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TO END THE TUBERCULOSIS EPIDEMIC

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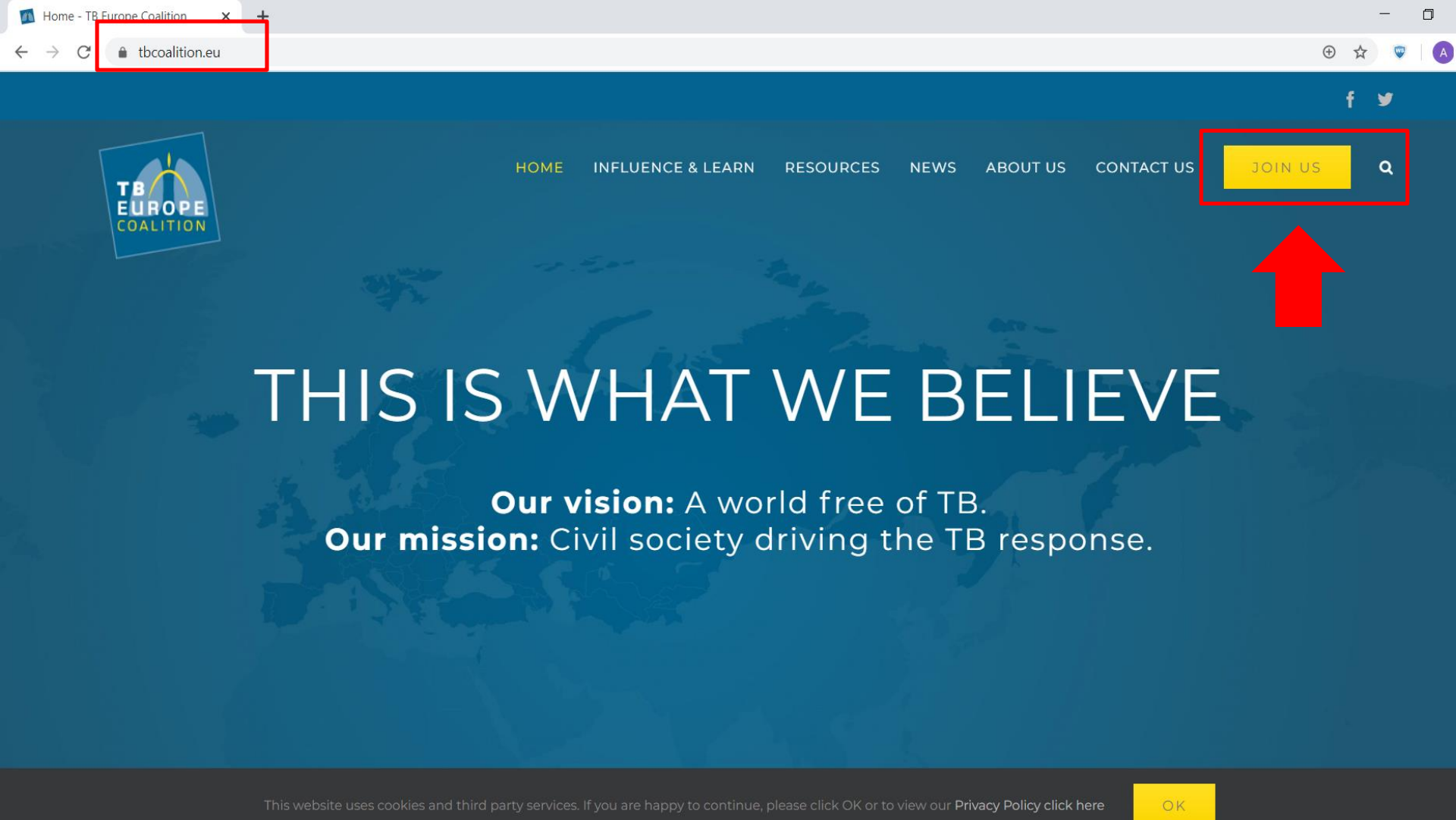
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## **SECOND Webinar within the cycle of webinars**

**Opportunities for civil society and TB communities from EECA  
region within the Global Fund Allocation Cycle 2020-2022**

**May 15, 2020**



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# THIS IS WHAT WE BELIEVE

**Our vision:** A world free of TB.

**Our mission:** Civil society driving the TB response.

# The United Nations High Level Meeting (UNHLM). Goals and Financial Consequences for the Countries of Eastern Europe and Central Asia

Opportunities for civil society and TB communities from EECA Region within the Global Fund funding cycle 2020-2022

D-r Asker Ismailov, Master of Public Health, PhD, technical advisor on advocacy at the *Secretariat of STOP TB Partnership, Geneva*

# The Global Plan to End Tuberculosis, 2018-2022

## People-centred global targets: 90-(90)-90

Reach at least

**90%**  
**OF ALL PEOPLE  
WITH TB**

and place all of them  
on appropriate therapy—  
first-line, second-line and  
preventive therapy as  
required

As a part of this approach,  
reach at least

**(90)%**  
**OF THE KEY  
POPULATIONS**

the most vulnerable,  
underserved, at-risk  
populations

Achieve at least

**90%**  
**TREATMENT  
SUCCESS**

for all people diagnosed  
with TB through  
affordable treatment  
services, adherence to  
complete and correct  
treatment, and social  
support.



