

The Union



worldlunghealth.org

THE 51ST UNION WORLD
CONFERENCE ON LUNG HEALTH

ADVANCING PREVENTION

20–24 OCTOBER 2020
VIRTUAL EVENT

CONFLICT OF INTEREST DISCLOSURE

☐ I have no Conflict of Interest to report.

☒ I have the following Conflict of Interest(s) to report:

Please tick the type of affiliation / financial interest and specify the name of the organisation:

☒ Receipt of grants/research supports: **IMI2**

☐ Receipt of honoraria or consultation fees: _____

☐ Participation in a company sponsored speaker's bureau: _____

☐ Tobacco-industry and tobacco corporate affiliate: _____

☐ Stock shareholder: _____

☐ Spouse/partner: _____

☐ Other: _____

THE EUROPEAN REGIMEN ACCELERATOR FOR TUBERCULOSIS (ERA4TB)

CONCEPT, VISION AND PROGRESS

Stewart Cole

22nd of October 2020

 @UnionConference #UnionConf

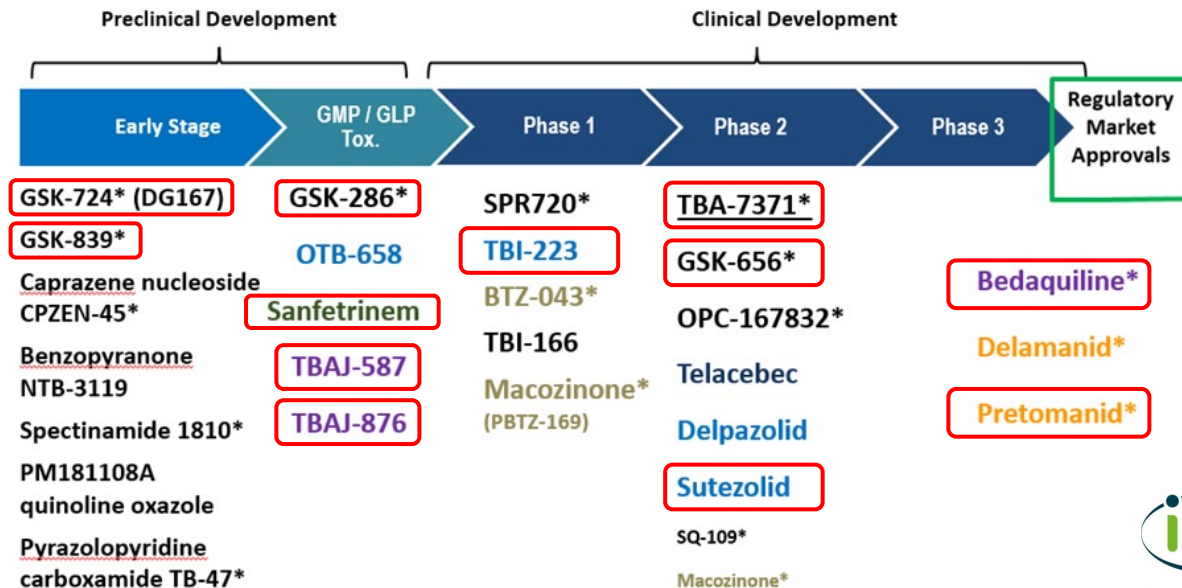
NEED FOR PUBLIC-PRIVATE COLLABORATION IN TB RESEARCH AND DEVELOPMENT

Tuberculosis (TB) is the **leading** infectious cause of death worldwide. To achieve the target of TB elimination by 2035, the WHO estimates that there is a funding **shortfall** of over \$1 billion per year in TB research.

