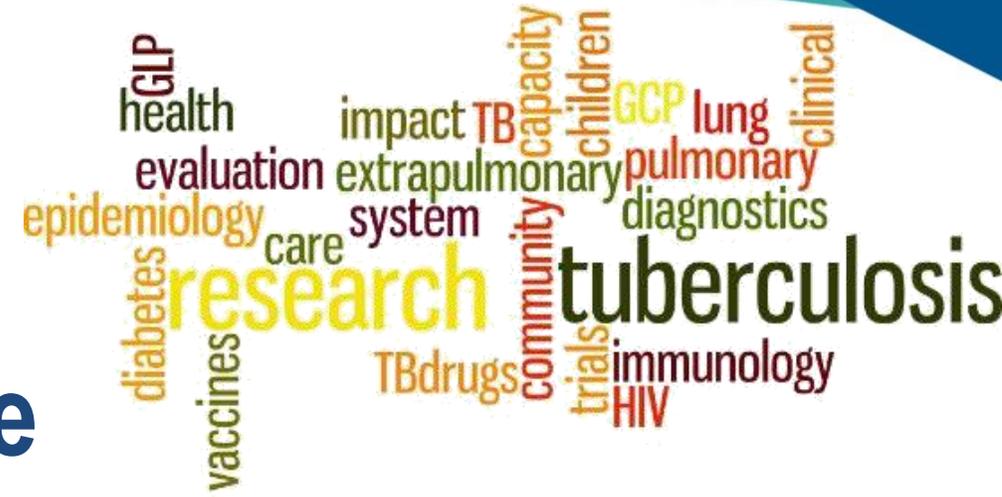


# WHO Global strategy for **TB Research** and **innovation** and its operationalisation at the Regional level (European **TB** **Research** priorities)



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# Outline

- TB Research Commitments
- Global Strategy for TB Research
- ERI Network and European TB Research Agenda

