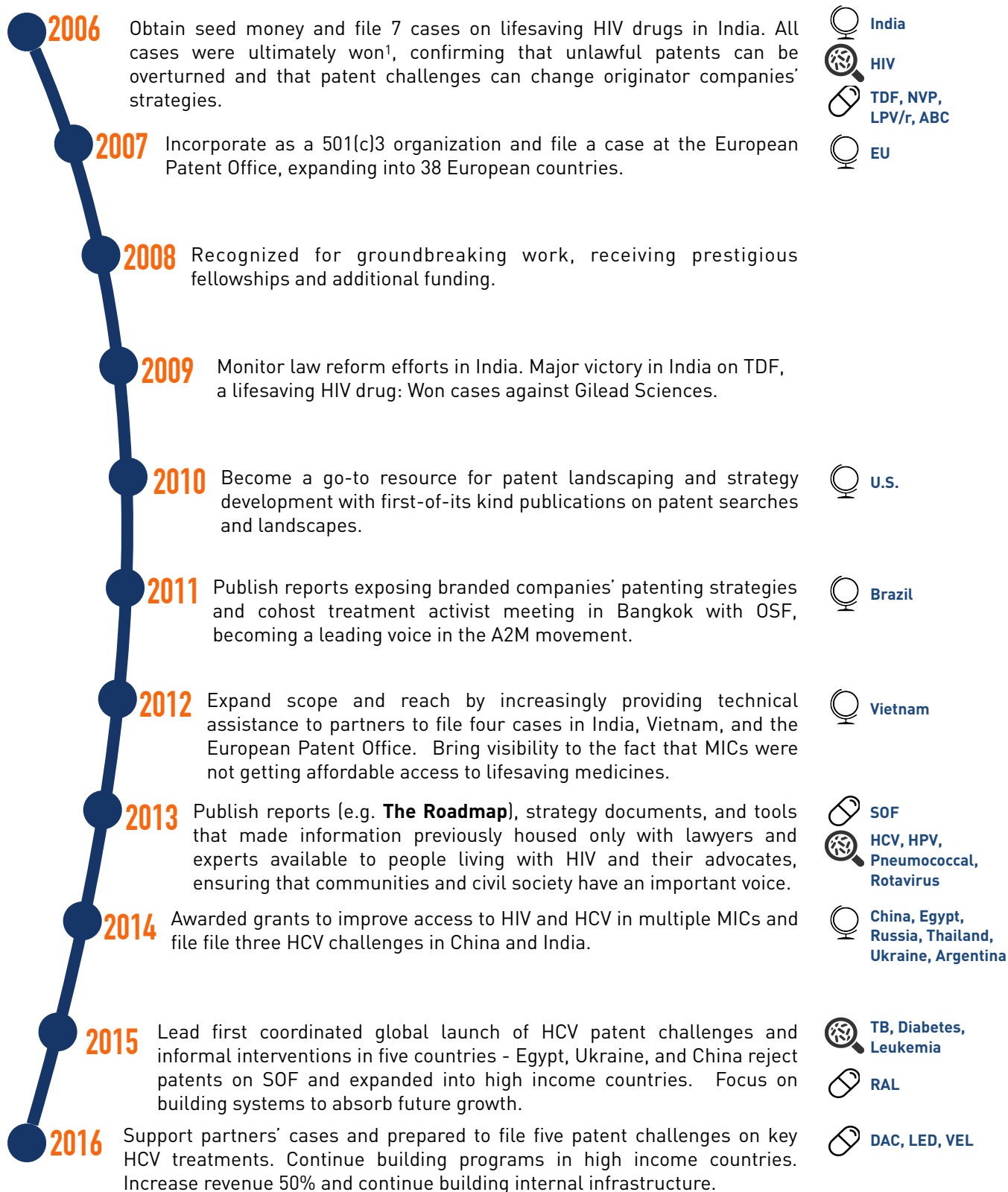
Tahir Amin



Priti Radha Krishtel

I-MAK's GROWTH TRAJECTORY

In 2006 I-MAK began working on one disease in one country. Today the organization has expanded its work to 20 therapies for eight diseases in 49 countries.