**All stakeholders, partners  
and country programs  
should use this plan for  
2018-2022 rr.**

# The UN High-Level Meeting (UNHLM) on TB, 26 September 2018.

United Nations



General Assembly

A/RES/73/3

Distr.: General  
18 October 2018

Seventy-third session  
Agenda item 129

## Resolution adopted by the General Assembly on 10 October 2018

[without reference to a Main Committee (A/73/L.4)]

### 73/3. Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis

The General Assembly

Adopts the following political declaration approved by the high-level meeting of the General Assembly on the fight against tuberculosis on 26 September 2018:

#### Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis

**United to end tuberculosis: an urgent global response to a global epidemic**

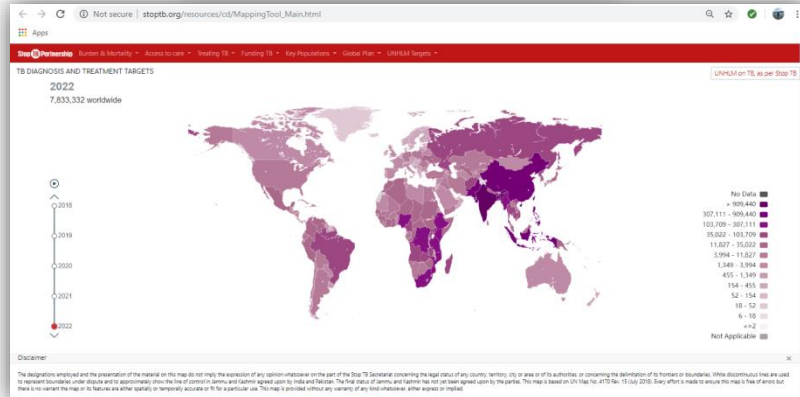
We, Heads of State and Government and representatives of States and Governments, assembled at the first time on the global tuberculosis epidemic, reaffirm our commitment to ending the tuberculosis epidemic globally by 2030 in line with the Sustainable Development Goals target, commit to work together to accelerate our national and global collective actions, investments and innovations urgently to fight

## UN HIGH-LEVEL MEETING ON TB KEY TARGETS & COMMITMENTS FOR 2022



Stop TB Partnership  
hosted by  
UNOPS

END  
TB



- Total people with TB: 40 mln
- Children with TB: 3.5 mln
- MDR TB cases: 1.5 mln
- Children with MDR TB: 115,000
- TB preventive therapy: >30 mln

- Total: US\$ 13 billion annually in 2018-2022 period.
- Investment in R&D of new medicines: US\$ 2 billion annually in 2018-2022 period

[http://www.stoptb.org/resources/cd/MappingTool\\_Main.html](http://www.stoptb.org/resources/cd/MappingTool_Main.html)

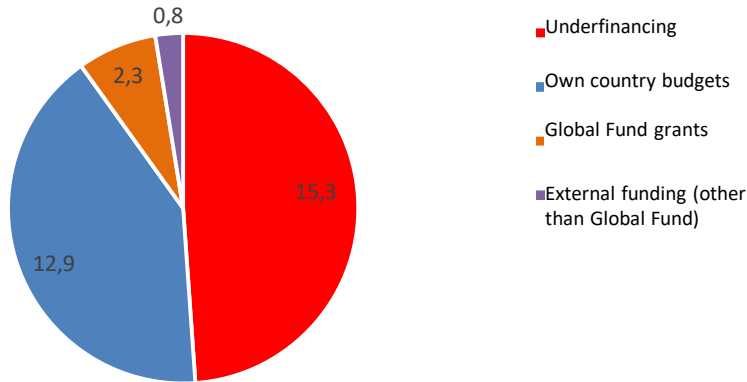
## UNHLM TB Related Targets for Individual Countries, 2018 – 2022

- ✓ TB related country targets
  - ✓ Drug-resistant TB country targets
  - ✓ Childhood TB country targets
  - ✓ Preventive therapy targets
  - ✓ Resource needs for TB prevention and care
- 
- ✓ For people already on treatment, these targets were specified for countries and years, with the exclusion of children with MDR TB, for which these targets will be specified after the receipt of data from WHO
  - ✓ Funding targets were specified for individual countries.