Significant scientific challenges to the discovery of new safer, simpler, shorter treatments regimens for TB

- **Collaborative** approaches needed to address these challenges
- **Shared** experience, learning and resources

ERA4TB: A UNIQUE OPPORTUNITY



2020 Global TB Drug pipeline

(details and legends: www.newtbdrugs.org)



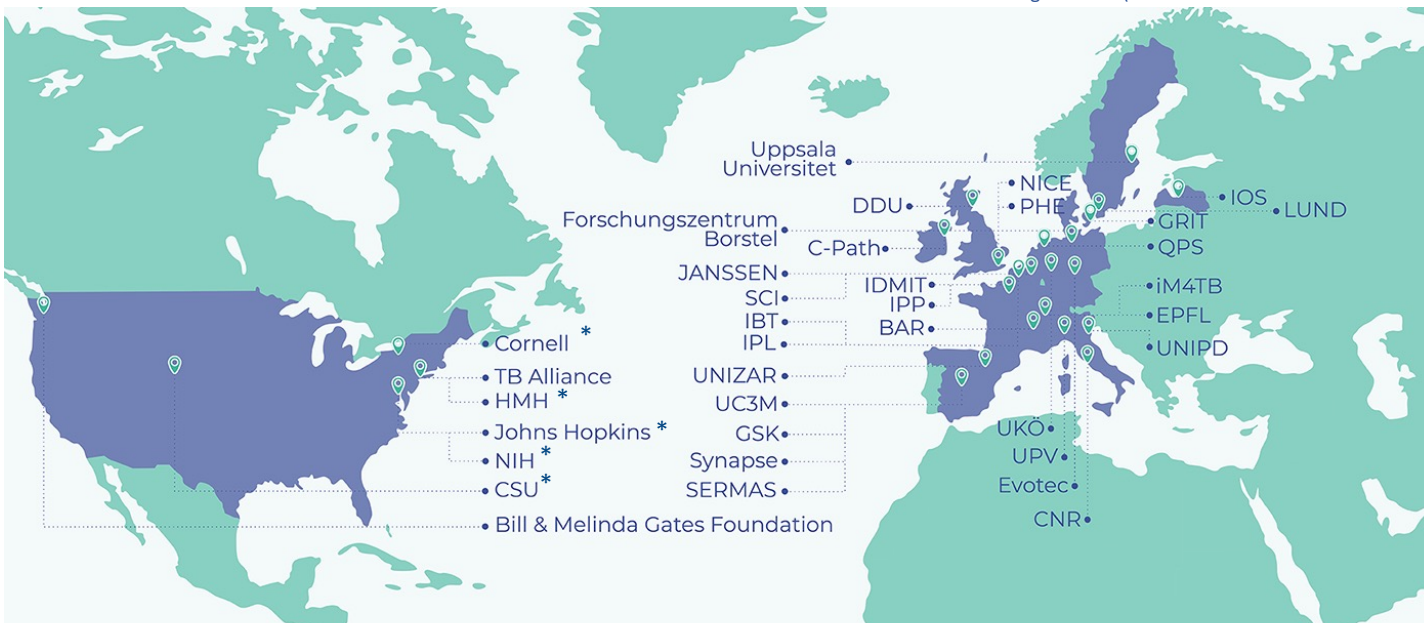
Call topic

Academic groups, SMEs,...



THE CONSORTIUM

*Collaborating Partners (no full members of the consortium)



- 25 European Academic Partners
- 6 EFPIA & Associated Partners
- 5 Collaborating Partners (no full members)

Overall Budget / 6 years:

- ca. 207 Million euros
- ca. 90 Million in EU IMI contributions

<https://era4tb.org>

ERA4TB IN THE IMI2 AMR ACCELERATOR PROGRAMME

Pillar A Capability Building Network

COMBINE

To coordinate and support projects across the Accelerator and deliver pre-competitive science to accelerate scientific discoveries in AMR

Pillar B TB Drug Development Networks

ERA4TB

UNITE4TB

Stage 2 proposal phase

To accelerate and validate scientific discoveries and advance the R&D pipeline of new and innovative agents to address the global tuberculosis epidemic

