

# Improving Clinical Trials for Candidate Vaccines Against AMR Infections: Perspectives from the COMBINE Project

## Inhalt

*Background.* Although preventive approaches are a promising tool to limit antimicrobial resistance (AMR), most pathogens on the WHO AMR priority list still lack a licensed vaccine. The feasibility of clinical studies to approve vaccines against (hospital-acquired and opportunistic) AMR pathogens is a major bottleneck. Hence, one goal of the COMBINE project, part of the IMI AMR Accelerator, is to improve the design of clinical trials to study the efficacy of candidate vaccines.

*Methods.* We have conducted a literature search and hosted a stakeholder workshop on recurrent problems in vaccine development. The results of these exercises are driving the re-analysis of individual patient data from past clinical trials as well as the examination of trial meta-data.

*Results.* Two major recurring problems in the clinical development were identified. The first issue is the lack of established correlates of protection, which makes it necessary to engage in large, resource-intensive clinical trials with prevention from the disease as primary endpoint. The second issue is the characterisation of the optimal target population - complicated, among others, by uncertainties around the risk factors.

*Conclusions.* The ultimate outcome of this work is to provide recommendations to facilitate the clinical development of candidate vaccines against AMR infections.

This work has received support from the EU/EFPIA Innovative Medicines Initiative 2 Joint Undertaking (COMBINE grant n° 853967).

## Keywords

Antimicrobial resistance; Vaccines; Clinical trial design; COMBINE

## Registration-ID code

ZOO23-535

## Professional Status of the Speaker

Postdoc

## Junior Scientist Status

Yes, I am a Junior Scientist.

**Thema Einordnung:** Vaccines & Immunology

**Typ des Beitrags:** Both Options Possible

## Kommentare:

Multiple topics from the workshop are possible: Vaccines & Immunology (preferred); Antimicrobial Use & Resistance; Public Health & Pandemic Preparedness.