

WEBINAR

February
8th and 9th, 2021

EXPERT WORKSHOP ON VACCINES FOR AMR PATHOGENS

The COMBINE project is part of the IMI AMR Accelerator. In this project, the consortium wants to address questions regarding the optimization of preclinical and clinical studies in the development of antibiotics, vaccines and other therapies to tackle AMR resistant pathogens.

Problem statement: Antibiotic resistance has created an imminent need for innovative approaches for prevention and therapy of nosocomial infections. This has also drawn the attention to vaccines for prevention of colonization and infection by antibiotic resistant pathogens. Notably, these vaccines are mainly applied to subjects with preformed natural immunity to the target pathogen, transient or chronic immunosuppression and an ill-defined microbiome status. To date, many efforts in vaccine development in this area have remained unsuccessful. In view of the clinical need, re-thinking of the study designs, the indications and the clinical endpoints seems warranted.

Aim of the workshop: This workshop will provide an open discussion forum to identify, propose and prioritize specific challenges, success and risk factors in the development of vaccines against nosocomial AMR pathogens.

Participants: 1) Experts in clinical vaccine development from industry, academia and regulatory agencies. 2) Experts in innovative clinical trial designs.

Questions: General topics that will be discussed during the workshop will include pre-existing clinical conditions in the target population, heterogeneity of bacterial strains, heterogeneity in the study population, study phase-specific issues and aspects of innovative trial design. We aim to answer the following questions: What factors are systematically associated with successful development of vaccines against AMR pathogens? How can an improved clinical trial design accelerate the R&D of bacterial vaccines?

Confidentiality: It is important for us to create a safe space to discuss outstanding issues. Therefore, by participating in the webinar, you agree to commit to the Chatham House Rule: 'Participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed'. **Participants are asked not to record the webinar.** A summary of the webinar will be published in anonymized form.

For registration and additional information about the webinar, please contact AMRCOMBINEScientific@pei.de.

Program (all times in CET):

Day 1 (Monday, February 8 th , 2021):		Day 2 (Tuesday, February 9 th , 2021)	
Introduction, <i>S. aureus</i> , <i>C. difficile</i>		<i>K. pneumoniae</i> , <i>E. coli</i> , <i>P. aeruginosa</i> , Clinical trial design	
15.00 - 15.30	Welcome and introduction to nosocomial AMR pathogens	15.00 - 16.00	Focus on <i>K. pneumoniae</i> and <i>E. coli</i>
15.30 - 17.00	Focus on <i>S. aureus</i>	16.00 - 17.00	Focus on <i>P. aeruginosa</i>
Biobreak		Biobreak	
17.30 - 19.00	Focus on <i>C. difficile</i>	17.30 - 19.00	Clinical trial design
19.00 - 19.15	Wrap-up	19.00 - 19.15	Wrap-up and farewell

P.S.: our **open call for matched clinical and preclinical data** is open! Visit <https://bit.ly/37NWLEF> for more information or contact AMR-data-technical.COMBINE@grit42.com (for technical questions) or AMRCOMBINEScientific@pei.de (for scientific questions).