Pillar C Portfolio Building Networks

Respiri-NTM

GNA-NOW

Respiri-TB

TRIC-TB

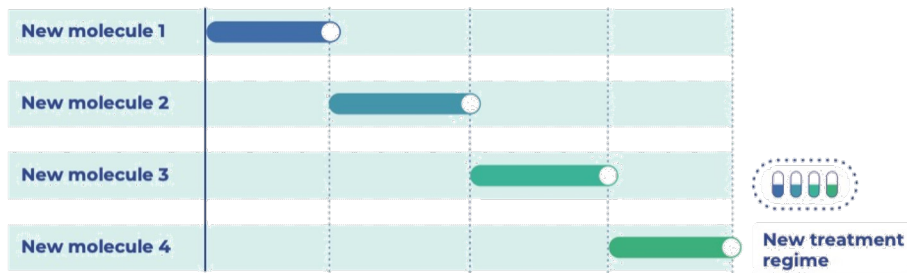
AB-DIRECT

To advance the R&D pipeline of new and innovative agents to address AMR topics

OBJECTIVE

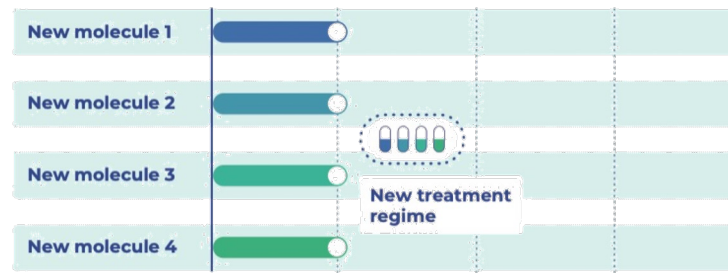
To create a European open platform to **accelerate the development of new regimens** for the treatment of tuberculosis

CONVENTIONAL APPROACH



Sequential development

ERA4TB STRATEGY



Parallel approach

VISION

To create a European open platform to **accelerate the development of new regimens** for the treatment of tuberculosis.

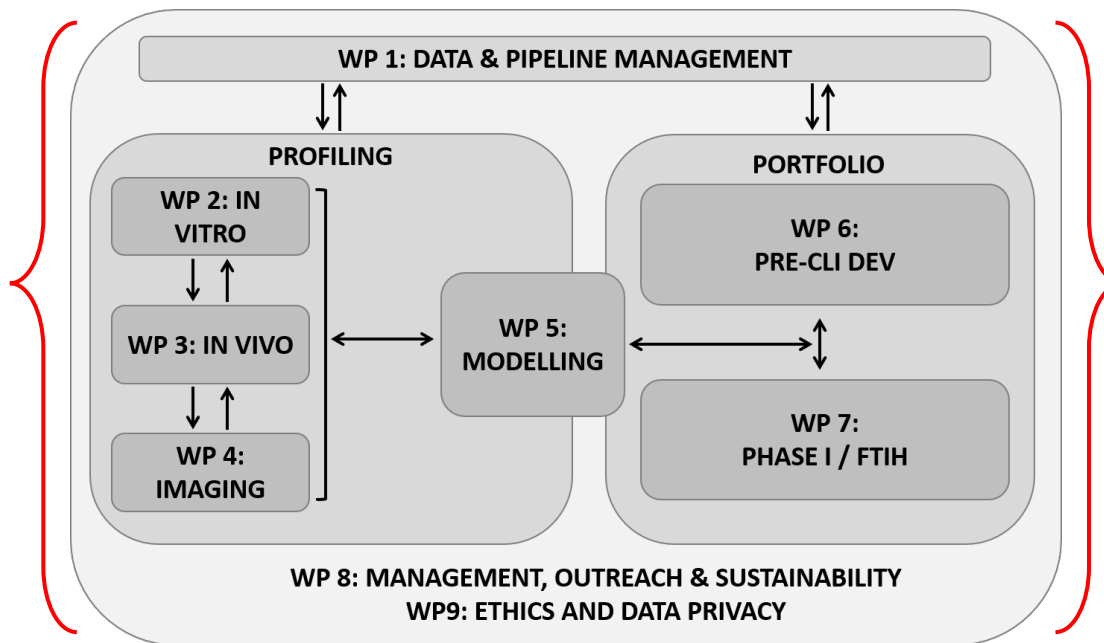
1. Community-focused **platform on TB translational research**.
2. Academia - industry integration to ensure the ***innovation*** needed to **accelerate the progression of novel drug candidates** into humans.
3. Optimize the **human dose** and **clinical trials** (FTIH) studies → further clinical development.
4. To ensure platform **sustainability** beyond the scope of the project.
5. To make **tangible impact** on TB pandemic.