What is our basis

# BACKGROUND FOR STRATEGY DEVELOPMENT



# The End TB Strategy: 3 pillars and 4 Principles

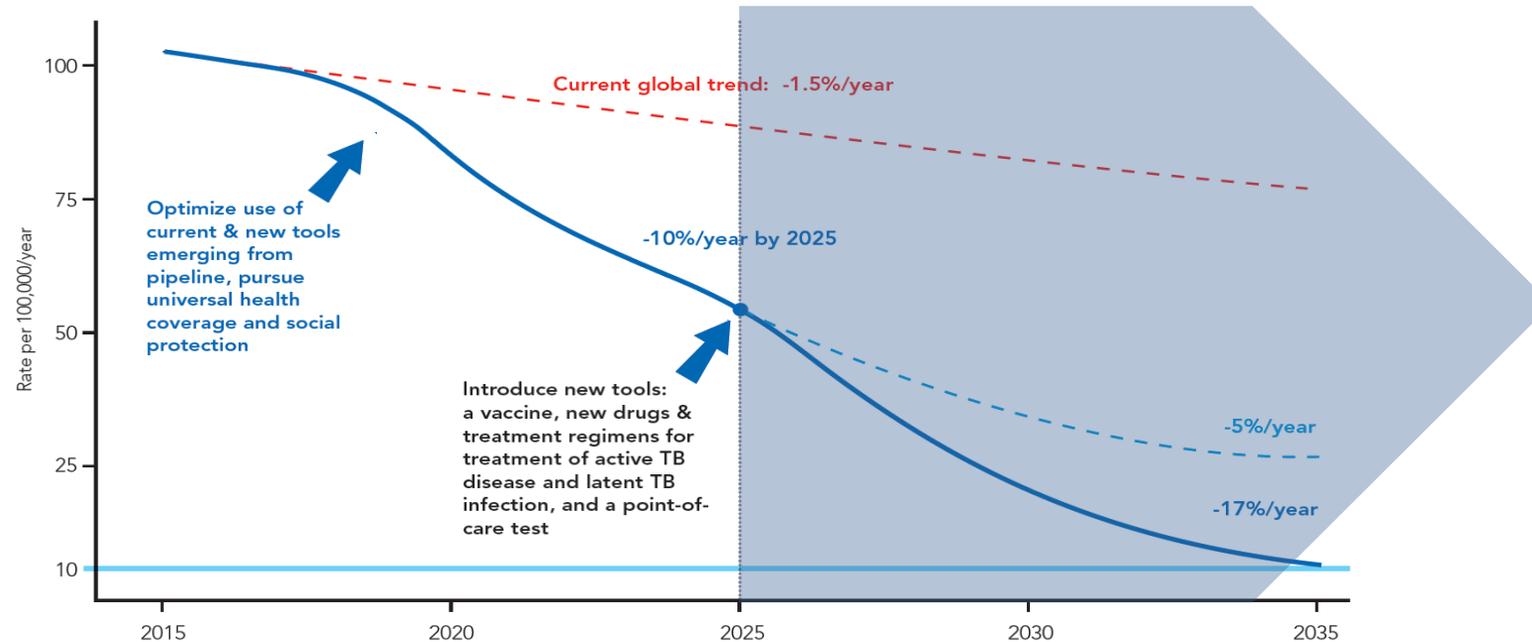


## **Pillar 3: INTENSIFIED RESEARCH AND INNOVATION**

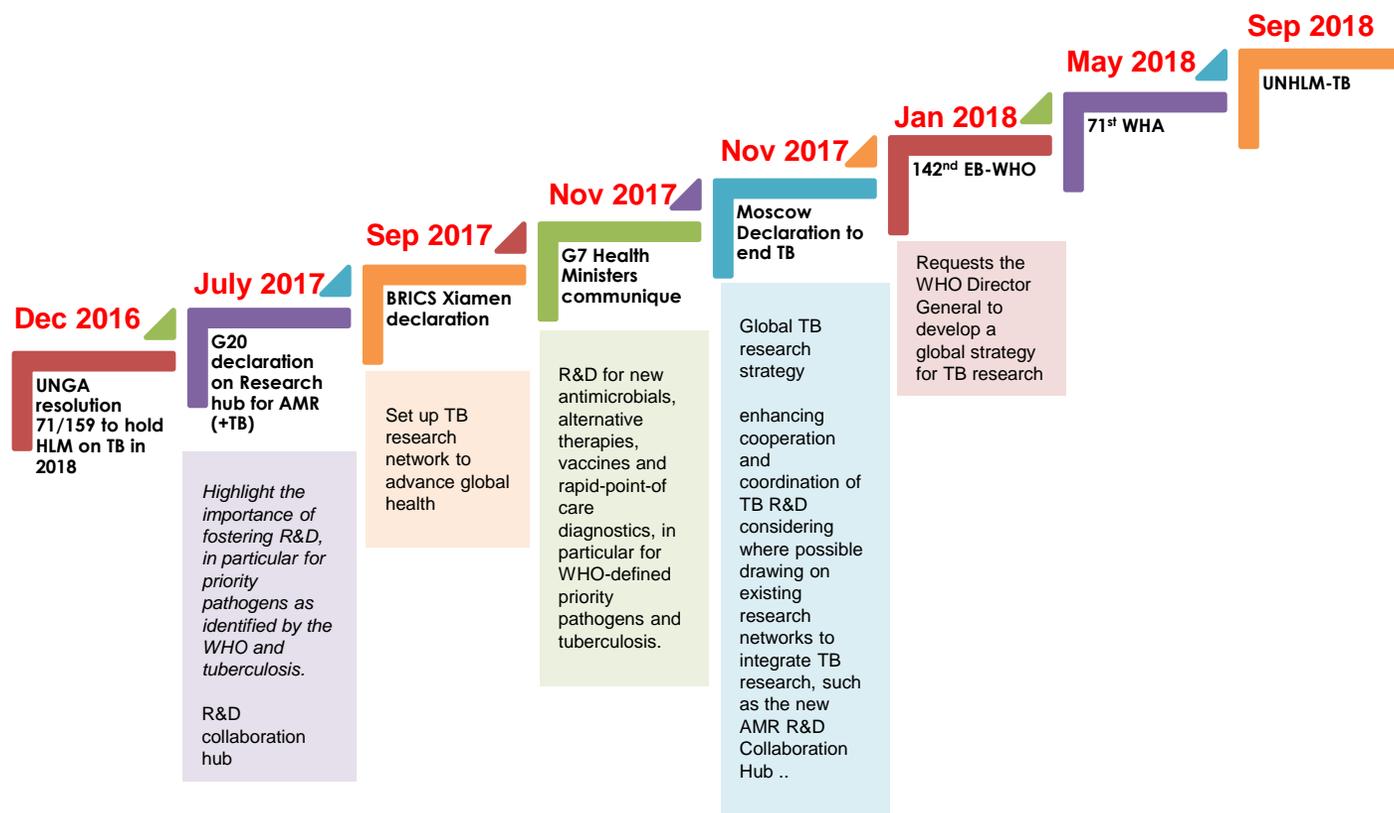
- Aims to intensify research from **the development of new tools** to their adoption and effective roll-out in countries.
- Pursues **operational research** for the design, implementation, and scaling-up of innovations.
- Calls for an urgent **boost in research investments**, so that new tools are developed, and made rapidly available and widely accessible in the next decade.

