

## Increasing Funding for TB Research: An Advocacy Strategy Webinar

November 16, 2016

Mike Frick, Treatment Action Group (TAG) Richard Chaisson, Johns Hopkins Center for Tuberculosis Research Christine Lubinski, Infectious Diseases Society of America (IDSA)

Moderator: Marcus Low, *Spotlight* Editor and former Head of Policy at Treatment Action Campaign (TAC)

## Webinar Instructions

to:

- All participants are in listen-only mode
- To ask questions, please use the chat feature on the webinar interface



## Agenda & Overview

- Agenda and Overview
  - Marcus Low, Spotlight Editor and Former Head of Policy at TAC
- U.S. Government funding for TB Research
  - Mike Frick, Senior TB/HIV Project Officer, TAG
- Scientific Community Perspective
  - Richard Chaisson, Director, JHU Center for TB Research
- TB Research & Development Advocacy
  - Christine Lubinski, Vice-President for Global Health, IDSA
- Q&A

## Mike Frick

Mike Frick is a senior project officer in TAG's TB/HIV Project, where he conducts advocacy to support TB vaccine research and promote community engagement in TB research more broadly. He coordinates the Community Research Advisors Group, the community advisory board to the U.S. CDC's Tuberculosis Trials Consortium and leads resource-tracking activities for TAG's annual *Report on Tuberculosis Research Funding Trends*. Mike holds a BA in international studies and Chinese from Kenyon College, and an MSc in global health and population from the Harvard School of Public Health.

# U.S. GOVERNMENT FUNDING FOR TB RESEARCH

AN ADVOCACY STRATEGY WEBINAR

MIKE FRICK TB/HIV SENIOR PROJECT OFFICER TREATMENT ACTION GROUP





#### **Stop TB** Partnership

#### 2016 Report on Tuberculosis Research Funding Trends, 2005–2015: No Time to Lose

October 2016 Treatment Action Group By Mike Frick

After Nov. 9, now more than ever!

#### GLOBAL TB R&D FUNDING, 2005–2015



# THE PUBLIC SECTOR PROVIDES 63% OF TB R&D FUNDING.

#### THE USG PROVIDED 67% OF PUBLIC FUNDING IN 2015.

# PRIVATE SECTOR FUNDING HAS DECLINED BY 40% SINCE 2011.



#### USG TB R&D FUNDING, 2005–2015 ALOOKAT THE BIG 3



## A CLOSER LOOK AT CDC FUNDING FOR TB R&D



- CDC conducts clinical trials of TB drugs and diagnostics (TBTC) and epidemiological studies (TBESC).
- Proven track record of success (3HP, PK/PD work, studies in PLHIV and children) yet nominal funding down by 33% between 2005–2015.
- To maintain purchasing power with 2009 funding (\$18.4 million), CDC funding would have needed to increase to \$21.0M in 2015; instead, it fell to \$13.3M.
- What would more funding enable? More MDR-TB trials. Studies to optimize existing TB drugs (e.g., PZA). Quicker study timelines. Mentorship for the next generation of TB scientists.

#### A CLOSER LOOK AT NIH TB R&D FUNDING



- Most funding comes from NIAID. In 2015, NIAID awards totaled \$178.7 million; all other NIH institutes and centers gave a combined \$34.9 million.
- NIH investments span from basic discovery to implementation science. The NIH gives 60% of all money spent on TB basic science worldwide.
- The activity of DAIDS clinical trials networks in TB research is of critical importance to TB drug, diagnostic, and pediatric research.
- NIH funding is critical at home—and abroad. For example, in 2015, South African TB research programs received more money from the NIH than from the SA MRC.



