

Workshop

# Joint SEAR-WPR workshop to plan the accelerated implementation of new WHO TB policies

1-4  
APRIL  
2025

Hanoi,  
Viet Nam



## Mid-term progress update



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# UNITE4TB: project outline



Part of the **Innovative Health Initiative**



## FACTS & FIGURES

Start Date	01/06/2021
End Date	31/05/2028
Call	IMI2 - Call 20
Grant agreement number	101007873

Type of Action:  
RIA (Research and Innovation Action)

Contributions	€
IMI Funding	92 500 000
EFPIA in kind	62 364 744
Associated Partners	30 135 256
<b>Total Cost</b>	<b>185 000 000</b>

*EFPIA = European Federation of Pharmaceutical Industries and Associations*



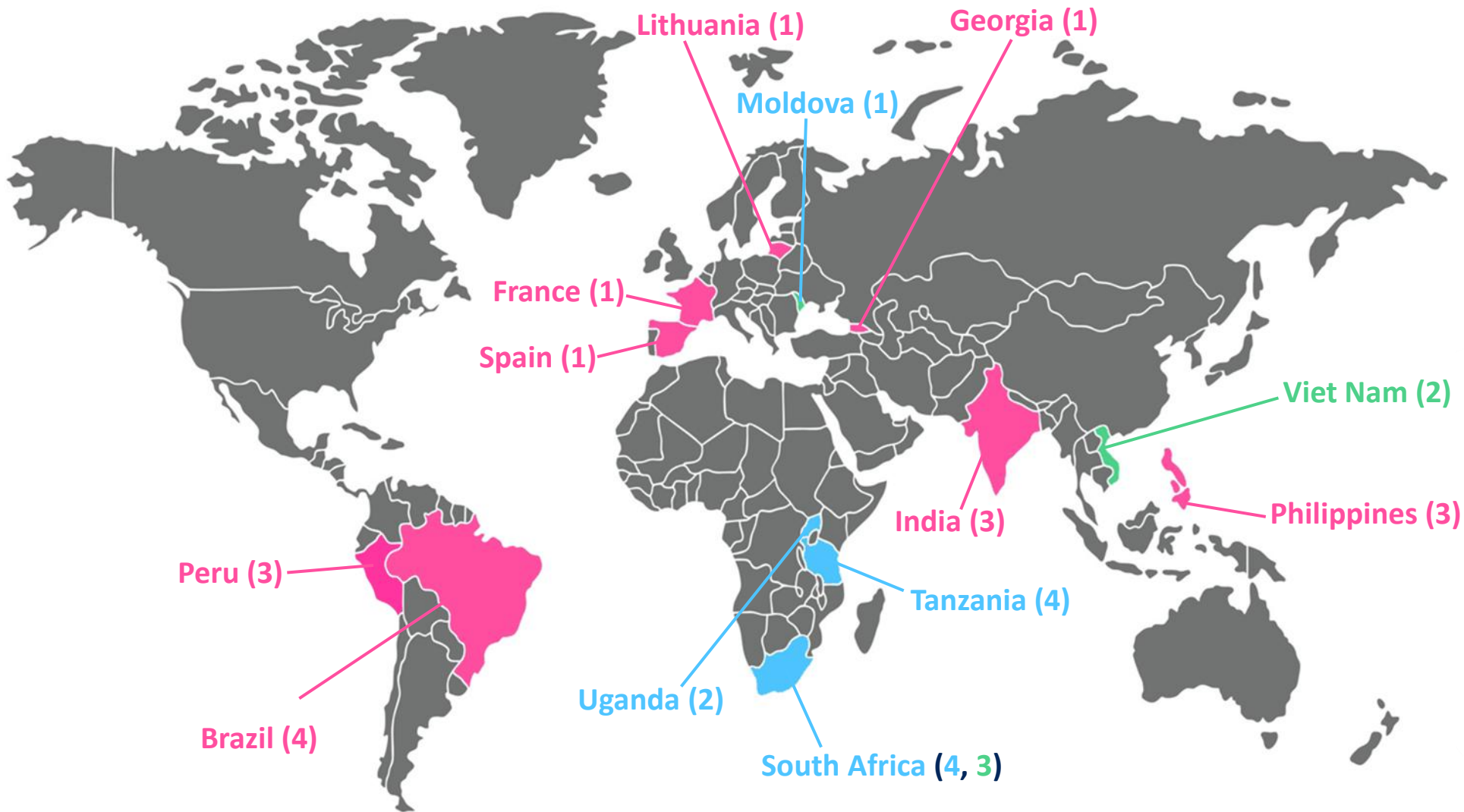
# UNITE4TB: clinical trials (May 2025)