# Research is critical to break the trajectory of the TB epidemic

- Better diagnostics, including new point-of care tests;
- Safer, easier and shorter treatment regimens;
- Safer and more effective treatment for latent TB infection;
- Effective pre- and post-exposure vaccines.



# TB research commitments 2016-2018



- Commit to mobilize .. **US\$ 2 billion**...for the development and evaluation of **better diagnostics, drugs, treatment regimens and vaccines as well as other innovative care and prevention approaches, such as to address social and economic factors of the disease;**
- Commit to **create an environment conducive to research** and development ...**limiting barrier to innovation**...
- Promote tuberculosis research and development efforts aiming to be **needs-driven, evidence-based and guided by the principles of affordability, effectiveness, efficiency, and equity,** and should be considered as a shared responsibility.

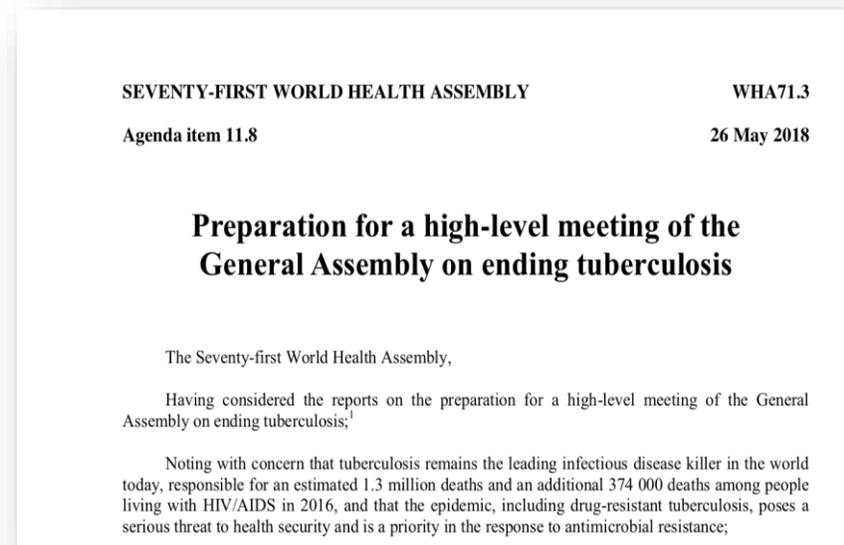
What is our plan

# GLOBAL STRATEGY FOR TB RESEARCH

# Development of a Global Strategy for TB Research

71<sup>st</sup> World Health Assembly:

- to develop a **global strategy for tuberculosis research** and innovation, taking into consideration both ongoing and new efforts, and to make further progress in enhancing **cooperation and coordination** in respect of tuberculosis research and development, considering where possible drawing on relevant existing research networks and global initiatives;



# Overall vision: from political commitment to action

**Main goal:** The aim of this strategy is to provide, for all Member States, a framework of interventions to remove barriers in TB research and innovation process to help achieve the goals and targets of the **End TB** Strategy

## Four strategic objectives

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



# A strategy that advances goals and targets of the End TB strategy and the SDGs

## Strategy goals (short, medium and long term)



Create an enabling environment for TB innovation



Increase financial investments in TB research and innovation



Ensure equitable access to the benefits of research



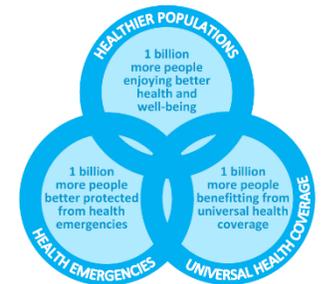
Promote and improve approaches to data sharing

Introduce new tools: a vaccine, new drugs & treatment regimens for treatment of active TB disease and latent TB infection, and a point-of care Test by 2025

Optimize use of current & new tools emerging from pipeline, pursue universal health coverage and social Protection

No TB affected families facing catastrophic cost ...95% reduction in TB deaths... 90% reduction in TB incidence rate

**SDG 3 “Ensure healthy lives and promote wellbeing for all at all ages”** SDG 3.B Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.