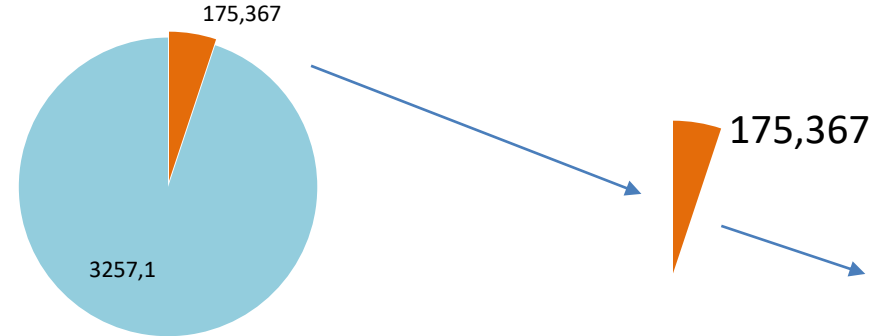
<http://www.stoptb.org/resources/countrytargets/>

# Financial needs in the countries eligible for the targeted global funding to achieve the UN goals on TB

Global needs, US\$ bln,  
2020 – 2022

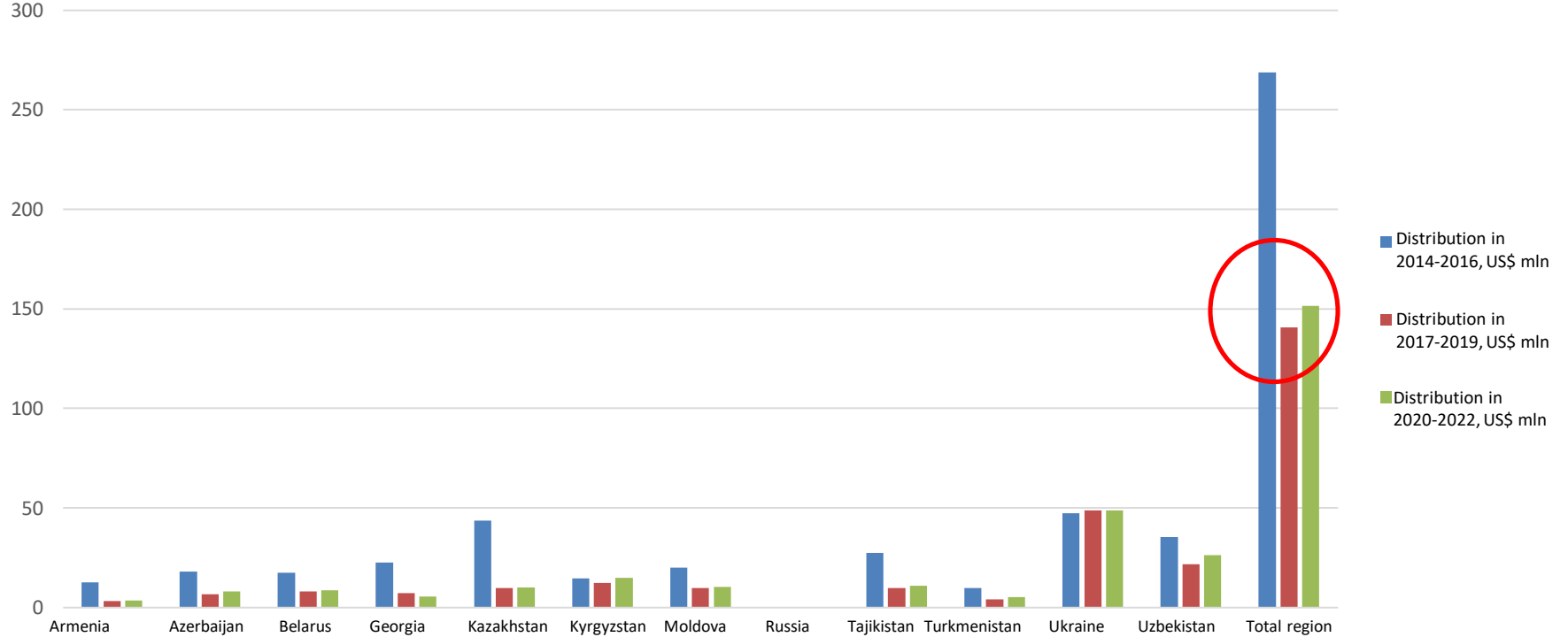


Needs in Eastern Europe and Central Asia, US\$  
mln  
2019

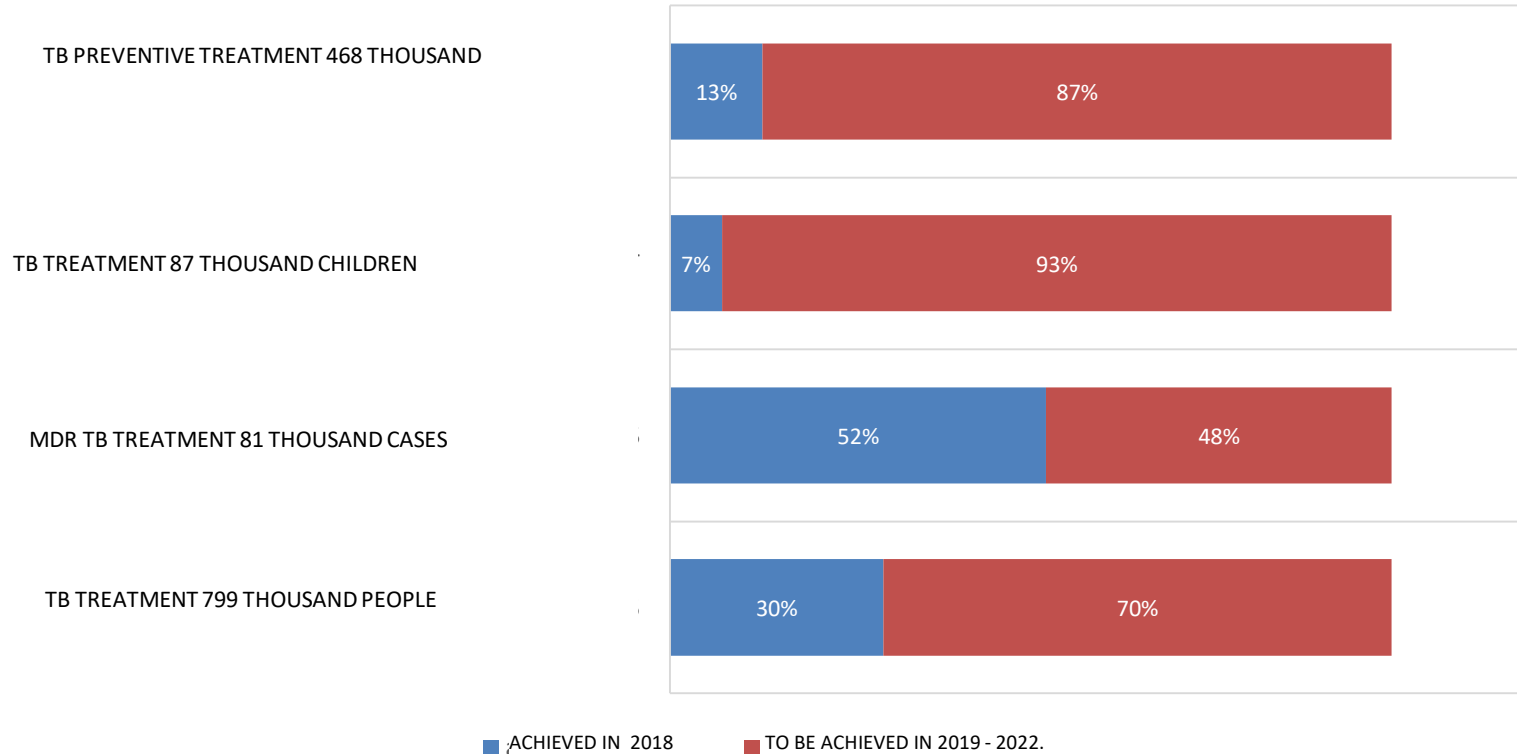




## Distribution of targeted global financing between the regions



# Progress in Eastern Europe and Central Asia in 2018 in comparison with the overall UNHLM treatment targets for 2018-2022



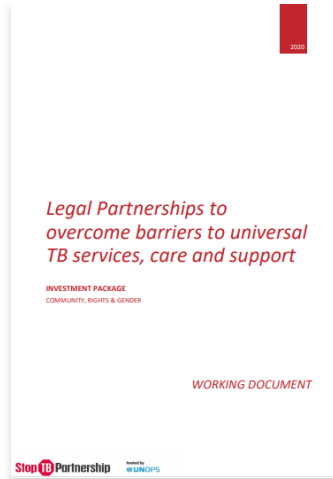
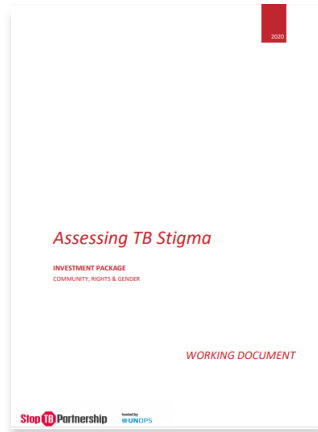
## Further development for the countries

- **Increased educational activities** on a country level in relation to UNHLM goals
- **Development / upgrading** of the national programs in line with the UNHLM goals and own country assessments
- **Evaluation, arrangement and planning of domestic financial resources**



# Evaluation, arrangement and planning of domestic financial resources

## CRG Investment Packages



(<http://www.stoptb.org/communities/>)

# Please, pay a special attention!

- TB and COVID-19: What should be done?
  - At least 5 years of progress have been lost
  - 3-month of strict isolation and 10 months needed to restore the system of service provision may result in additional 6.3 million TB infection cases and 1.4 million TB related deaths in 2020 - 2025

