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

Antimicrobial resistance (AMR) is a major threat to global public health and there were an estimated 1.27 million deaths attributable to bacterial AMR in 2019 (Murray et al., The Lancet, 2022). Developing new effective anti-bacterial products represents a huge challenge for R&D organizations.

COMBINE is part of the AMR Accelerator, an IMI programme to progress the development of novel medicines to treat or prevent AMR infections. COMBINE aims to standardise preclinical infection models, improve the translation from preclinical to clinical development, and optimize clinical trial design and data analysis. To fulfil these objectives, COMBINE is looking for **aggregated and/or matched clinical data from candidate medicines to prevent or treat AMR infections**.

OPEN CALL FOR AMR DATA

COMBINE is seeking collaboration partners willing to share their data and protocols for the analysis and subsequent development of innovative trial methodologies. We are looking for (i) **individual level 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. By making your data available to COMBINE, you are contributing today to making the development of products against AMR infections more expedited and efficient in the future.

What are WE looking for?

We are looking for data from **antibiotics, vaccines, monoclonal antibodies,** and other approaches to **treat or prevent AMR bacterial infections,** and we are equally interested in **successful and failed programs**.

We are specifically looking for clinical efficacy data at patient-level, e.g. PK/PD (when applicable), correlates of protection, dose-response data, and time-to-event data (both primary and secondary study endpoints). Additional relevant data include information to study specific subpopulations (gender, age, comorbidities) as well as study meta-data (e.g. study protocol).

What pathogens are WE interested in?

- ESKAPE pathogens (*Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacter* spp.)

- *Escherichia coli*, ideally ESBL positive *E. coli*

- *Clostridioides difficile*

What´s in it for YOU or your company?

Beyond the general goal of improving the robustness of preclinical models, translation to the clinics, and improved clinical trial designs, you might also find some direct benefits for your company:

- GET AN EARLY PREVIEW OF THE RESULTS: As project contributor, you will get access to the results of the aggregated analyses before they are made public.
- GET MORE OUT OF YOUR DATA: Should we identify new findings specifically from your data, we will notify you promptly. We may also consider running specific analyses on your data, if they are within the scope of COMBINE.
- GET INVOLVED IN THE ANALYSIS: Do you have a research question you were never able to answer using your data alone? Let us know: maybe we can investigate it on the aggregated data gathered by COMBINE.
- IMPROVE YOUR OVERALL DATA MANAGEMENT PROCESS: We can provide hands-on training to FAIRification of data for SME and academia - a process that is now increasingly becoming a pre-requisite imposed by funding agencies for grant application.

What about safety and data protection?

The COMBINE researchers commit to the highest standards of data security and protection in order to preserve the rights of data providers and personal rights and interests of all study participants, in the case of sensitive clinical data. Contact **AMR-data-technical.COMBINE@grit42.com** for more details and technical questions on data protection and FAIRification.

Are YOU interested?

Then get in touch! For technical questions on data protection and FAIRification, as well as to initiate the data sharing process, please contact **AMR-data-technical.COMBINE@grit42.com**. For questions, ideas and suggestions regarding the data analysis, please contact **IMI-COMBINE@pei.de.**

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

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

About AMR Accelerator

The aim of the Antimicrobial Resistance (AMR) Accelerator Programme is to progress the development of new medicines to treat or even prevent resistant bacterial infections in Europe and worldwide. The programme comprises the following three pillars: a Capability Building Network, a Tuberculosis Drug Development Network, and the Portfolio Building Networks. The scope of the AMR Accelerator is broad; under one structure, it addresses many of the scientific challenges of AMR, and it supports the development of new ways to prevent and treat AMR. More broadly, the AMR Accelerator contributes to the European action plan on AMR.

For more information on the AMR Accelerator, please visit www.amr-accelerator.eu.