49 COUNTRIES // 23 THERAPIES // 8 DISEASES

¹ Patent application rejected by patent office and/or the originator company withdrew the patent application, abandoned the application, or reduced the price.

I-MAK'S FIRST 10 YEARS

Over the last decade, I-MAK has challenged unlawful patents, which has enabled generic competition that has reduced prices by up to 93%. Challenging patents on 3 ARVs alone in India has resulted in a half billion dollars in cost savings in 5 years for global purchases of these medicines – money that can be reinvested to treat 1 million patients.

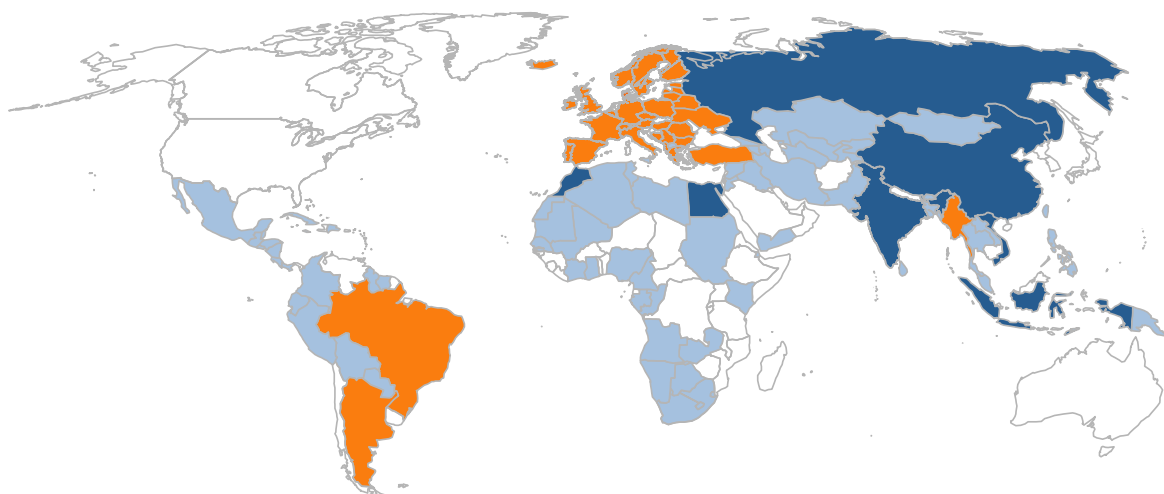


13 PATENT CHALLENGES FILED BY I-MAK

9 cases won¹ out of 11 decisions

>80% SUCCESS RATE

14 ADDITIONAL PATENT CHALLENGES FILED WITH I-MAK'S SUPPORT



Dark blue: Multi-country HCV interventions; Orange: Multi-country HCV & HIV interventions; Light blue: Countries impacted by I-MAK's work since 2006

PRICE

IMPACT



% PRICE REDUCTION ENABLED BY I-MAK²

51-76%

LPV/r

78%

ABC

84-89%

NVP
syrup

81-89%

TDF

72%

SOF

\$160B

HCV in 5
countries

I-MAK's cases on HCV patents in Argentina, Brazil, China, Russia, and Ukraine have the potential to impact 25 million people, resulting in cost savings of >160 billion dollars.

\$695M

ARVs in 4
countries

After two years of implementation, our interventions have already achieved approximately \$695M in annualized cost savings in Argentina, Brazil, Thailand, and Ukraine.³

* See page 2 for a complete list of acronyms.

¹ Patent application rejected by patent office and/or the originator company withdrew the patent application, abandoned the application, or reduced the price.