# Structure of the document

1. **Introduction and scope:** Overall **landscape** of the TB epidemic, and the research environment

2. **The challenge and way forward:**  
*Key needs, knowledge gaps, primary challenges and strategic goals in TB research (basic res, product development and implementation/operations research)*

3. **Strategic objectives** key for breaking the barriers,  
*(leveraging on existing strategies, platforms and opportunities)*

4. **Recommendations** for countries, global partners, civil society and international agencies

5. **Implementation and monitoring progress**



# Strategy roadmap



What EURO Region does to support it

# ERI TB NETWORK AND EUROPEAN TB RESEARCH AGENDA



# Establishing ERI-TB: as a milestone for the implementation of TBAP2020

Table A3.1. Areas of intervention under the action plan (contd)			
Problem	Proposed solutions	Major activities	Timeline
<b>3. Intensified research and innovation</b>			
<i>J. Discovery, development and rapid uptake of new tools, interventions and strategies</i>			
New technologies and service-delivery models are needed to achieve TB elimination. This will require an intensification of research, from fundamental research to drive innovations, to operational and health systems research to improve current programmatic performance. TB research is greatly underfunded, which has resulted in a meagre pipeline of new technologies for diagnosis, treatment and prevention. The research agenda is too wide to be tackled by individual countries.	Broad-based concerted effort is needed to develop research capacity, resource mobilization and advocacy. A European TB research initiative should be established to: <ul style="list-style-type: none"> <li>- identify needs, capacities and gaps (financial support for basic and operational research, language/translational support, etc.);</li> <li>- develop regional and national research agendas;</li> <li>- develop a platform for sharing new research and study results, and creating networks for research;</li> <li>- map collaboration between major research institutes and identify new areas for cooperation;</li> <li>- activate funding agencies to link with civil society organizations for research advocacy; and</li> <li>- provide the evidence base for policy and practice for TB prevention, control and care.</li> </ul>	A European TB research initiative should be established/formulated (in close consultation with WHO headquarters) to develop a research agenda, improve research capacity, and promote resource mobilization and advocacy.	By 2017

A European TB research initiative should be established/formulated (in close consultation with WHO headquarters) to:

(a) develop prioritized research agenda,

(b) improve research capacity, and

(c) advocate for resource mobilization to address evidence gaps.

