



World Health  
Organization



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

Dr Tereza Kasaeva  
Director, Global TB Programme  
World Health Organization





# 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

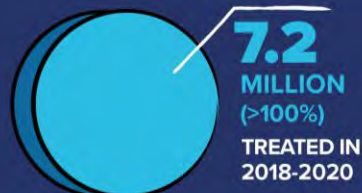


**8.7 MILLION**  
(29%)  
TREATED IN 2018-2020

#### PEOPLE LIVING WITH HIV

Target:

**6 MILLION**  
2018-2022

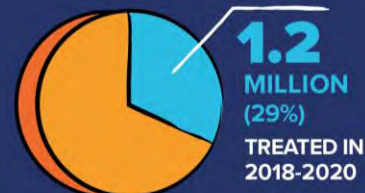


**7.2 MILLION**  
(>100%)  
TREATED IN  
2018-2020

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

Target:

**4 MILLION**  
2018-2022



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

#### HOUSEHOLD CONTACTS AGED ≥ 5 YEARS

Target:

**20 MILLION**  
2018-2022



**0.32 MILLION**  
(1.6%)  
TREATED IN  
2018-2020



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



# WHO GLOBAL TB PROGRAMME: LEADING EFFORTS TO END TB

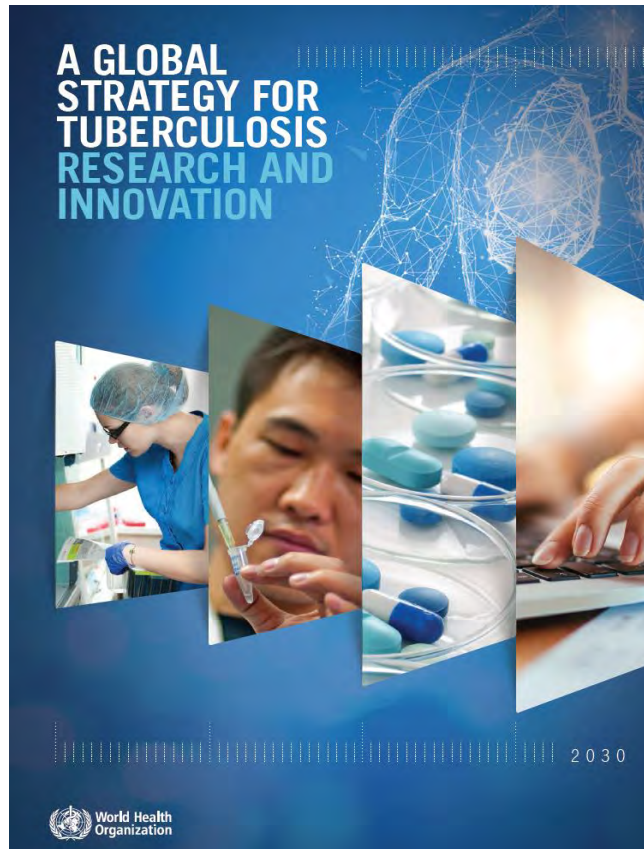


- Shape the TB research and innovation agenda, generation, translation and dissemination of knowledge
- Set norms and standards on TB prevention and care and facilitate their implementation
- Develop and promote ethical and evidence-based policy options for TB prevention and care