TB AND COVID-19 → **INTERACTIVE MAPS**

**MODELING STUDY**  
GLOBAL IMPACT OF COVID-19 ON TB TREATMENT AND CARE →

<http://www.stoptb.org/covid19.asp>

# TB AND COVID-19

**#ItsTimetoEndTB**

**#FightCOVID19**



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**May 15, 2020**

# Access to new DR-TB regimens

Sharonann Lynch  
Christophe Perrin  
MSF Access Campaign  
TBEC Webinar  
15 May 2020

## MSF Access Campaign Technical Brief

SEPTEMBER 2019  
(UPDATED OCTOBER 2019)



## MAKING THE SWITCH

### Saving More Lives with Optimal Treatment for Drug-Resistant TB

#### INTRODUCTION

Multidrug-resistant tuberculosis (MDR-TB) is defined as TB that is resistant to isoniazid and rifampicin, with or without resistance to other first-line drugs.<sup>1</sup> Pre-extensively drug-resistant TB (pre-XDR-TB) is defined as resistance to at least isoniazid and rifampicin as well as either second-line injectables or fluoroquinolones (levofloxacin or moxifloxacin) but not both. Extensively drug-resistant TB (XDR-TB) is defined as resistance to at least isoniazid and rifampicin, any fluoroquinolone and any of the three second-line injectable agents (amikacin, capreomycin or kanamycin).<sup>2</sup> XDR-TB is more difficult to treat, and cure, than MDR-TB.