² Price reductions represent the difference between originator and generic prices. Originator ARV prices are from MSF's ARV pricing guide ("Untangling the Web of Price Reductions") from the edition published in the year the patent case was won. Price ranges are provided for originators that offer two tiers of prices for low- and middle-income countries. Source for originator price of SOF is "Diagnosis and Treatment of Hepatitis C: A technical landscape." MSF Access Campaign, April 2014. Generic ARV prices represent the lowest generic prices in the 18th edition of MSF's pricing guide (July 2016). For TDF, the Clinton Health Access Initiative (CHAI) 2016 Antiretroviral (ARV) CHAI Reference Price List. For generic SOF, we used the current market price produced by leading suppliers in India (World Hepatitis Alliance. An Introduction to Access to Generic Hepatitis C Medicines. 1 November 2016. Available: <https://goo.gl/hD6wDJ>).

³ I-MAK supported the challenges by our consortium partners: Fundación Grupo Efecto Positivo (Argentina), Associação Brasileira Interdisciplinar de AIDS (Brazil), AIDS Access Foundation (Thailand), and The All-Ukrainian Network of PLHIV

2016 UPDATE

LEGAL WORK

HIV I-MAK supported our partners to prepare patent challenges and in their law reform efforts. In addition, I-MAK continually monitors related cases worldwide to support partners for current and future cases.

Provided technical assistance for: LPV/r in Ukraine and ETR in Brazil.

Supported law reform efforts in: Argentina and Thailand.

HCV I-MAK supported our partners' cases and prepared to file five patent challenges on key HCV treatments, conducting landscapes on four drugs. In addition, we evolved our strategy as decisions were announced in our previously filed cases. In October, the European Patent office significantly limited the scope of Gilead's patent, potentially opening the door to generic Sovaldi® in Europe in the coming years.

Provided technical assistance for challenges in: Thailand.

Prepared cases for: SOF, DAC, LED, VEL

India SOF Base: I-MAK and DNP+ challenged the Indian Patent Office's decision to reverse its rejection of Gilead's patent at the High Court.

HIGHLIGHTS

- To date, I-MAK has worked with partner organizations to remove patent barriers against SOF in 46 countries, including Argentina, Brazil, China, Egypt, India, Russia, Thailand, and Ukraine, and in Europe (covering 38 countries).
- Three countries have rejected SOF patents: China, Ukraine, and Egypt.
- Potential cost savings in China alone are \$59B.

ADVOCACY & POLICY WORK

Over the past year, I-MAK laid the foundation for transformative change in the long-term by stimulating conversation, reactions, policy change, and galvanizing support among key audiences and actors.

- Participated and commented at the UN Secretary-General's High Level Panel on Access to Medicines to support country level law reform efforts.
- Responded to Senators Ron Wyden and Charles Grassley's request to the health-care and patient community for responses to the policy questions in their report on the price of Sovaldi®.
- Engaged in reporter capacity building efforts to help drive the public conversation on pricing and innovation.
- Initiated a U.S.-focused opinion program, publishing two op-eds and writing letters to the editor in response to articles on rising drug prices and issues of access at the Washington Post, the Boston Globe, LA Times, and the Denver Post. (See [I-MAK in the Media](#)).

* See page 2 for a complete list of acronyms.

YEAR OF GROWTH

2016

I-MAK's 10th year was one of growth. As the founders reflected on the past and looked ahead, I-MAK spent considerable effort and resources in smart growth and external engagement to prepare the organization for the next ten years.

2016 GROWTH SNAPSHOT

TRIPLED REVENUE

- I-MAK hit the million dollar mark in 2016, tripling revenue from 2013 (See **Organizational Health**).
- Diversified our donor base and renewed commitments from existing donors.

EXPANDED OUR BOARD

- Began transitioning our Board of Directors into a Governance Board, under the guidance of new Board member Lara Galinsky.
- Identified areas for growth, invited new Board members to join us, and created new processes for Board expansion.
- Initiated a 5-year strategic planning process.

DEVELOPED EXECUTIVE LEADERSHIP

- Directors worked with an Executive Coach
- Directors completed 360 Leadership Audits
- Directors attended the Management Center's training and are implementing best practices
- Developed internal documentation to define I-MAK's culture and processes.

CREATED SYSTEMS TO ABSORB GROWTH

- Worked closely with a finance management advisor to evolve our financial systems and policies, and formalize our Board structure.
- Actively requested and implemented auditor's recommendations for compliance best practices for an organization at scale.
- Developed more systems that allow I-MAK to grow, absorb more funds, and hire staff.