ERA4TB THREE PILLARS

1. Excellent Science
2. Portfolio of assets and in-kind resources
3. Tools and assays for asset progression

WORK-PACKAGE STRUCTURE- 2 CRITICAL OUTCOMES

A set of complementary and cross-cutting tools that generate information to define best companion drugs and combinations for future TB regimens.



A platform that will accelerate the progression of new molecules to become ready for PhII clinical studies with TB patients.

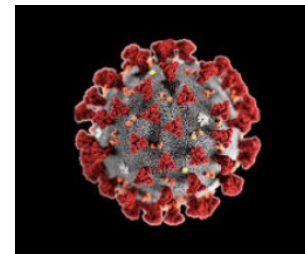
DELIVERABLES

- Create platform for preclinical development (CMC, Toxicity,...activities)
- Establish a network of Phase I units in Europe
- European-based platform of tools/assays of high translational value
 - *In vitro* assays for characterization and profiling of compounds
 - Hollow fibre model, Time Lapse microscopy, PET-CT, Maldi-tof
 - *In vivo* NHP and mouse models
- Implementation of modelling platform to predict activity of drugs and their combinations in humans (...towards virtual clinical trials?)
- Data repository platform

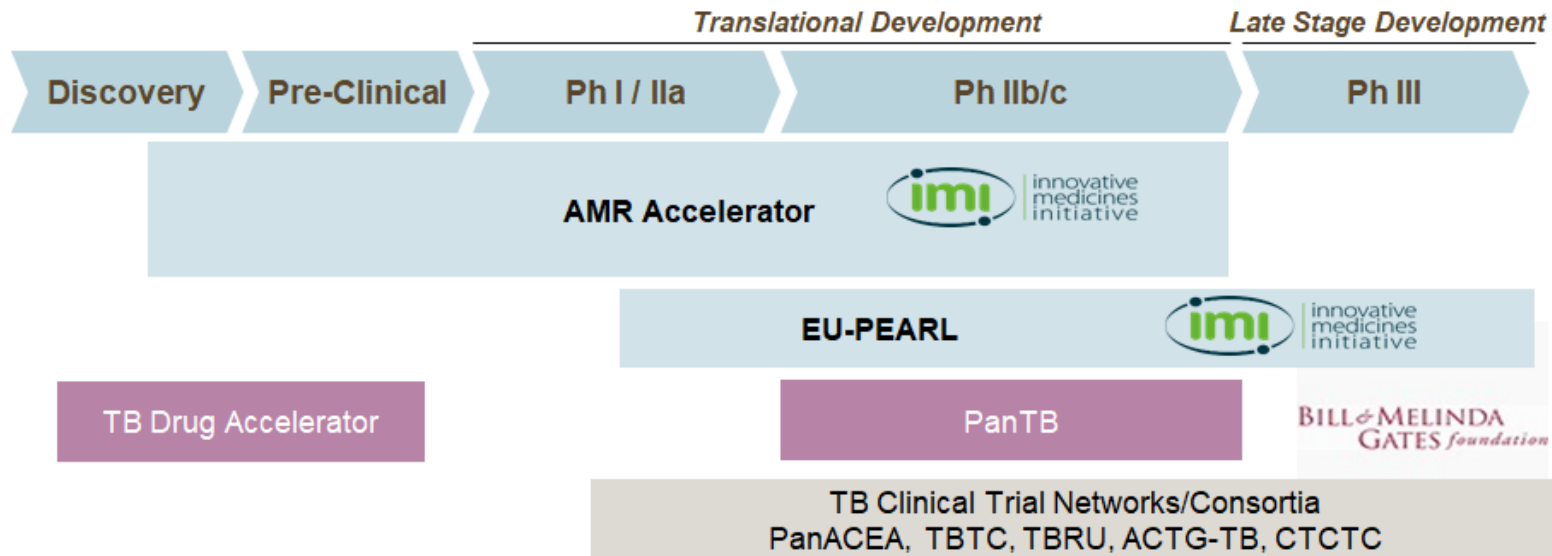
Provide up to 6 phase 2-ready assets (preferably novel MoAs)

