



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

11.03.2020 – Improving the success of R&D efforts in the fight against AMR is one of the long-term goals of COMBINE. To this end, the consortium calls upon the AMR community to share data from studies of prevention or treatment of bacterial infections.

Antimicrobial resistance (AMR) is an acute challenge for global public health with an estimate of 33,000 people dying each year in Europe alone due to infections with antibiotic-resistant bacteria. AMR and the urgent need for new effective anti-bacterial therapeutics and vaccines are also a huge challenge for organisations involved in the discovery and development of these. COMBINE is an IMI2-funded consortium, which supports the work of the IMI AMR Accelerator by identifying better ways to translate preclinical know-how into clinical practice and vice-versa. COMBINE will perform systematic cross-study analyses of relevant data sets originating from the AMR community. Experimental studies will then be run in order to validate findings, with the long-term goal of improving the success of R&D efforts across the AMR community.

Preclinical: To facilitate preclinical development, the team will optimise and validate standard protocols for preclinical infection models and make these available together with bacterial reference strains.

Clinical: To increase success rates in clinical trials, the team will develop a framework that enables COMBINE scientists to analyse (i) **matched preclinical and clinical data** to identify factors that predict outcome of the clinical trial; and (ii) **aggregated clinical trial data** to identify factors that hamper success but only become visible with aggregation of data from multiple trials.

OPEN CALL FOR AMR DATA

To achieve these aims, we are searching for collaboration partners interested in making their data and protocols available for analysis and development of innovative statistical methodologies.

The COMBINE consortium is launching its first **OPEN CALL FOR DATA** to find partners worldwide that are willing to share data from **studies of prevention or treatment of bacterial infections** suitable for this type of method development.

We urgently need new anti-infectives to treat patients with AMR-related infections. The extended analyses we can perform using your data will help the AMR community to learn from the body of available science. **YOU** can help to prevent future failures and increase success rates of future developments by giving COMBINE access to data.

What are WE looking for?

Data from the study of medicines or candidate medicines for prevention or treatment of bacterial infections, e.g. **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

Data from **all relevant trials, both former successes and failures, are highly relevant** to derive the desired learnings.

What pathogens are WE interested in?

- ESCAPE pathogens: *Enterococcus faecium*, *Staphylococcus aureus*, *Clostridioides difficile*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Enterobacteriaceae*

Enterobacteriaceae include *Escherichia coli* (ideally ESBL positive) and *Klebsiella pneumoniae*.

- *Neisseria gonorrhoeae*

- *Mycobacterium tuberculosis*

Are YOU interested?

- 1.) Please **SEND AN EMAIL by end of October 2020** to AMR-data-technical.COMBINE@grit42.com to submit your Expression of Interest (Eoi). If accepted, we will contact you to provide more details on the data sharing process.
- 2.) For technical questions on data protection and FAIRification, please contact the COMBINE consortium at AMR-data-technical.COMBINE@grit42.com.
- 3.) If you have a question or an idea on what type of analysis we could perform with your data sets or a specific interest – contact the COMBINE team at AMRCOMBINEscientific@pei.de.

What's in it for YOU or your company?

We can make your data work harder for you and help you to gain new insights into model selection, trial design and the overall potential of your pre-clinical or clinical asset as a new treatment or vaccine. The impact of your data and the scope of the analyses possible will be greatly multiplied by working with the COMBINE team. You will be directly involved in the analysis and you will be the first to have access to the results.

Who else will benefit?

For clinical trial data aggregation, we will need data sets from different companies/sponsors; we hope to find that analysis of these aggregated data provides new findings that will be made available to the data donors first.

Following a mutually agreed “innovation friendly” release process, results and methodology will be published in an accessible format and made available to the wider community.

Send your EOI to AMR-data-technical.COMBINE@grit42.com.

About COMBINE

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<https://www.imi.europa.eu/>



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