By Suraj Madoori Edited by Erica Lessem and Kenyon Farrow

June 2016

Proposed first-ever targets specific to USG funding for TB R&D:

Increase funding levels to \$300 million by FY2017
 Increasing funding from \$247M in 2014 to \$300M in 2017
 Not a true increase, just enough to keep pace with inflation
 Outlined how this \$53M increase could be spread across

various U.S. government agencies involved in TB research:

- NIH: \$17M
- USAID: \$15M
- **CDC**: \$16M
- **FDA**: \$5M
- Additional support to NSF, DOD, BARDA
- Increase funding levels to \$400 million by FY2020
   Average annual increase of \$33.3M would allow funding to outpace inflation (\$72M above 2009 purchasing power)

### **ILLUSTRATE RETURN ON INVESTMENT**

#### THAT INVESTMENT IN TB R&D IS LOW DOES NOT MEAN THAT TB R&D IS A BAD INVESTMENT

INNOVATION	PREVIOUS STANDARD OF CARE	ADVANTAGE OF NEW PRODUCT OR STRATEGY	U.S. AGENCIES Involved in Development	PARTNERS		
TB diagnosis						
GeneXpert MTB/RIF⁵	Sputum smear microscopy, which misses half of TB cases and cannot detect drug resistance. Doesn't work well in children or people with HIV	Rapidly and accurately detects TB, including resistance to the key drug rifampin, even in children and people with HIV	DoD, NIH, PEPFAR	find, Umdnj		
TB prevention						
<b>3HP</b> <sup>7,8</sup>	Nine months of daily therapy with isoniazid. Long, difficult to complete, and can cause liver damage	Much shorter and simpler 12 weeks of once-weekly therapy with isoniazid and rifapentine, which is less toxic to the liver	CDC (TBTC), NIH	Sanofi		
TB treatment (studies in progress)						
STREAM trials <sup>9</sup>	Treatment for MDR-TB over 18–24 months with expensive, toxic drugs including injections	If successful, treatment shortened to 9 or 6 months total, potentially with an injection-free regimen	USAID	The Union, Janssen		
<b>S31</b> <sup>10</sup>	Six months of daily treatment for standard (drug-sensitive) TB	If successful, treatment shortened to four months total	ACTG (NIH), CDC (TBTC)	Sanofi		

ACTG: AIDS Clinical Trials Group; CDC: Centers for Disease Control and Prevention; DoD: Department of Defense; FIND: Foundation for Innovative New Diagnostics; MDR-TB: multidrug-resistant tuberculosis; NIH: National Institutes of Health; PEPFAR: President's Emergency Plan For AIDS Relief; TB: tuberculosis; TBTC: Tuberculosis Trials Consortium; UMDNJ: University of Medicine and Dentistry of New Jersey; USAID: U.S. Agency for International Development.

## DEMONSTRATE THE BROAD BENEFITS OF TB RESEARCH

TO THE FIGHT AGAINST TB, AND TO MEDICAL SCIENCE AT LARGE



#### **TB R&D FUNDING UNDER TRUMP** A REALITY CHECK

- Cannot assume individuals in charge of science policy will be scientists or have scientific training. (Most will not).
- Those influencing science policy may even hold animosity toward science and academic research.
- Or they may exalt science as a concept while impugning the scientific method or weakening its essential elements (e.g., academic freedom, the university tenure system, independent drug regulation).
- Space travel is the only area of science for which Trump has expressed specific support—a statement he later tempered.
- As always, many debates about science funding and policy will take place in Congress, where the above points also apply.
- In this climate, approaches to science advocacy grounded in evidence and ethics will be more important than ever.

#### NEW MESSAGES. NEW MEDIA. NEW MOBILIZATIONS.

#### **TB R&D FUNDING UNDER TRUMP** SOME PARTING ENCOURAGEMENTS

• Science has both instrumental and intrinsic value.

Instrumental: enabling medical advances that save lives.

**Intrinsic**: "science is a form of human culture, a complex collaborative endeavor of meaning-making and creativity."[1]

- There may be a tendency in the coming years to only speak about science in its instrumental sense and in terms of a narrow instrumentality (e.g., national security). We can't stop speaking about the intrinsic value of science.
- We need both halves to make a whole case.

Scientific advancement and access to its benefits is indispensable for leading a life in human dignity and is a prerequisite for realizing other rights (e.g. health, life).

At the same time, good science is animated by and depends on democratic values. Freedom of expression. The right to

information. Universal education. Respect for persons.