# The ERI-TB Objectives:

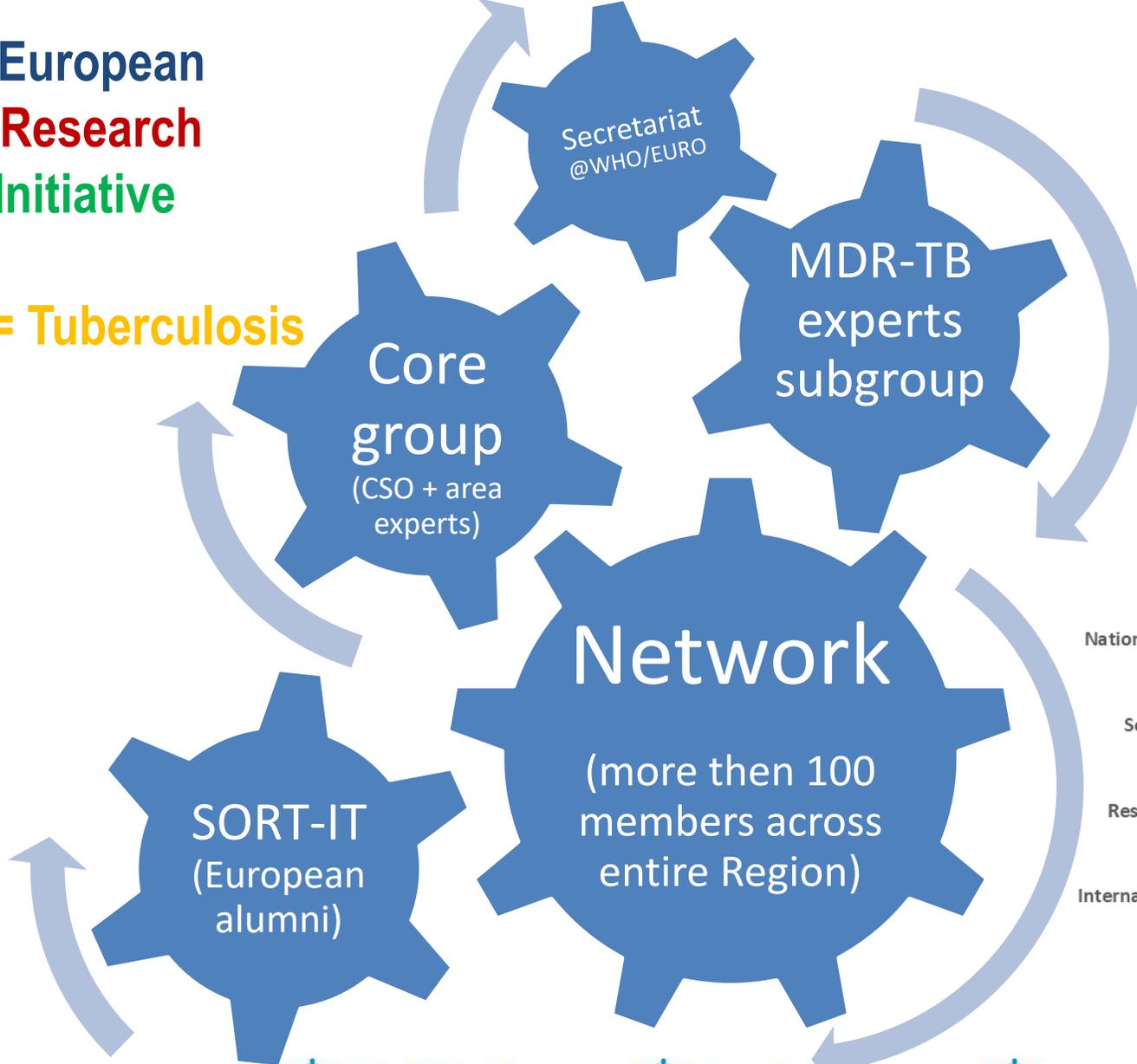
- i. To map ongoing and planned TB-related research activities in the Region;
- ii. To develop and update **regional research priority agenda** on a regular basis;
- iii. To facilitate **collaboration between research institutions** and key research stakeholders, and identify and promote areas for further cooperation;
- iv. To ensure **engagement of civil society organizations**, (ex)-patients and other relevant non-state actor representatives in TB research;
- v. To facilitate **dissemination of the results of research and their translation to evidence-based policies** and programmatic implementation via relevant fora and mechanisms;
- vi. To **document the funding gaps** in research and share with potential funding agencies, bilateral and multilateral organizations.

**Stetted Research  
Priorities**

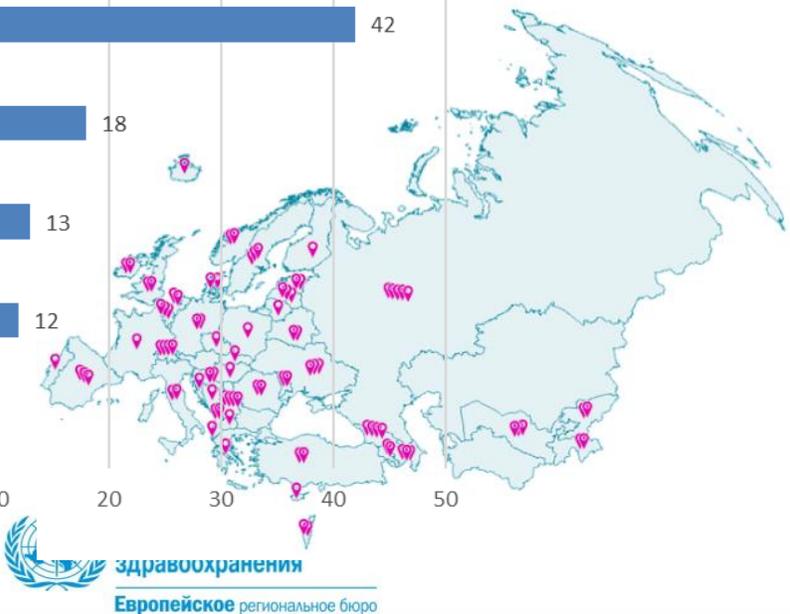
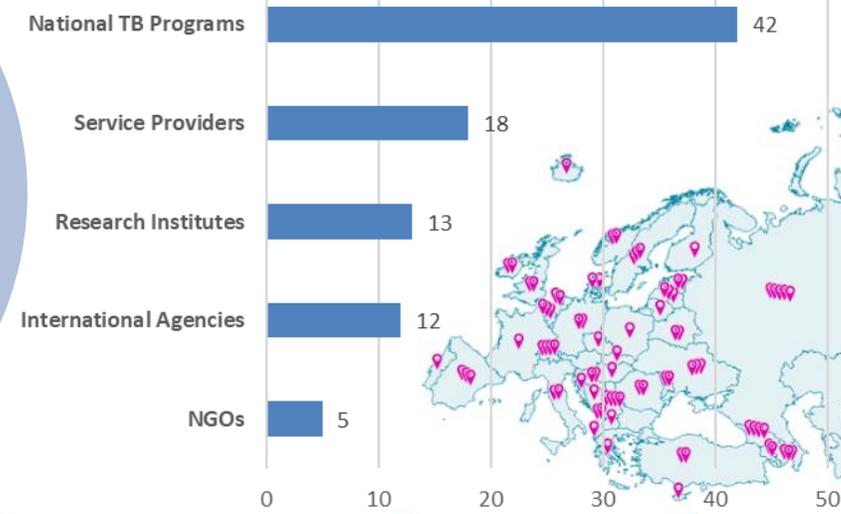
**ERI-TB OR Course  
to support these  
activities**

