



World Health  
Organization



# INNOVATIVE APPROACHES FOR ACCESS TO NEW ANTI-TB MEDICINES AND REGIMENS

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# TB IS THE SECOND TOP INFECTIOUS KILLER

## MILLIONS CONTINUE TO MISS OUT ON ACCESS TO LIFE-SAVING TB PREVENTION AND CARE

### Fewer people accessed life-saving TB care in 2020

#### TB PREVENTIVE TREATMENT (ALL AGES)

Target:

**30 MILLION**  
2018-2022

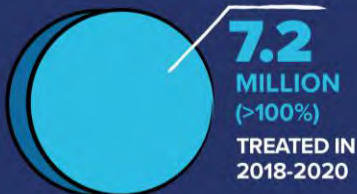


**8.7 MILLION**  
(29%)  
TREATED IN 2018-2020

#### PEOPLE LIVING WITH HIV

Target:

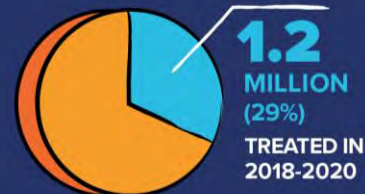
**6 MILLION**  
2018-2022



#### CHILD HOUSEHOLD CONTACTS OF PEOPLE WITH TB AGED < 5 YEARS

Target:

**4 MILLION**  
2018-2022



#### HOUSEHOLD CONTACTS AGED ≥ 5 YEARS

Target:

**20 MILLION**  
2018-2022



**9.9 MILLION PEOPLE**  
FELL ILL WITH TB\*



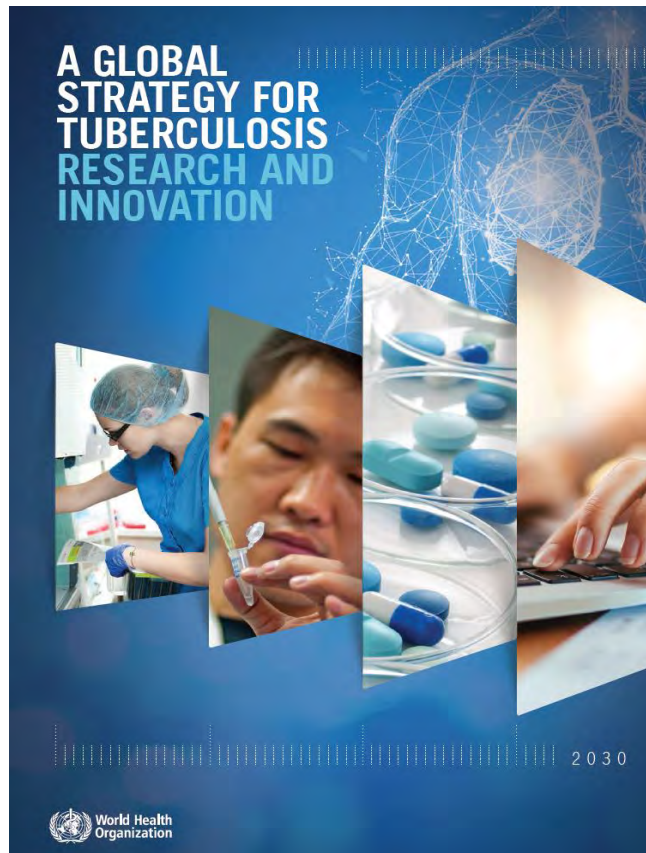
# WHO GLOBAL TB PROGRAMME: LEADING EFFORTS TO END TB



- Shape the TB research and innovation agenda, generation, translation and dissemination of knowledge
- Set norms and standards on TB prevention and care and facilitate their implementation
- Develop and promote ethical and evidence-based policy options for TB prevention and care