[1] Lea Shaver "The Right to Science: Ensuring that Everyone Benefits from Scientific and Technological Advancement"

# REMEMBER WHAT WE'RE FIGHTING FOR

#### **THANK YOU!**

FOR IDEAS, QUESTIONS, OFFERS TO HELP---GET IN TOUCH:

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## **RICHARD CHAISSON**

Richard E. Chaisson, M.D., is Professor of Medicine, Epidemiology and International Health and directs the Center for AIDS Research and the Center for Tuberculosis Research at the Johns Hopkins University School of Medicine and Bloomberg School of Public Health in Baltimore, MD, USA. He received his BS and MD degrees from the University of Massachusetts and trained in internal medicine, infectious diseases, and clinical epidemiology at the University of California, San Francisco. In 1988 he was recruited to Johns Hopkins to run its AIDS Service and for 10 years led a clinical program providing care to more than 3000 people with HIV and conducted research on the natural history and treatment of the disease. He was Medical Director of the Baltimore City Health Department's Tuberculosis Control Program from 1992-1998. He is founder and director of the Center for TB Research, a multidisciplinary institute dedicated to the study of TB from bench to bedside to community. His research interests focus on tuberculosis and HIV infection, including global epidemiology, clinical trials, diagnostics and public health interventions. From 2002-2014 he led the Consortium to Respond to the AIDS-TB Epidemic (CREATE), a Gates Foundation-sponsored research consortium studying novel public health approaches to reduce the burden of HIV-related TB. Since 2011 Dr. Chaisson has served as Chair of the TB Transformative Science Group of the AIDS Clinical Trials Group and is leading the network's efforts in developing new TB therapeutic regimens. He assumed leadership of the Johns Hopkins CFAR, re-establishing and revitalizing a trans-disciplinary program to catalyze innovative HIV research at Hopkins, with a special focus on combatting the Baltimore epidemic. Dr. Chaisson has published over 490 scientific papers and book chapters.

### Scientific community perspective

### Richard E. Chaisson, MD Center for AIDS Research Center for TB Research Johns Hopkins University





## Outline

- Why is research needed?
- A framework for research to accelerate TB control
- Diagnostics
- Treatment
- Prevention
- Implementation and delivery

# **The Global Burden of TB -2015**



	Estimated number of cases	Estimated number of deaths	
All forms of TB	10.4 million (8.7–12.2 million) (IR=142/100,000)	1.8 million* (1.5-2.1) *1.4 million among HIV negative	
HIV-associated TB	1.2 million (11%) (1.0–1.3 million)	<b>390,000 (22%)</b> (320,000-460,000)	
MDR TB / RR TB	580,000 (520,000-640,000)	250,000 (160,000–340,000)	

Source: WHO Global Tuberculosis Report 2016

## **TB** is now leading infectious cause of death globally

Estimated number of deaths from HIV/AIDS and TB in 2015. Deaths from TB among HIV-positive people are shown in grey.<sup>a,b</sup>



WHO. Global Tuberculosis Report 2016

#### Modeled approaches to reaching TB elimination



Dye, et al., Ann Rev Publ Health 2013

### A Platform for Controlling Global Tuberculosis and the Research Needs to Achieve It

- FIND the TB that is there
  - Improved diagnostic technologies
  - Improved diagnostic strategies
- TREAT the TB that is found
  - New drugs to shorten TB treatment
  - Improved treatment for M/XDR
  - Improved strategies for delivering care
- **PREVENT** the TB that hasn't occurred yet
  - Biomarkers to identify those at greatest risk
  - Better preventive therapy regimens
  - Better control of susceptibility (e.g., diabetes, HIV, smoking)
  - New vaccines



Priorities and Opportunities in TB Diagnostics

- Rapid, sensitive, and specific molecular diagnostics
  - Drug susceptible TB
  - MDR/XDR TB
- Whole-genome sequencing to understand drug resistance
  - Design better diagnostic assays
  - As a clinical test?
- Biomarkers to predict risk, disease, and response to treatment

## Priorities and Opportunities in TB Diagnostics

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  - Design better diagnost
  - As a clinical test?