I-MAK IN THE MEDIA

The drug pricing crisis is exploding in high income countries. This year, we seized this opportunity to start elevating the root causes of the access problem in the US. By engaging with the media, we shine a light on drug company abuses and start to offer solutions to ensure people in the US and around the world get access to the medicines they need to stay healthy and alive.

THE DOWNFALL OF INVENTION: A BROKEN PATENT SYSTEM

Huffington Post // Tahir Amin

"A patent system with integrity will foster genuine inventions and the search for new knowledge – the benchmark of real progress that could allow better outcomes and better value for all."

THE FIRST-EVER DRUG TO TREAT ALL MAJOR HEP C STRAINS JUST GOT APPROVED

Fortune // Sy Mukherjee

"Gilead is abusing the patent system and driving prices out of reach, making it hard for consumers to have affordable access to treatment, and forcing taxpayers to foot the bill."

PHARMA'S SECRET WEAPON TO KEEP DRUG PRICES HIGH

Stat // Priti Radhakrishnan

"Our patent system should reward only true inventions in science and medicine. In the face of public health epidemics and out-of-control drug pricing, we need a patent system that achieves a better balance between the interests of corporations and the public."

INDIA'S PATENT PROBLEMS

Foreign Affairs // Sarah Asrar & Fran Quigley

Discussed how the Indian Patent Office's decision to reverse its refusal of a Sovaldi® patent "was due to political pressure."

ORGANIZATIONAL HEALTH

Between 2014-2016, I-MAK experienced 131% growth and tripled our operating budget. Our spending continues to be program-focused with only 15% General & Administrative expenses, which were necessary in order to build organizational capacity to absorb new revenue and restricted grants.

\$1,085,532

OPERATING SUPPORT & REVENUE SOURCES

Grants & contracts	\$1,084,530
Program service revenue	\$1,002

TOTAL **\$1,085,532**
% Change from 2015 **↑62%**

\$928,422

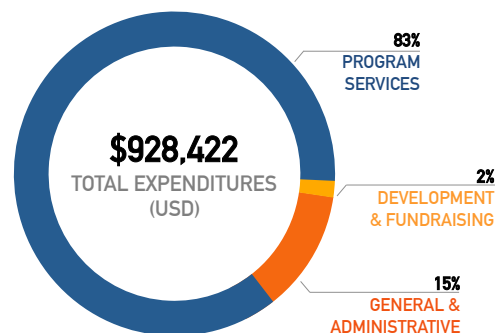
PROGRAM AND OPERATING EXPENSES

Program services	\$773,380
General and administrative	\$140,087
Development and fundraising	\$14,955