**E = European**  
**R = Research**  
**I = Initiative**

**TB = Tuberculosis**



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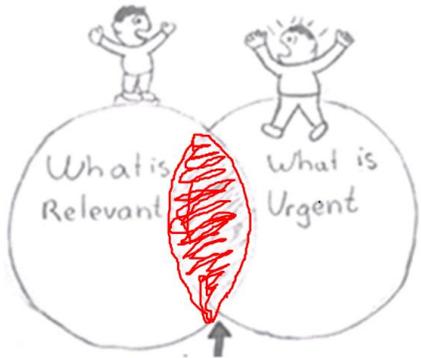
 **World Health Organization**  
 REGIONAL OFFICE FOR **Europe**

 **Organisation mondiale de la Santé**  
 BUREAU REGIONAL DE L' **Europe**

 **Weltgesundheitsorganisation**  
 REGIONALBÜRO FÜR **Europa**

 **здоровоохранения**  
 Европейское региональное бюро

# Defining TB research priorities for WHO European Region



© infographic by Maria DADU

High priority



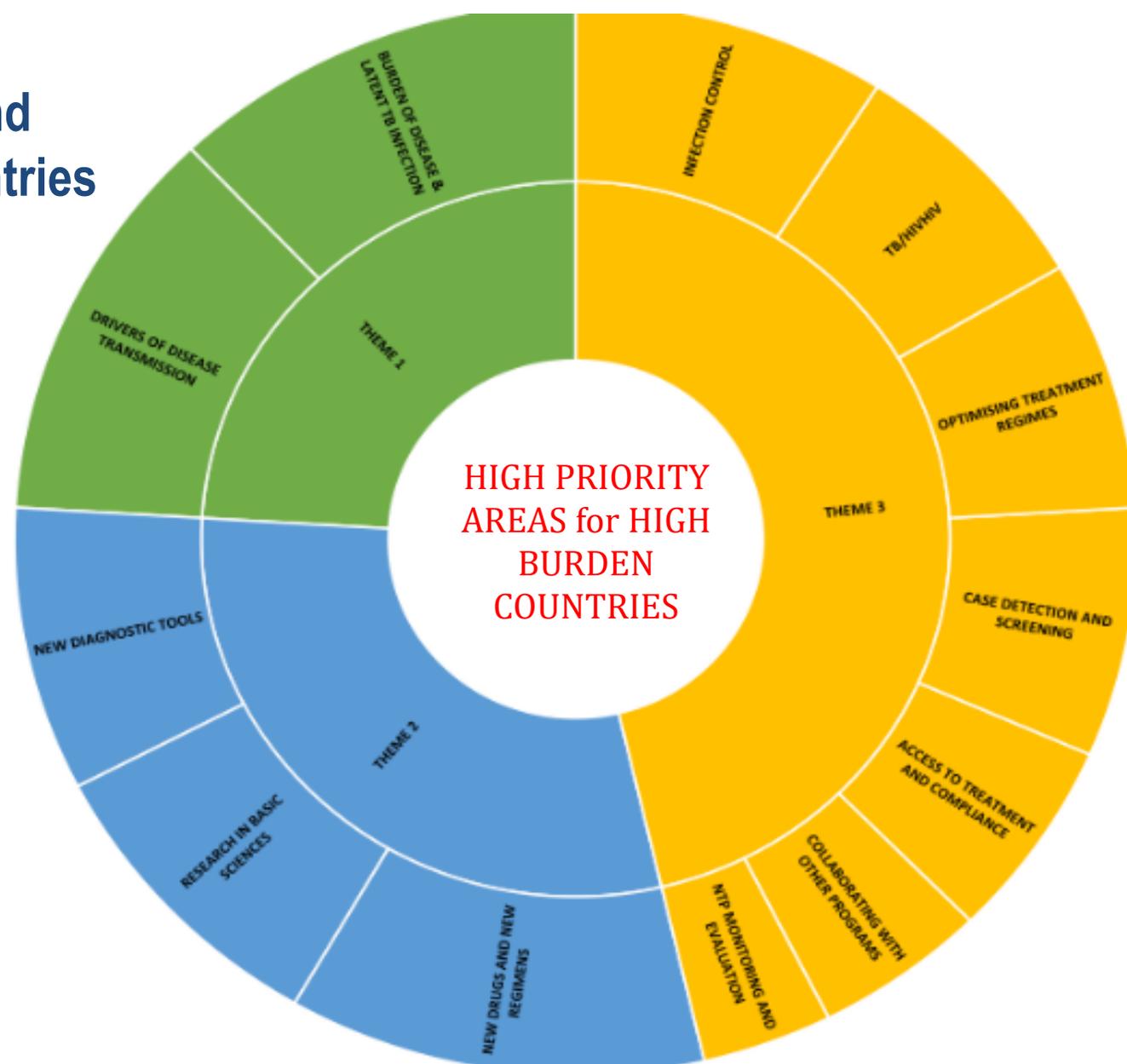
	High relevance	Middle relevance	Low relevance
High urgency	Priority 1	Priority 3	Priority 4
Middle urgency	Priority 2	Priority 4	Priority 5
Low urgency	Priority 4	Priority 5	Priority 6