PARADIGM4TB	BTZ-043 DECISION	ENABLE (with ERA4TB)	STEP2C (with PanACEA)	? (with TB Alliance)
Platform Assessing Regimens And Durations In a Global Multisite consortium for TB	BTZ-043 Dose Evaluation in CombInation and SelectION)	EthioNamide AlpiBectir puLmonary tubErculosis		
Phase 2B/C: efficacy, safety,duration of regimens with Wave 1: <b>Ganfeborole</b> and/or <b>BTZ-043</b> Wave 2: <b>Quabodepistat</b> or <b>Delpazolid</b>	Phase 2B: efficacy, safety, tolerability, PK and exposure-response of <b>BTZ-043</b> and its metabolites in combination with Bedaquiline and Delamanid	Phase 2A: Exposure- response of <b>Alpibectir</b> to reduce Ethionamide	Phase 2B/C: efficacy, safety. Stages 1 & 2 (PanACEA): opt-R, opt- Z, <b>BTZ-043</b> . <u>Stage 3</u> (UNITE4TB): <b>Alpibectir</b> /Ethionamide <b>Ganfeborole</b> , <b>BTZ-043</b> , <b>Delpazolid</b>	Phase 2A: <b>TBAJ-587</b>

opt-R = optimized Rifampicin dose  
opt-Z = optimized Pyrazinamide dose



# UNITE4TB: active and planned trial sites (May 2025)



- Active sites
- In final stage of approval
- In early stage of preparation/approval

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# UMIL stakeholder analysis: 10 key recommendations (1/2)

1. Ensure that **clinical trial outcomes meet WHO requirements** to develop policies and guidelines
2. Pursue **initial strategic discussions to make costs** of new treatment regimens, drug susceptibility testing (DST), and other tests **affordable** to low- and middle-income countries to guarantee equitable access to all in all settings
3. Encourage development of **fixed-dose combinations** to be presented to regulatory authorities as soon as a new regimen is approved
4. Strengthen **coordination among TB clinical trial research consortia** to limit duplications of R&D efforts
5. Engage major **international stakeholders to facilitate dialogue among research consortia** to coordinate efforts and solve bottlenecks in TB drug R&D and policy implementation



# UMIL stakeholder analysis: 10 key recommendations(2/2)

6. Carefully **select clinical trial sites** to include vulnerable and high-risk populations;
7. Enhance **engagement of NTPs in the conduct of clinical trials** to ensure proper selection of sites and to facilitate local research capacity;
8. Support **NTPs in identification of bottlenecks** for rapid uptake of new regimen;
9. Advocate with investors and donors for **adequate and stable funding** of advanced clinical trial phases;
10. Encourage effective, regular, and timely **information sharing** with stakeholders of relevant scientific discoveries emerging from trials





# Stakeholder engagement (2023-2025): activities

Activity		Q1	Q2	Q3	Q4
Bilateral meetings	2023	Brazil, WHO <b>8 NTPs, 2 policy makers, 6 donors, 3 NGOs, 1 research inst.</b>	Georgia, ECDC, GDF, Global Fund	India, Philippines, Vietnam, BMGF, NIH, Rede TB, Unitaïd, USAID	South Africa, Tanzania, Uganda, FCDO, LIGHT, Union
	2024	Georgia, ECDC, WHO <b>8 NTPs, 2 policy makers, 6 donors, 1 NGO, 1 research inst.</b>	Brazil, India, Philippines, BMGF, EDCTP3, Global Fund, Union, Unitaïd	South Africa, Uganda, GDF, USAID	Tanzania, Vietnam, NIH
	2025	Georgia, India, Philippines, ECDC, EDCTP3, WHO, WHO-CSTF, Union	Brazil, China, BMGF, Global Fund, Unitaïd, USAID	Indonesia, Lithuania, Moldova, South Africa, Vietnam, GDF, NIH	Tanzania, Uganda
Stakeholder events	2023		WHO-AMR (10/05)	WHO-SEAR (11/07)	
	2024		UNITE4TB ((16-17/05)	Unitaid (15/06)	
	2025		WHO-WPRO, WHO-EURO		Union



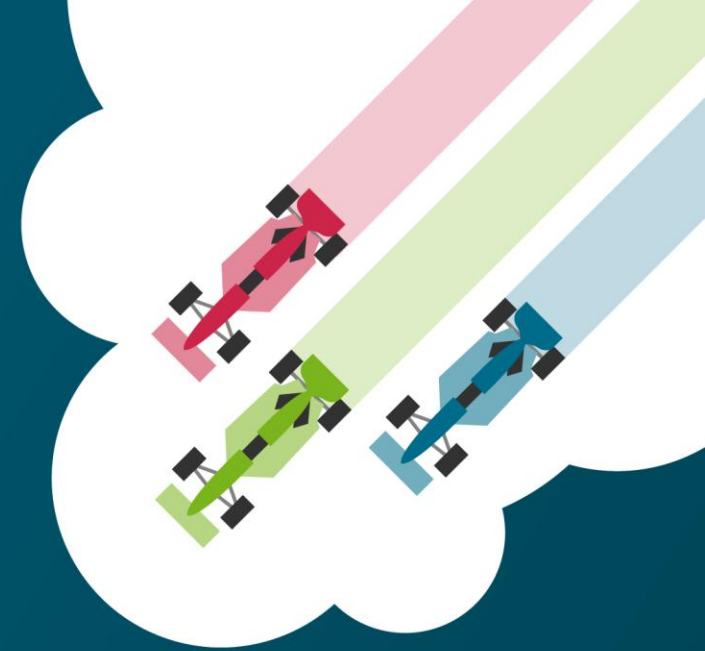
# WP11-Implementation, dissemination, communication

<https://www.unite4tb.org/>





# Thank you



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