TOTAL **\$928,422**
% Change from 2015 **↑69%**

2016

OPERATING EXPENSES

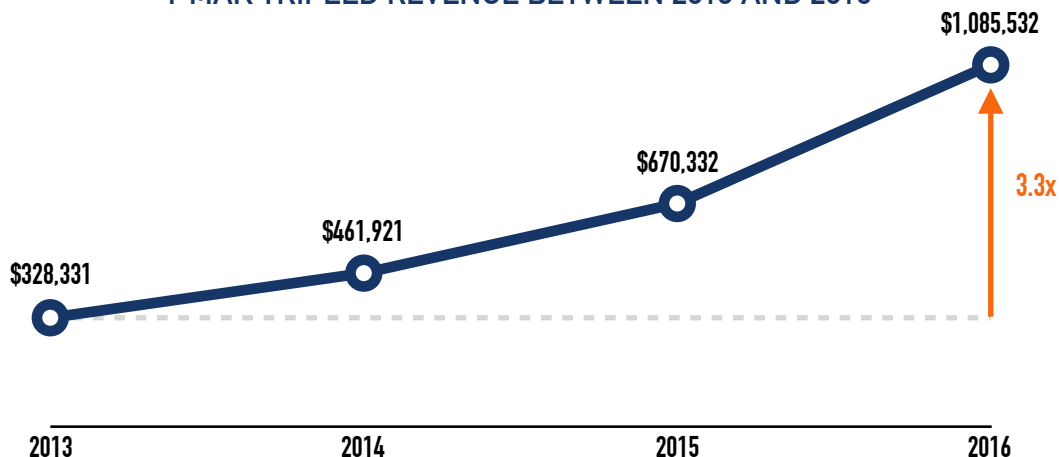


NET ASSETS

Beginning of year 2016
\$473,061

End of year 2016
\$781,794

I-MAK TRIPLED REVENUE BETWEEN 2013 AND 2016



"I-MAK'S PHILOSOPHY IS THAT GROWTH FOR GROWTH'S SAKE IS NOT THE WAY TO GO -- RATHER, A DELIBERATE, CAREFULLY THOUGHT OUT STRATEGY FOR WHERE THE NEED IS; WHERE THEY CAN BEST SERVE; AND KNOWING HOW TO BEST SCALE AND INVEST IN THE ORGANIZATION'S STAFF AND INFRASTRUCTURE IN ORDER TO SUPPORT THE GROWTH THAT IS CENTRAL TO OUR STRATEGY. FOR THIS REASON, I AM CONFIDENT THAT I-MAK IS POISED TO TAKE ON THE NEXT DECADE WITH RENEWED FOCUS, ENERGY, TALENTED STAFF AND STRONGER OPERATIONS."

Renu Saini

Board Chair, I-MAK Board of Directors & Program Officer, Walton Family Foundation

Complete financial statements available on request. Find I-MAK on www.guidestar.com.

I-MAK'S PARTNERS

I-MAK collaborates with global health organizations, local governments, civil society organizations and technical experts at some of the most prestigious universities to improve access to medicines in LMICs. These collaborations not only increase the number of people on life-saving medicines in LMICs, but also strengthen local capacity to ensure continued access.

GLOBAL

AIDS FONDS

ECHOING GREEN

INTERNATIONAL TREATMENT
PREPAREDNESS COALITION (ITPC)

MÉDECINS DU MONDE

MÉDECINS SANS FRONTIÈRES

OPEN SOCIETY FOUNDATIONS
PUBLIC HEALTH PROGRAM

PUBLIC CITIZEN

THIRD WORLD NETWORK

TREATMENT ACTION GROUP

WORLD HEALTH ORGANIZATION

COUNTRY

AIDS ACCESS FOUNDATION
(THAILAND)

ALL-UKRAINIAN NETWORK OF
PLHIV

ASIA PACIFIC NETWORK OF PEOPLE
LIVING WITH HIV/AIDS

ASSOCIAÇÃO BRASILEIRA
INTERDISCIPLINAR DE AIDS (ABIA)
(BRAZIL)

DELHI NETWORK OF POSITIVE
PEOPLE (DNP+) (INDIA)

FUNDACIÓN GRUPO EFECTO
POSITIVO (FUNDACIÓN GEP)
(ARGENTINA)

INDIAN NETWORK FOR PEOPLE
LIVING WITH HIV (INP+) (INDIA)

ITPCRU (EASTERN EUROPE/
CENTRAL ASIA) AND MIDDLE EAST
AND NORTH AFRICA

TREAT ASIA

I-MAK'S BOARD

Since its founding, I-MAK's voluntary Board of Directors has been composed of donors, academics, and practitioners in patent law, engineering, philanthropy, and business design.

REENA ABRAHAM Vice President of Education Programs at Local Initiatives Support Corporation

TAHIR AMIN Co-Founder & Director of Intellectual Property at I-MAK

LARA GALINSKY Entrepreneur in Residence at The Future Project

PRITI KRISHTEL Co-Founder & Director of Treatment Access at I-MAK

MONICA MEHTA Clinical Pharmacist in Infectious Diseases at New York-Presbyterian Hospital/ Columbia University Medical Center; Vice President of Public Policy for New York Society of Health-system Pharmacists (NYSCHP).

RENU SAINI Program Officer at Walton Family Foundation

DAVID WATSON Music producer and co-founder of the Zoo; Seed funder of I-MAK

I-MAK

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Access & Knowledge

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