## 4 steps:

1. Inventory of the country level research needed
2. Mechanism for setting Research agenda:
  - Delphi 1 = 128 RQs
  - Delphi 2 = 96 RQs
3. Public consultation: based on priority and relevance
  - 3 themes
  - 17 areas
  - 76 RQs
4. high priority and high relevant research question (RQ)
  - 3 themes
  - 10 areas
  - 19 RQs

# Structure TB research priorities for Region and distribution of those for the high burden countries

Theme 1 Epidemiological Research	<ol style="list-style-type: none"> <li>1. BURDEN OF DISEASE, INCLUDING LATENT TB INFECTION</li> <li>2. DYNAMICS AND DRIVERS OF DISEASE TRANSMISSION</li> </ol>
Theme 2 Innovation & Fundamental Research	<ol style="list-style-type: none"> <li>3. RESEARCH IN BASIC SCIENCES</li> <li>4. NEW DIAGNOSTIC TOOLS</li> <li>5. NEW DRUGS AND NEW REGIMENS</li> <li>6. NEW VACCINES</li> </ol>
Theme 3 Operational Research	<ol style="list-style-type: none"> <li>7. CASE DETECTION AND SCREENING</li> <li>8. ACCESS TO TREATMENT AND COMPLIANCE</li> <li>9. OPTIMISING TREATMENT REGIMENS</li> <li>10. HEALTH SYSTEMS AND PUBLIC PRIVATE MIX</li> <li>11. COLLABORATION WITH HIV PROGRAMS</li> <li>12. COLLABORATING WITH OTHER PROGRAMS</li> <li>13. INFECTION CONTROL</li> <li>14. NATIONAL TB PROGRAM MONITORING</li> <li>15. COMMUNITY PARTICIPATION</li> <li>16. SOCIAL DETERMINANTS OF TB</li> <li>17. LINKING TB RESEARCH WITH OTHER DISCIPLINES</li> </ol>



# HIGH PRIORITY RESEARCH QUESTIONS BY BOTH EUROPEAN HIGH AND LOW BURDEN COUNTRIES

## Theme 1 Epidemiological Research

- |   |   |
|---|---|
| 1. Burden of disease, including latent TB infection | <ol style="list-style-type: none"><li>1. "What are the trends of drug-resistant TB among the countries in the Region with specific reference to resistance to the new (bedaquiline, delamanid) and repurposed TB drugs (including clofazimine, the fluoroquinolones, and linezolid)?"</li><li>2. "Which are the most cost-effective TB case-finding screening methods among high risk populations?"</li></ol> |
| 2. Dynamics and drivers of disease transmission     | <ol style="list-style-type: none"><li>3. "Which are the most cost-effective interventions to reduce the spread of drug-resistant TB in the Region?"</li><li>4. "What are the social and biological drivers of drug-resistant TB in the Region?"</li></ol>   |