# RESEARCH AND INNOVATION

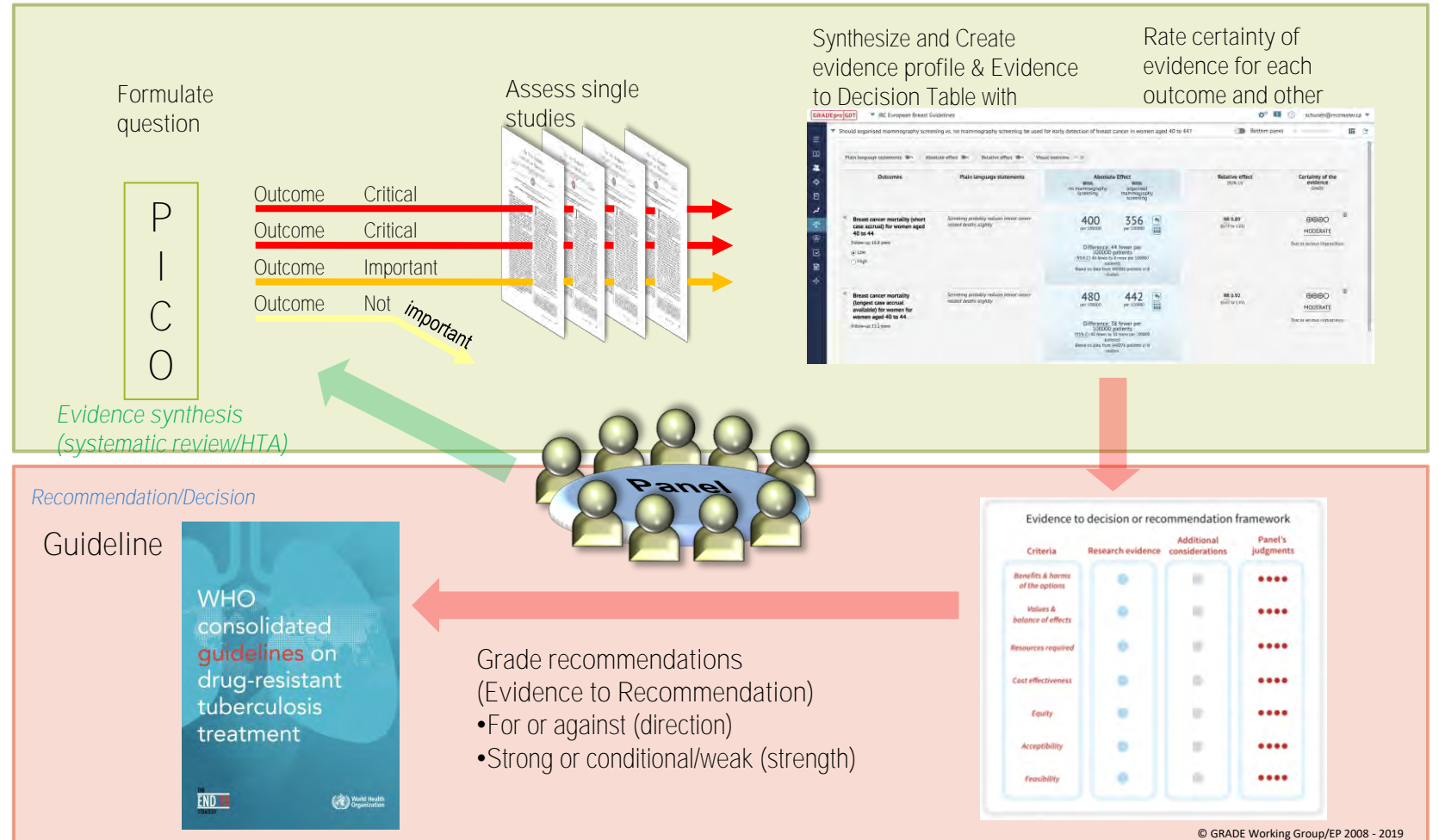


## Objectives of the global strategy

- 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

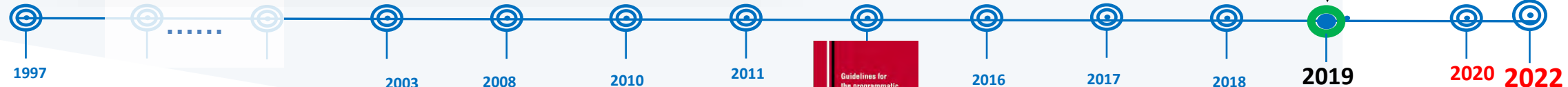
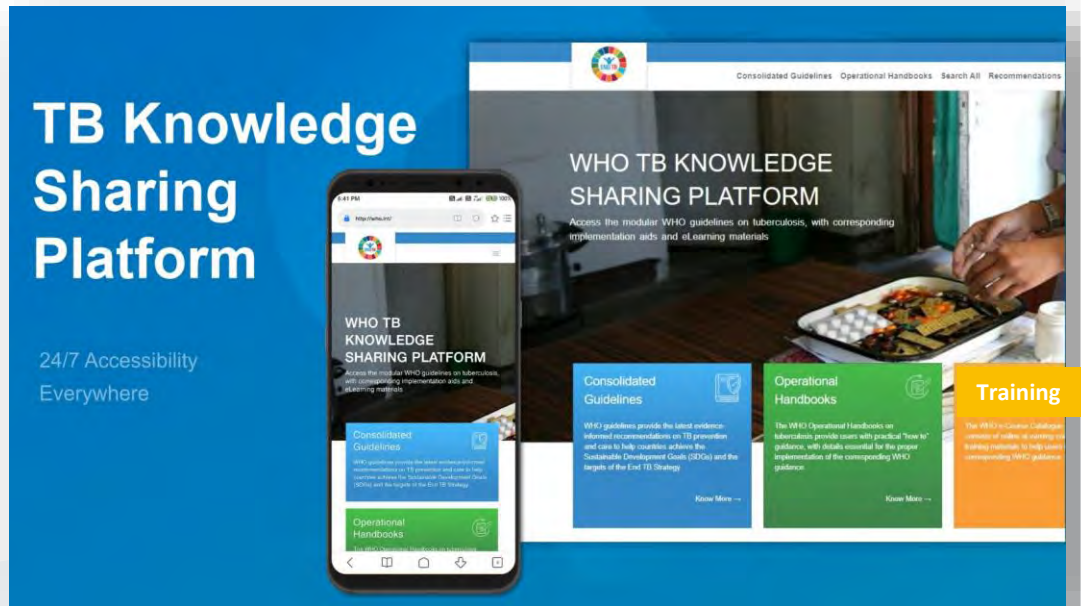


# GUIDELINE DEVELOPMENT: GRADE PROCESS

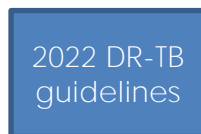
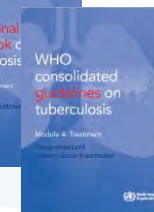
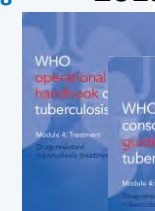




# GUIDELINE DEVELOPMENT: **REGULAR UPDATE/ DIGITAL FORMAT**

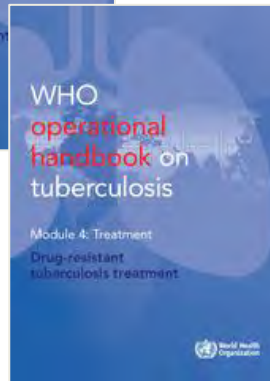
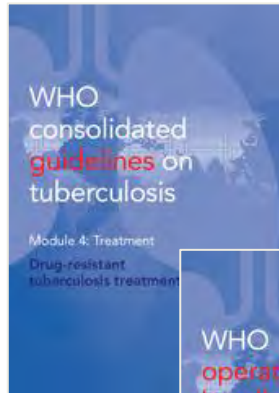


DR-TB GUIDELINES





## 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>
High-dose rifampicin for treatment of drug-susceptible TB
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) (BEAT TB trial)
Bedaquiline–pretomanid–moxifloxacin–pyrazinamide (BPamZ) (SimpliciTB trial)
Bedaquiline–pretomanid–linezolid (ZeNix trial) - Linezolid optimization
Bedaquiline with two OBRs <sup>c</sup> (all-oral, 9 months; with injectable, 6 months) (STREAM trial)
Bedaquiline–linezolid–levofloxacin with OBR <sup>c</sup> for MDR-TB (NExT trial)
Bedaquiline and delamanid with various existing regimens for MDR-TB and XDR-TB (endTB trial)
Bedaquiline–delamanid–linezolid–clofazimine for fluoroquinolone-resistant MDR-TB (endTB-Q)
Several 2-month regimens for drug-susceptible TB (TRUNCATE-TB trial)

## 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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