Biomarkers to predict risk, disease, and response to treatment

### A blood RNA signature for tuberculosis disease risk: a prospective cohort study

Daniel E Zak\*, Adam Penn-Nicholson\*, Thomas J Scriba\*, Ethan Thompson†, Sara Suliman†, Lynn M Amon, Hassan Mahomed, Mzwandile Erasmus, Wendy Whatney, Gregory D Hussey, Deborah Abrahams, Fazlin Kafaar, Tony Hawkridge, Suzanne Verver, E Jane Hughes, Martin Ota, Jayne Sutherland, Rawleigh Howe, Hazel M Dockrell, W Henry Boom, Bonnie Thiel, Tom H M Ottenhoff, Harriet Mayanja-Kizza, Amelia C Crampin, Katrina Downing, Mark Hatherill, Joe Valvo, Smitha Shankar, Shreemanta K Parida, Stefan H E Kaufmann, Gerhard Walzl, Alan Aderem, Willem A Hanekom, for the ACS and GC6-74 cohort study groups‡

#### The process of TB diagnosis.



Dowdy DW, Cattamanchi A, Steingart KR, Pai M (2011) Is Scale-Up Worth It? Challenges in Economic Analysis of Diagnostic Tests for Tuberculosis. PLOS Medicine 8(7): e1001063. doi:10.1371/journal.pmed.1001063

## Global TB Drug Pipeline<sup>1</sup>

Discovery Preclinical Development		Clinical Development			
				)	
Lead Optimization	Early Stage Development	GLP Tox	Phase 1	Phase 2	Phase 3
Diarylouinolines	TBI-166	BTZ-043*	Q203*	Sutezolid (PNU-100480)	Rifapentine - Moxifloxacin for Drug Sensitive TB
InhA Inhibitor, Ureas	CPZEN-45*	PBTZ-169*	PBTZ169*	Linezolid EBA	Delamanid (OPC-67683) with
Macrolides, Azaindoles	1599*	TBA-7371*	OPC-	SQ-109*	OBR for MDR-TB
Mycobacterial Gyrase Inhibitors Pyrazinamide Analogs	SATB-082*	GSK-070*	167832*	High Dose Rifampicin for DS-TB	Pretomanid-Moxifloxacin- Pyrazinamide Regimen (STAND)
Ruthenium(II)Complexes Spectinamides				Bedaquiline (TMC207)- Pretomanid (PA-824) - Pyrazinamide Regimen	Bedaquiline-Pretomanid- Linezolid NiX-TB Regimen
Mmp13, Oxazolidinones, Pyrimidines DprE1, Aryl Sulfonamides, PKS13, Squaramides				Levofloxacin with OBR for MDR-TB	Bedaquiline-STREAM MDR-TB Trial Stage 2 with oral OBR (9 mo) or OBR with injectables (6 mo)
					Bedaguiline-Linezolid with OBR

Chemical classes: fluoroquinolone, rifamycin, oxazolidinone, nitroimidazole, diarylquinoline, benzothiazinone, , imidazopyridine amide. New chemical class\*

<sup>1</sup>Details for projects listed can be found at <u>http://www.newtbdrugs.org/pipeline.php</u> and ongoing projects without a lead compound series identified can be viewed at <u>http://www.newtbdrugs.org/pipeline-discovery.php</u>

<sup>2</sup>OBR = Optimized Background Regimen



for MDR-TB (NExT Trial)