# HIGH PRIORITY RESEARCH QUESTIONS BY BOTH EUROPEAN HIGH AND LOW BURDEN COUNTRIES

Theme 2 Innovation & Fundamental Research	
3. Research in basic sciences	<p>5. "Which biomarkers are useful to determine the risk of progression from latent TB infection to active disease and to distinguish relapse from reinfection?"</p> <p>6. What are the genetic mutations associated with resistance to new and repurposed medicines?"</p> <p>7. "What are the candidate molecular targets for anti-TB drugs?"</p>
4. New diagnostic tools	<p>8. "What is the evidence that rapid molecular diagnostic techniques for the initial diagnosis of TB and resistant forms of TB (such as Xpert® and Whole Genome Sequencing) improve the diagnosis and treatment outcome, especially among children and people living with HIV?"</p> <p>9. "How effective and cost-effective are the new diagnostic platforms (including most recent molecular drug sensitivity tests and Whole Genome Sequencing platforms)?"</p>
5. New drugs and new regimens	<p>10. "What are the observed efficacy, safety and tolerability of new and repurposed medicines (especially among children, adolescents, people living with HIV and the elderly)? Are there any interactions with antiretroviral (ARV) drugs?"</p> <p>11. "What are the optimal doses of new and repurposed medicines in children?"</p> <p>12. "What are the most effective and patient- friendly short-term regimens for MDR/ extensively drug-resistant (XDR)- TB (taking into account the pill burden, use of injectable drugs and duration of treatment) in the Region?"</p>

# HIGH PRIORITY RESEARCH QUESTIONS BY BOTH EUROPEAN HIGH AND LOW BURDEN COUNTRIES

## Theme 3 Operational Research

6. Case detection and screening	<p>13. "What is average time to TB diagnosis among the various risk groups and what are reasons for diagnostic delay?"</p> <p>14. "What are the most effective approaches to the management of close contacts of MDR and XDR-TB index patients?"</p>
7. Access to Rx and compliance	<p>14. "What are the main reasons for patients to discontinue treatment in the Region?"</p>
8. Optimising treatment regimes	<p>15. "What is the optimal preventive regimen for tolerability, efficacy, safety and compliance for close contacts of isoniazid resistant, MDR and XDR-TB index patients?"</p> <p>16. "What are the extent and impact of the short course MDR- TB regimen in National TB programmes in the Region?"</p>
9. Collaboration with HIV programs	<p>17. "What is the optimal screening algorithm for active TB and latent TB infection among people living with HIV"</p> <p>18. "Integrating TB-HIV care: What are the best models for delivering TB-HIV treatment and monitoring?"</p>
10. Infection control	<p>19. "For how long do patients with drug-sensitive and drug-resistant TB remain infectious after starting treatment?"</p>

# Why operational research for new drugs/regimens/diagnostics

Randomized Clinical Trials

**In trial conditions**, generates knowledge on new treatment

- Risk
- Safety

Operational Research

**In Real world conditions**, generates knowledge on

- **'How to apply'** that knowledge
- Supports **evidence based management**
- Policy and practice implications

Patients and communities benefits

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## The European Tuberculosis Research Initiative (ERI-TB)

The goal of ending the global tuberculosis (TB) epidemic by 2035 was set by the WHO End TB Strategy and endorsed by the World Health Assembly in May 2014. To achieve this goal, the development and implementation of innovative tools (such as new vaccine(s), diagnostics, medicines, preventive and treatment regimens, and innovative service deliveries) is essential. Effective and timely development and implementation of the new tools should be supported by intensified efforts across the continuum of basic science to applied research and development and operational research.



WHO

This important task is included as the third pillar in the Global End TB Strategy and the Tuberculosis Action Plan for the WHO European Region 2016–2020.

The establishment of the European Tuberculosis Research Initiative (ERI-TB) is one of the key milestones of the TB Action Plan for the WHO European Region 2016–2020 and its accompanying resolution, which were endorsed by the 65th session of the Regional Committee of the WHO Regional Office for Europe.