# RESEARCH AND INNOVATION

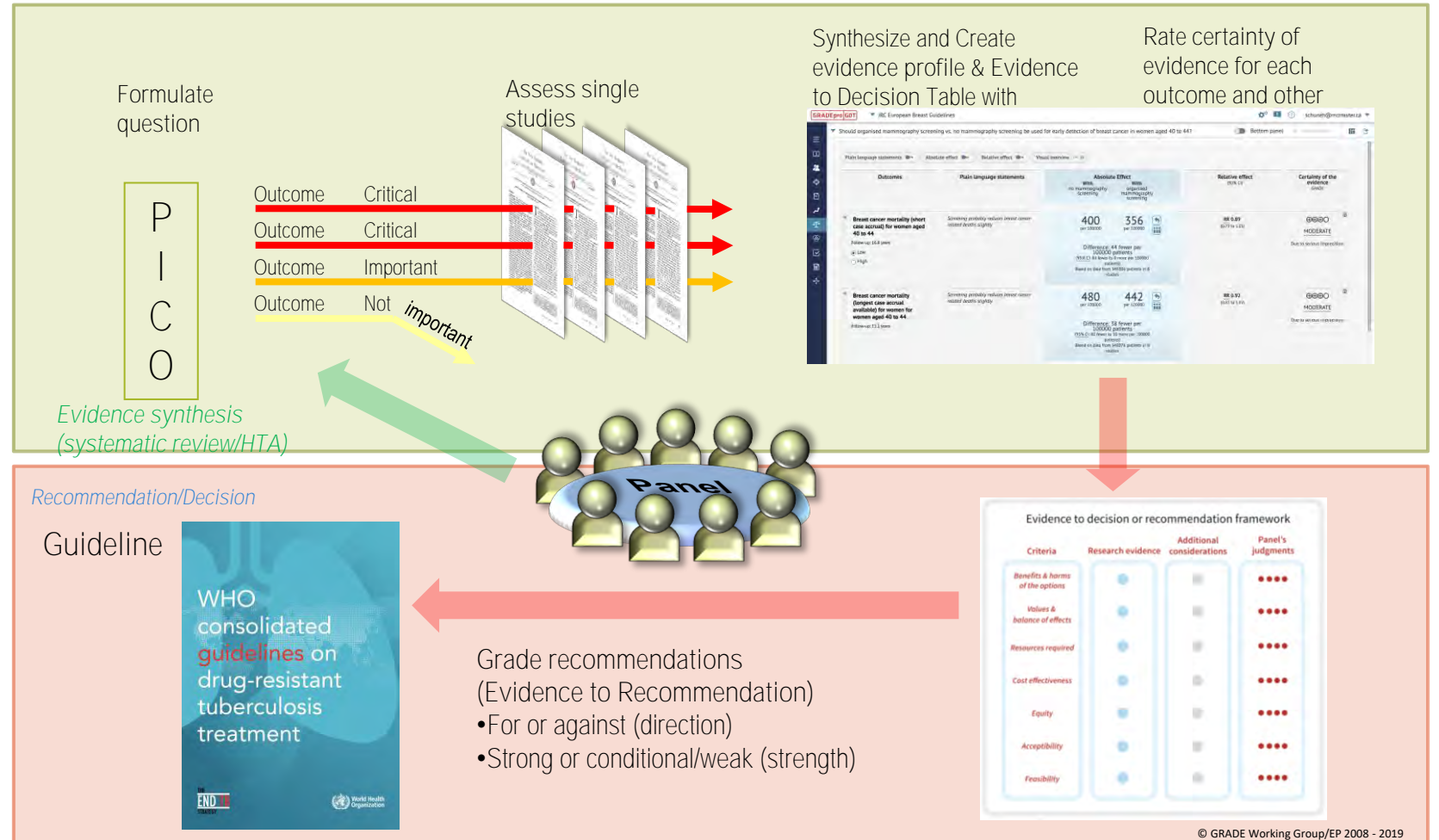


Objectives of the global strategy

- Create an enabling environment for TB research & innovation
- Increase financial investments in TB research and innovation
- Promote and improve approaches to data sharing
- Ensure equitable access to the benefits of research and innovation



# GUIDELINE DEVELOPMENT: GRADE PROCESS





# GUIDELINE DEVELOPMENT: REGULAR UPDATE/ DIGITAL FORMAT

## TB Knowledge Sharing Platform

24/7 Accessibility Everywhere

WHO TB KNOWLEDGE SHARING PLATFORM

Access the modular WHO guidelines on tuberculosis, with corresponding implementation aids and eLearning materials.

- Consolidated Guidelines**  
WHO guidelines provide the latest evidence-informed recommendations on TB prevention and care to help countries achieve the Sustainable Development Goals (SDGs) and the targets of the End TB Strategy.
- Operational Handbooks**  
The WHO Operational Handbooks on tuberculosis provide users with practical "how-to" guidance, with details essential for the proper implementation of the corresponding WHO guidance.

