IMI AMR Accelerator
Public Private Partnership for prevention and treatment of MDR bacterial infections

4th AMR Conference
27 August 2020
Graham Somers – GlaxoSmithKline Pharmaceuticals
IMI2 : How it works

1. The public contribution
   - 1,638 Billion €
   - From H2020

2. The private industry in-kind contribution
   - 1,638 Billion €
   - EFPIA direct and indirect members

3. What are the results?
   - 1,425 ERFU direct and indirect members
   - 213 Other sectors

   - 1,638 Billion €
   - 3,276 Billion €

   - Private Partners
   - Public Partners

   - CASH for grants for PUBLIC PARTNERS

   - Improve R&D
   - Improve outcomes & safety
   - Speed up patient access

EU-Industry Contribution to IMI2

The public contribution

The private industry in-kind contribution

1. 2.

What are the results?
= in IMI2 consortia
1,638 3,276

From H2020

2014 - 2024

Other sectors

Private
Partners

Public
Partners

3. in IMI2 consortia

3,276 Billion €

213

People

Consumables

Laboratories

Cash

213

Other sectors

CASH for grants for PUBLIC PARTNERS

Topic definition phase

Stage 1

Industry consortium

Applicant consortium

Stage 2

Definition of topics by industry consortium

SP Submission & Evaluation

FP Submission & Evaluation

Granting phase

Signature of Consortium and Grant Agreements

Project launch!

Call launch

Selected stage 3 team merge with industry team

Start of the Granting phase
**Programme Concept**

**IMI’s Antimicrobial Resistance (AMR) Accelerator programme**
comprises several projects with the shared goal of progressing the development of new medicines to treat or even prevent resistant bacterial infections in Europe and worldwide.

The AMR Accelerator

Currently 58 participants, >295 M€ budget

Current Goals: by 2025
10 new preclinical candidates
Up to 5 Phase II-ready compounds
AMR Accelerator Projects (www.amr-accelerator.eu)

ERA4TB

ERA4TB is expected to revolutionize the way in which tuberculosis treatments are developed thanks to its parallelized, multi-entry pipeline structure, analogue to a production line. This structure will enable to systematically investigate the efficacy of several drug candidates and combinations simultaneously while allowing new molecules to enter the project pipeline at the research stage corresponding to the degree of knowledge on said candidate drugs gathered before the project.

With this approach, the ERA4TB consortium expects to reduce the time required for the development of new tuberculosis treatment regimens by up to a quarter.

GNA NOW

COMBINE will coordinate the AMR Accelerator and support the delivery of projects across the Accelerator in order to progress a pipeline of potential new medicines to treat and prevent infections with resistant bacteria.

COMBINE will exploit an IT infrastructure for management, integration and analysis of combined data from across all Accelerator projects, perform regular data management reviews, leverage best practices, create software specifications, review, testing tasks.

COMBINE will facilitate communication among Accelerator projects, with the AMR community and beyond as well as disseminate news and results, work in close collaboration with existing AMR drug development initiatives.

COMBINE will share and analyse vaccine and antibacterial data, to improve the design and analysis of clinical trials.

COMBINE will improve the understanding of animal infection models reproducibility and translation to clinical efficacy.

Ab-Direct

TRIC-TB

The specific objectives of this IMI project are to deliver one Phase II ready booster molecule, having a) completed preclinical CTA enabling studies and b) completed Phase I (SAD and MAD) for safety and PK evaluation in healthy volunteers.

Ultimately, the results from this project will pave the way for the booster to be integrated into new, improved regimens to treat TB including MDR-TB. A small molecule booster in combination with lower ETH/4TH doses will deliver a better tolerated and more potent drug combination than standard doses of ETH alone, and this can massively impact the current TB treatment smear-negative and significantly improve both patient experience and treatment outcomes.
AMR Accelerator Projects: currently under development

UNITE4TB
(Stage 2 negotiation Call 20)
~200 M€ budget

Modelling the Impact of mAbs and vaccines on the reduction of AMR
(Call 23)

- Evaluate burden of disease
- Develop a model to estimate the cost and benefits of mAbs and vaccines in AMR
The COMBINE Project – Coordination Role

The COMBINE project was created to coordinate the AMR Accelerator projects and provide them with the resources they need to achieve their goals.

SCIENTIFIC OBJECTIVES
Standardise animal models & Improve clinical trials

OUTREACH ACTIVITIES

SUPPORT
- Coordination Committee
- Data Management Group
- Ethics Advisory Board
- Communication Advisory Board

ERA4TB
TRIC-TB
RespiriTB
RespiriNTM
AB-Direct
GNA NOW
The COMBINE Project - Scientific Mission

The COMBINE project also has scientific goals around capability building.

- WP1 Coordination & Support
- WP2 IT Infrastructure & Data Management
- WP3 Communication & Networking
- WP4 Improve Clinical Trial Design and Analysis
- WP5 Standardize Animal Infection Models

**WP4** Improve Clinical Trial Design and Analysis

- Define data requirements
- Inform planning of new trials & experiments in AMR Accelerator projects; uptake of learnings

**WP5** Standardize Animal Infection Models

- Non-clinical data with predictive value
- PREDICTION of human efficacy and trial design for higher success rate

**WP2** IT Infrastructure & Data Management

- Data access

**WP1** Coordination & Support

- Preclinical and clinical data sets

**WP3** Communication & Networking

- Use

The COMBINE project also has scientific goals around capability building.

The COMBINE project also has scientific goals around capability building.
You Can Help! - Open Call for Data

Call for non-clinical (preclinical) and clinical data sets from the study of prevention or treatment of bacterial infections

Antibiotics, vaccines, monoclonal antibodies, pathoblockers and phages

We are specifically looking for
1) Matched pairs of preclinical toxicology data and Phase 1 studies
2) Matched pairs of preclinical PK/PD analysis and clinical PK/PD studies
3) Matched pairs of preclinical efficacy in challenge models and data from efficacy trials
4) Data from clinical trials for prevention or treatment of bacterial infections

What pathogens?
- ESCAPE pathogens: Enterococcus faecium, Staphylococcus aureus, Clostridioides difficile, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacteriaceae
- Neisseria gonorrhoeae
- Mycobacterium tuberculosis

Submit your Expression of Interest:
AMR-data-technical.COMBINE@grit42.com
Deadline extended to October 2020
A new focus with the future health initiative via a Cross-Sector Partnership with a potential €3B public private partnership

IHI Vision is to

- **Push boundaries of the pre-competitive space:** mobilise and combine expertise across pharma, biologic, med tech and health IT
- **Pioneer paradigm changes** and cross-sector innovation
- **Strengthen translational research ecosystem** in Europe

Five new focus areas for the IHI

1. Genetics, biology & technology across continuum of care
2. Big Data & AI in R&D, products & services for integrated healthcare
3. Patient-centric integrated care across HC continuum
4. Engaging patients to manage & improve their Health
5. Value initiatives to guide investment & rewarding of innovation in HC

Source: EFPIA
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https://www.imi.europa.eu/