AMR Accelerator Participants

ARES GENETICS GMBH | ASCLEPIA OUTSOURCING SOLUTIONS | BEAM ALLIANCE | BILL & MELINDA GATES FOUNDATION | BIOASTER | BIOCOM | BIOVERSYS | CENTRE HOSPITALIER REGIONAL UNIVERSITAIRE DE TOURS | CHU DE POITIERS | CIM – Sant Pau | CLINICAL STUDIES SWEDEN FORUM SOUTH | CONSIGLIO NAZIONALE DELLE RICHERCHE | C-PATH | DANMARKS TEKNISKE UNIVERSITET | DZIF | EBERHARD KARLS UNIVERSITÄT TÜBINGEN | ÉCOLE POLYTECHNIQUE FEDERALE DE LAUSANNE | ERASMUS MC UNIVERSITY | EUROPEAN LUNG FOUNDATION | EUROPEAN LUNG FOUNDATION EUROPE | EUROPEAN RESPIRATORY SOCIETY | EVI | EVOTEC | FFUND BV | FORSCHUNGSZENTRUM BORSTEL | FOUNDATION FOR INNOVATIVE NEW DIAGNOSTICS | FOUNDATION INNOVATIVE MEDICINES FOR TUBERCULOSIS | FRAUNHOFER GESELLSCHAFT | GRITSYSTEMS AS | GSK BIOLOGICALS SA | GSK INVESTIGACION Y DESARROLLO SL | GSK RESEARCH AND DEVELOPMENT LTD | HELMHOLTZ CENTRE FOR INFECTION RESEARCH | HELMHOLTZ INSTITUTE FOR PHARMACEUTICAL RESEARCH SAARLAND | HELMHOLTZ ZENTRUM MUENCHEN DEUTSCHES FORSCHUNGSZENTRUM FUER GESUNDHEIT UND UMWELT GMBH | HOSPITAL OF LITHUANIAN UNIVERSITY OF HEALTH SCIENCES KAUNO KLINIKOS | IDIPAZ | IDMIT | IMABIOTECH | INSERM | INSTITUTE OF HEALTH CARLOS III | INSTITUTE PASTEUR | INSTITUTE PASTEUR DE LILLE FOUNDATION | IRD | ISPUP | JANSSEN PHARMACEUTICA | JANSSEN VACCINES & PREVENTION B.V. | KLINIKUM DER UNIVERSITAT MUNCHEN | KNCV | LEIDS UNIVERSITAIR MEDISCH CENTRUM | LIFE SCIENCE NETWORK GGMBH | LIOS | LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE ROYAL CHARTER | LUDWIG-MAXIMILIANS-UNIVERSITAET MUENCHEN | LYGATURE | MEDICAL UNIVERSITY OF VIENNA | MITOLOGICS | NHS | NICE | NOSOPHARM | OTSUKA NOVEL PRODUCTS GMBH | PEI | PFIZER | PUBLIC HEALTH ENGLAND | QPS NETHERLANDS | SCIENSANO | SERVICIO ANDALUZ DE SALUD | SSI | STICHTING RADBOUD UNIVERSITAIR MEDISCH CENTRUM | SYNAPSE RESEARCH MANAGEMENT PARTNERS | TASK FOUNDATION NPC | TB ALLIANCE | THE REGENTS OF THE UNIVERSITY OF CALIFORNIA | THE UNIVERSITY COURT OF THE UNIVERSITY OF ST ANDREWS | TUBERCULOSIS NETWORK EUROPEAN TRIALS GROUP EV | UMC UTRECHT | UNIVERSIDAD CARLOS III MADRID | UNIVERSITAET HAMBURG | UNIVERSITA DEGLI STUDI DI MILANO | UNIVERSITA VITA-SALUTE SAN RAFFAELE | UNIVERSITE DE POITIERS | UNIVERSITE GRENOBLE ALPES | UNIVERSITEIT LEIDEN | UNIVERSITE PARIS SORBONNE | UNIVERSITET ANTWERPEN | UNIVERSITY COLLEGE LONDON | UNIVERSITY OF COPENHAGEN | UNIVERSITY OF DUNDEE | UNIVERSITY OF GENEVA | UNIVERSITY OF KÖLN | UNIVERSITY OF LANCASTER | UNIVERSITY OF LIVERPOOL | UNIVERSITY OF OXFORD | UNIVERSITY OF PADOVA | UNIVERSITY OF PAVIA | UNIVERSITY OF VERONA | UNIVERSITY OF ZARAGOZA | UPPSALA UNIVERSITET