Drug-resistant tuberculosis (DR-TB) requires use of second-line treatment regimens, which may include repurposed or newer TB drugs. The previously recommended DR-TB treatment regimens used by most countries had a high pill burden, long treatment duration (of up to two years), painful daily injections (for up to eight months), severe side effects (due to toxic drugs) and poor treatment outcomes. These suboptimal regimens achieved treatment success rates of only 55% for people with multidrug-resistant/rifampicin-resistant tuberculosis (MDR/RR-TB) and 34% for people with XDR-TB.<sup>3</sup>

The World Health Organization (WHO) issued new MDR/RR-TB treatment guidelines<sup>4</sup> in March 2019. This technical brief provides a summary of the treatment regimens now recommended by WHO, which represent hope for people with DR-TB and their caregivers because they offer better cure rates and fewer side effects using safer all-oral treatment. Médecins Sans Frontières (MSF) urges countries to make a timely switch to these regimens given the clear benefits of providing bedaquiline for all people with MDR-TB and the urgent need to discontinue use of harmful injectable agents.

In July 2019, WHO Director-General Dr Tedros Adhanom Ghebreyesus called for countries to transition to the all-oral regimens to treat DR-TB by World TB Day, 24 March 2020. By this time 100% of people newly enrolled on treatment should be offered the optimal regimen.<sup>5</sup>

#### BACKGROUND: NEW WHO TREATMENT GUIDELINES

In August 2018, WHO released the Rapid Communication “Key changes to treatment of multidrug- and rifampicin-



Natalia began treatment at MSF's DR-TB treatment project in Zhytomyr Oblast, Ukraine in October 2018.

resistant tuberculosis,” which for the first time recommended all-oral regimens as the standard to treat MDR-TB.<sup>6</sup> Following this communication, WHO released a pre-final text of the “WHO treatment guidelines for multidrug- and rifampicin-resistant tuberculosis” in December 2018, and released the “Consolidated guidelines on drug-resistant tuberculosis treatment” in early 2019.<sup>4,7</sup> These guidelines replace all other previous WHO recommendations on DR-TB treatment.

The new WHO recommendations are based on reviews of evidence available from:

- A multi-country meta-analysis of individual patient data
- Phase III trials on delamanid and shorter MDR-TB regimens
- Bedaquiline and delamanid trials in patients under 18 years of age
- Programmatic data using bedaquiline, delamanid and other novel regimens

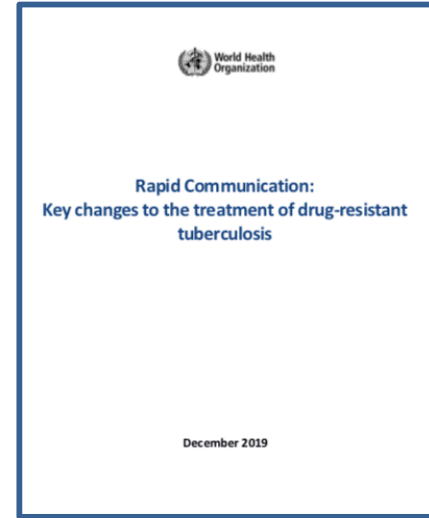
The multi-country meta-analysis assessed:

- Newer all-oral long regimen: number of drugs that should be used and duration of treatment in order to achieve better treatment outcomes
- Short-course regimen: efficacy and safety compared with the older long regimen (using injectable agents)
- Monitoring: benefit of monthly culture over smear microscopy monitoring

# 1) WHO recommendations

<https://msfaccess.org/making-the-switch>

- All people with MDR-TB should benefit from a shorter or longer **all-oral** regimen
- MDR-TB: Most can receive **bedaquiline-based, all-oral, shorter regimen**, consisting of the 2016 WHO standardised shorter regimen with bedaquiline substituted for the injectable agent
- Pre-XDR and XDR and complicated MDR-TB:
  - Individualised longer regimen based on 2018 WHO drug groups
  - A regimen consisting of bedaquiline, pretomanid and linezolid (BPaL) may be used under operational research conditions for people with XDR-TB