#### www.newtbdrugs.org

Updated: October 2016

## Global TB Drug Pipeline<sup>1</sup>

Discovery Preclinical Development		Clinical Development						
	, I							
Lead Optimization	Early Stage Development	GLP Tox	Phase 1		2	>	Phase 3	
Diarylquinolines DorE Inhibitors	TBI-166	BTZ-043*	Q203*	Sutezolid (PNU-3	100480)	Rifapenti Drug Sens	ne - <mark>Moxifloxacin for</mark> sitive TB	
InhA Inhibitor, Ureas	CPZEN-45*	PBTZ-169*	PBTZ169*	Linezolid EBA		Delamani	d (OPC-67683) with	
Macrolides, Azaindoles	1599*	TBA-7371*	OPC-	SQ-109*		OBR for MDR-TB		
Mycobacterial <u>Gyrase</u> Inhibitors Pyrazinamide Analogs	SATB-082*	GSK-070*	167832*	High Dose Rifam DS-TB	picin for	Pretoman Pyrazinan	<mark>id-Moxifloxacin-</mark> nide Regimen (STAND)	)
Ruthenium(II)Complexes Spectinamides				Bedaquiline (TM Pretomanid (PA- Pyrazinamide Re	IC207)- 824) - gimen	Bedaquili Linezolid	ne- <u>Pretomanid-</u> NiX-TB Regimen	
Mmp13, Oxazolidinones, Pyrimidines DprE1, Aryl Sulfonamides, PKS13, Squaramides				Levofloxacin wit MDR-TB	- h OBR for	Bedaquili Trial Stage or OBR wi	ne-STREAM MDR-TB 2 2 with oral OBR (9 m ith injectables (6 mo)	10)
~~~~~						Bedaquili	ne-Linezolid with OBF	3

Chemical classes: fluoroquinolone, rifamycin, oxazolidinone, nitroimidazole, diarylquinoline, benzothiazinone, , imidazopyridine amide. New chemical class\*

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<sup>2</sup>OBR = Optimized Background Regimen

www.newtbdrugs.org

ON NEW TB DRUGS

NG GROUP

for MDR-TB (NExT Trial)

Updated: October 2016

## The Path to New TB Drugs



## **TB Clinical Trials Sites**





#### **TB Trials Consortium**

AIDS Clinical Trials Group/IMPAACT

Other trials groups: PanACEA, Inter-TB, END TB Multiple additional trial sites for specific studies

## The ACTG TB Transformative Science Group Scientific Agenda

#### 1.0 **TB TREATMENT SHORTENING**

To identify regimens to shorten Drug-Susceptible TB treatment to  $\leq$ 3 months in patients with and without HIV

#### 2.0 **MDR-TB TREATMENT**

To identify regimens for MDR TB treatment in <6 months in patients with and without HIV

#### 3.0 **PREVENTIVE THERAPY**

To identify regimens to treat latent TB in 1 month and MDR-TB infection in 6 months; to improve latent TB therapy in HIV-infected individuals



## A5356: Schema

- Study design: Phase 2a, open-label, RCT
- Projected duration: 24 weeks per participant
- Sample Size: 320 participants (80/arm)
- Study Regimens/Treatment Arms (Arms A, B, and C exclude injectable second-line TB drugs):
  - -Arm A: Linezolid 300 mg/d + delamanid 100 mg twice daily + OBT
  - -Arm B: Linezolid 600 mg/d + delamanid 100 mg twice daily + OBT
  - Arm C: Linezolid 1200 mg every other day + delamanid 100 mg twice daily + OBT
  - -Arm D: delamanid 100 mg twice daily + OBT (with injectable)



#### A5362 – Clofazimine plus standard therapy to shorten TB treatment

#### 2-Stage Trial



<u>Hypothesis</u>: CFZ-containing regimen 12-week culture conversion proportion will be sufficiently high to rule out an unacceptable lower bound



<u>Hypothesis</u>: Relative to SOC, CFZ-containing regimens will have <u>non-inferior</u> 52-week treatment outcomes

#### Nix-TB Trial

Patients who have XDR TB, who have failed MDR TB treatment or who have MDR TB treatment intolerance



\*\*Just amended from 600 mg bid strategy



### Planned trials of treatment of latent MDR TB

	TB-CHAMP	V-QUIN	PHOENIx
Intervention	Levofloxacin vs.placebo daily for 6 months	Levofloxacin vs placebo daily for 6 months	Delamanid vs INH daily for 26 weeks
Design	Cluster randomized; superiority Community-based	Cluster randomized; superiority Community-based	Cluster randomized; superiority
Target Population	<ul> <li>0-5 y regardless of TST or HIV status</li> </ul>	<ul> <li>All ages (&lt;15y currently on hold)</li> <li>TST +</li> </ul>	<ul> <li>HIV +</li> <li>Children 0-5 yrs</li> <li>TST/IGRA + &gt; 5 y</li> </ul>
Assumptions	LVF decreases TB incidence from 7 to 3.5%; 80% power	LVF decreases TB incidence by 70% from 3% untreated; 80% power	DLM decreases TB incidence by 50% from 5% to 2.5%; 90% power
Sample size	778 Households 1556 contacts	1326 Households 2785 contacts	1726 Households 3452 contacts
Sites	South Africa	Viet Nam	ACTG & IMPAACT sites

### TEMPRANO: Immediate vs Deferred ART Initiation and IPT Delivery for African Patients Not 'Eligible' for ART



# Provision of TB preventive treatment to people living with HIV, 2005–2015<sup>a</sup>



WHO. Global TB Report, 2016

#### The Cascade of Care for Latent TB



Alsdurf et al., Lancet ID, 2016

