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

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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-intense 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.

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Professional Status of the Speaker

Postdoc

Junior Scientist Status

Yes, I am a Junior Scientist.

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