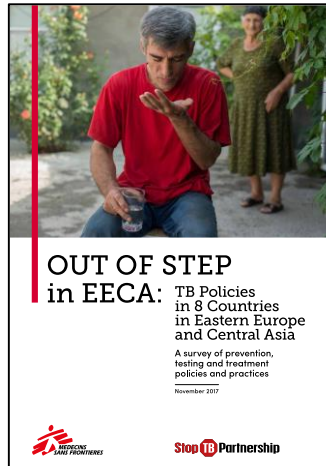


11 December 2019

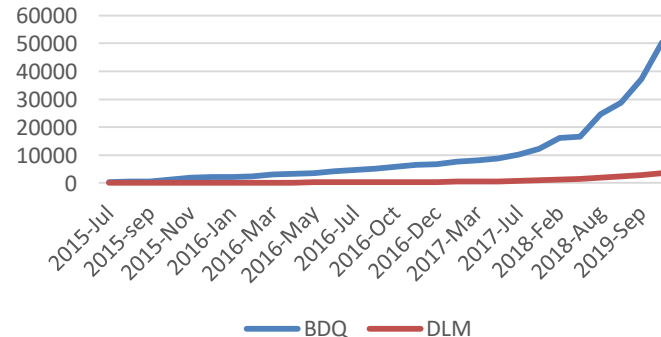


## 2) Progress - uptake & scale-up

- WHO called for all-oral regimens for 100% of people starting MDR-TB treatment by March 2020
- Cumulative numbers as of end of 2019 since 2012
  - BDQ: 50,290 (51.3% from South Africa)
  - DLM: 3,652 (fewer than 1,000 patients per year reported)
- Global coverage less than 11% based on need
- 9 EECA countries – 50% have started implementing all-oral for MDR-TB treatment



Cumulative Use of BDQ and DLM Over Time



### 3) DR-TB drug benchmark prices

Medicine	Current price per patient per month
Bedaquiline	Countries purchasing through GDF + South Africa: <b>Janssen (J&amp;J) US\$ 67</b>
	<i>CIS and Georgia: <b>Pharmstandard US\$ 246</b></i>
Pretomanid	Countries purchasing through GDF <u>once WHO guidelines published</u> : <b>Mylan US\$ 61</b>
Delamanid	Countries purchasing through GDF: <b>Otsuka US\$ 283</b>
Linezolid (600 mg)	<b>US\$ 13</b>
Moxifloxacin (400 mg)	<b>US\$ 10</b>
Clofazimine (100 mg)	<b>US\$ 15</b>
Prothionamide (250 mg)	<b>US\$ 5</b>
Levofloxacin (500 mg)	<b>US\$ 2.50</b>

\* Lowest GDF price (multi-generic source drug)

[http://www.stoptb.org/gdf/drugsupply/drugs\\_available.asp](http://www.stoptb.org/gdf/drugsupply/drugs_available.asp) (click on Ordering List of TB Medicines)

\*\* Target price ranges are based on the estimated costs of active and inactive pharmaceutical ingredients, formulation, packaging, and a cost-plus model,

which includes a reasonable profit margin. Prices could reach these levels with adequate market competition and transparency.

<https://doi.org/10.1093/jac/dkw522>

## 4) DR-TB regimen prices

Regimen (number of months)	Regimen price based on lowest GDF price 2019, US\$
<b>Shorter all-oral regimens</b>	
Bdq (6)-Lzd (2)-Lfx-Cfz-Z-H <sup>h</sup> -E (4) / Lfx-Cfz-Z-E (5) <sup>‡</sup>	607
Bdq-Lfx-Pto-Cfz-Z-H <sup>h</sup> -E (4) / Bdq-Lfx-Cfz-Z-E (6) <sup>§</sup>	763
Bdq-Dlm-Lfx-Cfz-Lzd (6) <sup>§</sup>	3,122
Bdq-Dlm-Cfz-Lzd (6) <sup>§</sup>	3,108

- **Longer all oral fluoroquinolone-sensitive regimens**

18 month Bdq-based regimens: **US\$ 1,000 – 1,800**

- **Longer all oral fluoroquinolone-resistant regimens**

- 20 month Bdq/Dlm combined regimens: **US\$ 8,000 – 12,000**

- 6 month BPaL regimen: **US\$ 1,040** (*WHO guidelines awaited by Q1 2020*)

⇒ **Bedaquiline, Delamanid & Pretomanid prices = main cost drivers**

<sup>‡</sup> Modified short regimen implemented in South Africa

<sup>§</sup> Under operational research conditions

## 5) More evidence



### endTB Observational Study

Largest multi-country,  
prospective  
observational study of  
regimens  
containing  
bedaquiline or  
delamanid

**17 > 2600**

Countries Patients

Apr 2015-Sep 2018



- BDQ and DLM can be used safely together
- BDQ or DLM can be extended safely beyond 6 months

## 5) More evidence (endTB)

- **77.6% favourable end of treatment outcomes (cured, treatment completed) for the first cohort of 1082 patients with 27 months of follow up who received a longer regimen with BDQ and/or DLM**
  - Excellent outcomes in a very sick, extensively treated cohort of patients
  - These routine program results rival those of recent clinical trials: 79% STREAM, 77% DLM Phase 3
  - An analysis of the comparative effectiveness of different regimens and treatment durations used in the observational study is still needed