1997



DR-TB GUIDELINES

2003



2008

2010

2011



2016

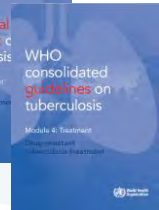


2017

2018

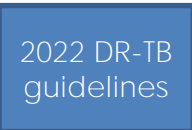


2019



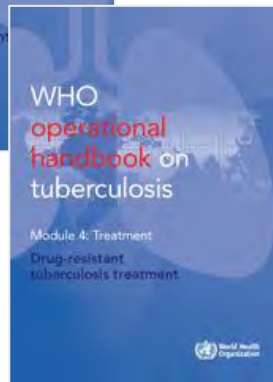
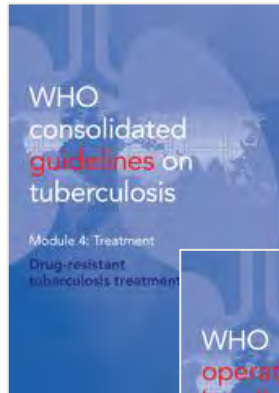
2020

2022





# GUIDELINE DEVELOPMENT: **RAPID COMMUNICATION FOR FASTER UPTAKE**



FULLY-ORAL SHORTER  
TREATMENT REGIMENS FOR  
DRUG RESISTANT TB



MORE THAN 6 TIMES LESS PILL BURDEN  
COMPARED WITH THE STANDARD  
TREATMENT REGIMEN BEFORE 2018



## 2022: **RAPID COMMUNICATION**

- 6-month BPaLM and **BPaL** regimens
- 9-month, all-oral, bedaquiline-containing regimens
- Individualized longer regimens for patients with XDR-TB and those not eligible or those who failed shorter regimens



**NO INJECTIONS**



# ACTIVE AND EARLY ENGAGEMENT WITH PARTNERS: GLOBAL CLINICAL DEVELOPMENT PIPELINE/ EVIDENCE AVAILABLE IN 2021-22,

Phase III <sup>a</sup>
Bedaquiline (TMC-207) <sup>b</sup>
Delamanid (OPC-67683) <sup>b</sup>
Pretomanid <sup>b</sup>
<b>High-dose rifampicin for treatment of drug-susceptible TB</b>
Bedaquiline–delamanid–linezolid–levofloxacin–clofazimine (6-month oral regimen for RR-TB) or bedaquiline–delamanid–linezolid–clofazimine (6–9 month oral regimen for pre-XDR and XDR-TB) ( <b>BEAT TB trial</b> )
Bedaquiline–pretomanid–moxifloxacin–pyrazinamide (BPaMZ) ( <b>SimpliciTB trial</b> )
Bedaquiline–pretomanid–linezolid ( <b>ZeNix trial</b> ) - Linezolid optimization
Bedaquiline with two OBRs <sup>c</sup> (all-oral, 9 months; with injectable, 6 months) ( <b>STREAM trial</b> )
Bedaquiline–linezolid–levofloxacin with OBR <sup>c</sup> for MDR-TB ( <b>NExT trial</b> )
Bedaquiline and delamanid with various existing regimens for MDR-TB and XDR-TB ( <b>endTB trial</b> )
Bedaquiline–delamanid–linezolid–clofazimine for fluoroquinolone-resistant MDR-TB ( <b>endTB-Q</b> )
Several 2-month regimens for drug-susceptible TB ( <b>TRUNCATE-TB trial</b> )

## DR-TB

- STREAM phase 2
- BEAT TB trial (SA)
- SimpliciTB
- ZeNix – evidence used in 2022 DR-TB GDG
- NExT – evidence used in 2022 DR-TB GDG
- TB PRACTECAL – evidence used in 2022 DR-TB GDG

## MDR-END

## DS-TB

- TRUNCATE-TB
- RIFASHORT
- PredictTB
- CLO-FAST





## OPERATIONAL RESEARCH LANDSCAPE (2022)

- ❖ Modified shorter regimens for MDR/RR-TB, implementation of ShORRT protocol with TDR support (BPaI for FQ-R and modified STR for FQ-S for 6-9 months)
- ❖ BPaL for pre-XDR-TB with support of KNCV and TB Alliance (BPaL with Lzd 600mg)
- ❖ Modified shorter regimen for MDR/RR-TB, EURO initiative (39 weeks Lfx-Bdq-Lzd-Cfz-Cs or Lfx-Bdq-Lzd-Cfz-Dlm )
- ❖ BEAT TB India prospective cohort (Bdq-Dlm-Lzd-Cfz)





# GLOBAL CLINICAL DEVELOPMENT PIPELINE: LONGER TERM PERSPECTIVE

UNITE4TB

Innovative Medicines Initiative  
(IMI)  
European Union  
The European Federation of  
Pharmaceutical Industries and  
Associations (EFPIA)



PAN-TB collaboration

Project to Accelerate New Treatments for  
Tuberculosis  
Bill & Melinda Gates Medical Research  
Institute and the Bill & Melinda Gates  
Foundation  
Evotec, GSK, Johnson & Johnson, Otsuka  
Pharmaceutical



New concepts for Phase 2 trials to develop successful regimens with new medicines ready for phase 3 research



INVEST TO END TB, SAVE LIVES.

**THANK YOU!**



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