#### TEKO Study – IGRA Blood Test vs Skin Test to Screen HIV+ People for TB



Martinson and Golub, 2016

#### TEKO Study – IGRA Blood Test vs Skin Test to Screen HIV+ People for TB



Martinson and Golub, 2016

## What could more investment achieve?

#### • Discovery

- New drugs, vaccine candidates, diagnostic technologies, biomarkers
- Trials
  - Treatment shortening
  - MDR/XDR treatment (shortening)
  - ?Universal regimen
  - Preventive therapy
- Implementation and Delivery
  - Improved uptake and impact of interventions

## Christine Lubinski

Christine Lubinski is vice president of Global Health and director of global health activities at the Infectious Diseases Society of America (IDSA) – a membership organization representing physicians, scientists and other health care professionals who specialize in infectious diseases. Under the leadership of a world-renowned group of HIV and TB scientific experts, Ms. Lubinski and her staff f haven been focused on the U.S. government response to the global HIV and TB epidemics, including research and development and service programs, and have recently expanded the focus to include other global infectious disease threats. IDSA Global Health brings the voices of physician scientists to federal policy and funding discussions about the world's leading infectious disease killers.

## **TB Research & Development Advocacy**

Christine Lubinski Vice-President for Global Health Infectious Diseases Society of America



# Momentum in TB R& D

- There is progress and we should highlight it in advocacy
- Progress in the pipeline with more resources needed to move products through trials and to the bedside
- TB progress is vital to ending HIV as a public health threat, reductions in maternal and child mortality and achievement of many SDGs, including universal health care.

#### NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Vision: The United States will work domestically and internationally to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria by implementing measures to mitigate the emergence and spread of antibiotic resistance and ensuring the continued availability of therapeutics for the treatment of bacterial infections.

September 2014



## Antimicrobial resistance is a bipartisan concern

- Congress has appropriated funds and many Republicans are on board.
- UK report says drug-resistant TB is a major AMR threat and is and will continue to be huge contributor to sickness and death.
- MDR-TB is already a reality in the US, and Ebola and Zika have demonstrated that global threats are local threats.

#### NATIONAL ACTION PLAN FOR COMBATING MULTIDRUG-RESISTANT TUBERCULOSIS



Vision: The United States will work domestically and internationally to contribute to the prevention, detection, and control of multidrug-resistant tuberculosis in an effort to avert tuberculosis-associated morbidity and mortality and support a shared global vision of a world free of tuberculosis.

December 2015



# A new day- White House & Congress

- Calling on TB advocates and researchers from New York and Indiana
- Educating new Senators Todd Young
- A poll conducted by Research America found only 17 percent of Americans could name a living scientists- We need to mobilize living TB scientists
- Most Americans could not identify anywhere where research is conducted-only 15 percent named NIH.

#### National Institutes of Health Director Francis Collins



## Federal agency leaders matter to TB R & D

- NIH director plays a significant role in allocating research dollars to Institutes and diseases.
- The USAID director has a role in allocating R&D dollars to TB
- The CDC director oversees a portfolio on global and domestic TB including R& D activities.
- We must engage them

# **Questions?**

• To ask questions, please use the chat feature on the webinar interface



## Additional resources

- 2016 Report on Tuberculosis Research Funding Trends, 2005– 2015: No Time To Lose
- An Activist's Guide to Tuberculosis
   Drugs 2016 Update
- Breakthrough: Catalyzing R&D to End TB



#### AN ACTIVIST'S GUIDE TO Tuberculosis Drugs

ROFALIN ROFALIN	BRATE BRATE	RIFALE	BRATE BRATE
REAL	Erre	ROFALS	ARTE
REALE	BRANTE	REFOLDE	GRACTE
2016 UPDATE	11/10/01/14		TAG

....available at: www.treatmentactiongroup.org/tb/publications

# Thank you!

- Contact:
  - Mike Frick, Senior TB/HIV Project Officer, mike.frick@treatmentactiongroup.org
  - Suraj Madoori, Senior Health Policy Officer, <u>suraj.madoori@treatmentactiongroup.org</u>