# 6) TB and Covid-19



World Health Organization (WHO) Information Note

Tuberculosis and COVID-19

Date: 12 May 2020

COVID-19: Considerations for tuberculosis (TB) care

- “People-centred outpatient and community-based care should be strongly preferred over hospital treatment for TB patients ... to reduce opportunities for transmission.”
- “[t]he rapid roll-out of measures that reduce the need for daily encounters with healthcare staff becomes more critical. These include WHO recommended, all-oral TB treatments for multidrug-resistant TB and extensively drug-resistant TB”

## 7) Global Fund windows

<https://eecapplatform.org/en/gf-funding-request-submission/>

- **Window 2 submission dates:**

Window 2a: 30 April

Window 2b: 31 May

Window 2c: 30 June

**Window 3 submission dates:**

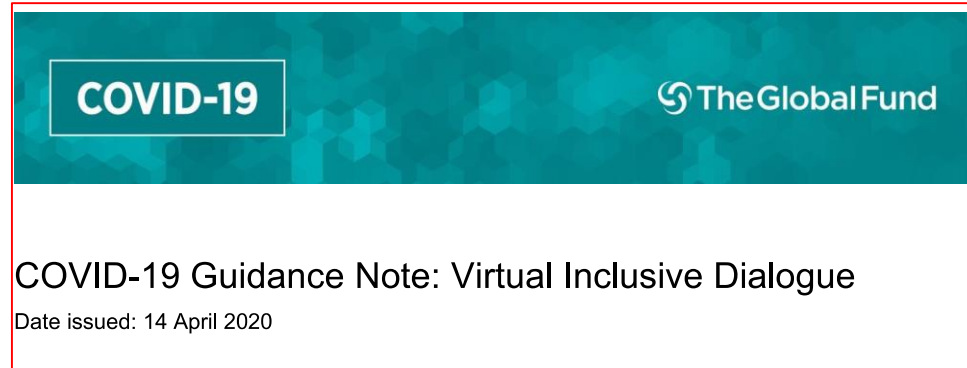
Window 3a: 31 July

Window 3b: 31 Aug

Armenia	
Azerbaijan	Window 1
Belarus	
Georgia	
Kazakhstan	
Kosovo	Window 2b
Kyrgyzstan	Window 1
Moldova	Window 2c
Tajikistan	Window 1
Turkmenistan	Window 3b
Ukraine	Window 2b
Uzbekistan	Window 3b

[https://www.theglobalfund.org/media/9261/fundingmodel\\_2020-2022fundingrequeststatus\\_tracker\\_en.xlsx?u=6372393387200000](https://www.theglobalfund.org/media/9261/fundingmodel_2020-2022fundingrequeststatus_tracker_en.xlsx?u=6372393387200000)

## 8) How NGOs can engage during lockdown



[https://www.theglobalfund.org/media/9536/covid19\\_virtualinclusivedialogue\\_guidancenote\\_en.pdf?u=637250529610000000](https://www.theglobalfund.org/media/9536/covid19_virtualinclusivedialogue_guidancenote_en.pdf?u=637250529610000000)



## 9) Global Fund Covid-19 Mechanism



<https://eecaplatform.org/wp-content/uploads/2020/05/200508-GFS-Brief-on-COVID-19-Global-Fund-financing-two-mechanisms.pdf>



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**May 15, 2020**

# Technical assistance available under the Communities, Rights and Gender SI and other GF support opportunities

Varentsov Ivan, Eurasian Harm Reduction Association



# Global Fund CRG Short-term Technical Assistance Program

## General Info

The Community, Rights and Gender (CRG) Technical Assistance Program provides support to civil society and community organizations to meaningfully engage in the Global Fund model, including during:

- Country dialogue
- Funding request development
- Grant-making
- Grant implementation

The program currently does not support:

- Strengthening Country Coordinating Mechanisms
- Long-term capacity building of civil society organizations
- Funding request writing

Organizations can request CRG technical assistance at any time throughout the funding cycle by sending a request form to [crgta@theglobalfund.org](mailto:crgta@theglobalfund.org).

**EECA countries eligible for CRG technical assistance:** Albania, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kosovo, Kyrgyzstan, Moldova, Montenegro, North Macedonia, Romania (TB only), Russia, Serbia, Tajikistan, Turkmenistan (TB only), Ukraine, Uzbekistan.

# Global Fund CRG Short-term Technical Assistance Program

## What is different this year

- The major focus of the CRG TA Program in 2020 - to ensure that key affected populations are meaningfully engaged in country dialogues and funding request development processes in those countries which submit proposals this year. Other requests could be postponed.
- TA related to the processes after the submission of the funding requests (fulfillment of TRP comments, anything related to the grant making stage) is also the priority
- The Program budget for this year is limited so GF CRG colleagues have to be mindful of that when reviewing budget for requests.
- In cases where planned TA has been postponed, the CRG Department will work with country teams to review the alternatives to ensure that communities receive appropriate support. In addition, CRG Department is committed, once travel and convening restrictions are effectively scaled down, to exploring with country teams how they can support additional face to face TA as needed.
- The CRG Strategic Initiative guidance to its TA providers is that any travel and/or in country activities related to the provision of in-country TA should take into account the dynamic and evolving nature of the COVID-19 and must be informed by the latest WHO and local government guidance. In addition, in-country activities should only be undertaken with informed consent of the consultant and requestor provided in writing and after discussion and agreement with the relevant Global Fund country teams.