PROGRESS TO DATE

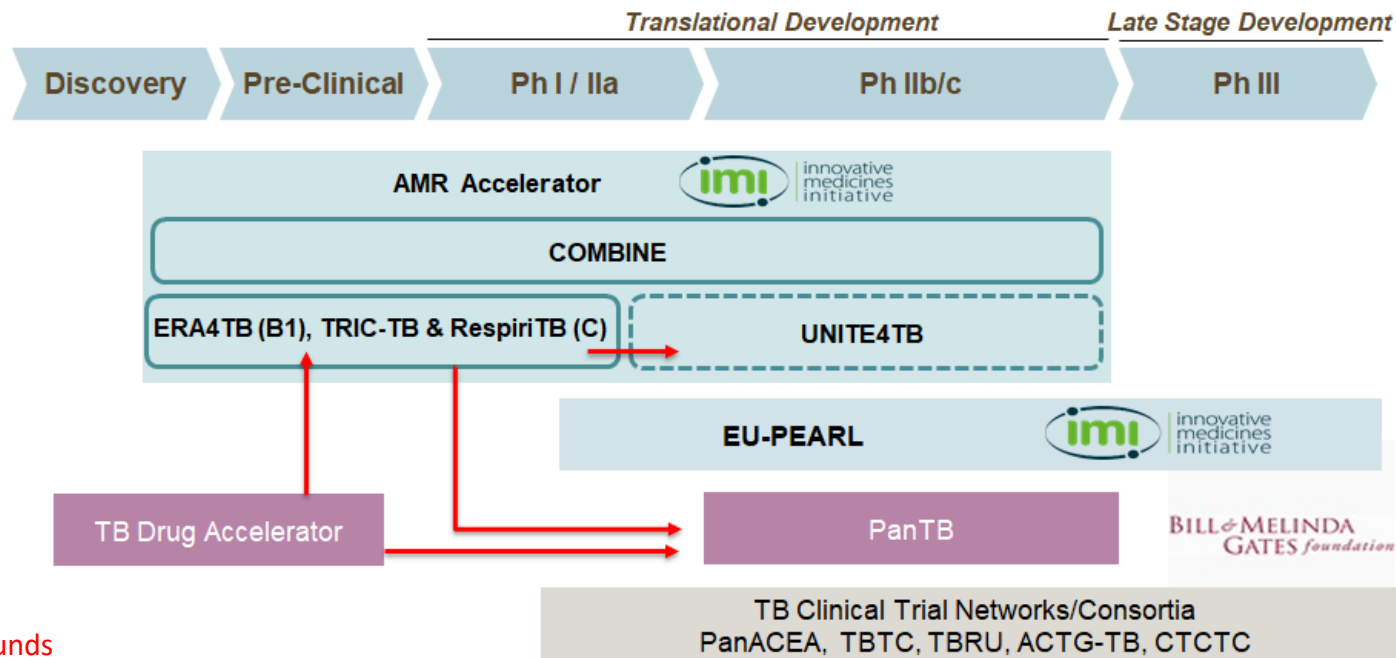
- All WPs operational but variably impacted by Covid-19
- WP1, 5, 6, 8, 9 << WP2, 3, 4, 7
- Some highlights:
 - WP1 – Establishment of platform to share data generated/results
 - WP2 – In vitro profiling/characterization ongoing, Hollow fibre model being implemented
 - WP3 – NHP TB models (Validation and benchmarking ongoing)
 - WP4 – Implementation PET-CT for rodents and NHP, Maldi-tof in BSL3 facility, Development of Time lapse microscopy technology
 - WP6 – 4 compounds being progressed (DDU209, DDU384, MPL-204, GSK839)
 - WP7 – 2 compounds endorsed to enter into FTIH (GSK2556286, TBAJ-587)



AN EVOLVING LANDSCAPE OF COMPLEMENTARY AND SYNERGISTIC COLLABORATIONS IN TB DRUG DISCOVERY & DEVELOPMENT



AN EVOLVING LANDSCAPE OF COMPLEMENTARY AND SYNERGISTIC COLLABORATIONS IN TB DRUG DISCOVERY & DEVELOPMENT



→ compounds

Thanks for joining!