# Global Fund CRG Short-term Technical Assistance Program

## What important to remember when preparing the application?

- This is a short-term TA: all requested activities should be completed, and the expected results are obtained in 3 - 5 months
- The budget of one request could be up to 50 000 USD,
- The content of the request should be coordinated with other NGOs involved in the relevant processes in the country (and preferably with CCM and FPM)
- It could take on average 2 - 3 months from the time of the request submission to the beginning of its implementation
- The number of requests submitted from one country is not limited, but given the limited resources, CRG colleagues might have to prioritize and support one out of the two requests from the same country. It will also depend on how many requests they receive in total.
- Applications will be accepted till the end of the year

## All information and application forms available:

ENG <https://www.theglobalfund.org/en/funding-model/technical-cooperation/community-rights-gender-technical-assistance-program>

RUS <http://eecaplatform.org/>

# Global Fund COVID-19 Flexibilities and Response Mechanism

## Global Fund COVID-19 Flexibilities

Grant flexibilities, announced on 4 March 2020, allow countries with current grants to: 1) use up to 5% of their current grant value if there are savings, and/or 2) reprogram up to 5% of the value of a grant to meet immediate COVID-19 response requirements..

Total available funding for flexibilities is up to US\$500 million. As of 5 May 2020, funding has been approved for 73 countries and five regional grants for a total of US\$109 million.

**Eligibility:** Countries and multi-country grants with current grants from the 2017-2019 allocation period.

**Application process:** For the use of savings and reprogramming, the Principal Recipient issues a request to the Global Fund's Fund Portfolio Manager. Preferably, it is endorsed by the CCM. The Global Fund responds within five working days. The request should include a brief budget, describe the activities to be funded, how it will fit into the national response, and outline potential consequences to and mitigants for HIV, TB and malaria programming.

More information is available here: <https://www.theglobalfund.org/en/covid-19/grants/>

# Global Fund COVID-19 Flexibilities and Response Mechanism

## Global Fund COVID-19 Response Mechanism

The COVID-19 Response Mechanism (C19RM), approved in April 2020, authorizes US\$500 million in funding in addition to grant flexibilities. C19RM can be used across the three diseases and the health system, even if a country only has a single Global Fund grant for one component. The CCM will assess the most urgent needs and direct activities through one or more of the principal recipients.

**Eligibility:** Countries with a Global Fund allocation for the 2020-2022 period can access an amount equivalent to up to 10% of their allocation. This ceiling includes the use of savings and reprogramming under existing grants.

**Implementation:** C19RM funds must be implemented through an existing country grant and principal recipient, regional and multi-country grants. It can be used for three areas, to:

1. mitigate the impact of COVID-19 on current HIV, TB and malaria programs.
2. reinforce the national COVID-19 response
3. invest in urgent improvements in health and community systems

**Application Process:** The application is submitted through the CCM or the regional coordinating mechanism preferably by 31 May and no later than September 2020 so that emergency funding can reach countries as soon as possible.

Countries are asked to submit [this request form](#) completed and endorsed by the CCM to C19RM@theglobalfund.org with the Global Fund Country Team in copy. Instructions to apply [can be found here](#).



# Other TA opportunities

## UNAIDS Technical Support Mechanism

UNAIDS has established a Technical Support Mechanism (TSM) to enable high quality technical assistance (TA) provision to accelerate AIDS response implementation, including the Global Fund grants, towards the Fast-Track Targets and the 2016 Political Declaration on HIV and AIDS response Goals

Requests on next thematic areas could possibly be supported:

- Community-led research (if leads to concrete output to improve GF implementation)
- Legislation analysis
- Advocacy planning (if expected to lead to tangible change i.e. change of discriminatory laws)
- Advocacy implementation (if expected to lead to tangible change i.e. change of discriminatory laws)
- Governance and other organizational development for KP networks (if expected to support acceleration of HIV service delivery and uptake)

Country eligibility criteria are the same as Global Fund eligibility criteria. Allocations amount should preferably not exceed 50,000 USD. Types of contract: consultancy. Duration: short-term assignment.

For more information please contact the UNAIDS colleagues in your country \ regional offices.



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«Practical  
recommendations to  
CSO on how to get  
technical assistance  
while writing an  
application to the GF »

**Ibragimova Oksana**  
**Kazakhstan Union of PLWH**  
**15.05.2020**



# Types of Technical Assistance on CRG

**Support for program  
development**

**Current situation  
analysis and needs  
assessment**

**Participation in the  
country dialogue**

**Support of supervision  
and monitoring of  
grant implementation  
and program review  
activities.**

**Participation in the  
development of  
strategies to ensure  
sustainability and  
smooth transition**

# Practical Steps



**To prepare an application: goal, reasons, activities, budget**



**Reaching agreement with the CCM, national partners, communities and Portfolio Manager**



**To take time frame into account (budget agreement procedures, logistics)**



**To identify an organization that would provide support**



**To develop Terms of Reference for the advisor**



**After the completion of the Country Dialogue – to monitor inclusion of activities in the Application**

# QUESTIONS