

# COMBACTE-CARE

## Combatting Bacterial resistance in Europe- Carbapenem-Resistance

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COMBACTE-CARE (Combatting Bacterial resistance in Europe-Carbapenem-Resistance) will bring highly innovative studies and activities related to the treatment of patients with infections caused by Carbapenem-Resistant Enterobacteriaceae (CRE). Being very difficult to treat due to lack of options, CRE are considered to be one of the most urgent antibiotic resistant threats in the world. University Medical Center Utrecht is the project's managing entity and AstraZeneca is the coordinator.

Antibiotic resistance is a global public health threat and infections due to multi-drug resistant Gram-negative bacteria (MDR-GNB) are rapidly increasing. Especially infections caused by Carbapenem-Resistant Enterobacteriaceae (CRE) are of major concern. The US Centers for Disease Control and Prevention recently concluded that CRE represent an immediate public health threat that requires urgent and aggressive action. CRE expresses resistance to most available antibiotics, leaving few available options for therapy. New treatments are therefore urgently needed. In addition, the epidemiology of CRE is characterized by large heterogeneity in genotypes and phenotypes, seriously hampering the rapid detection of CRE.

### PROJECT OUTLINE

The EUR 83 million COMBACTE-CARE projects aims – during the 5-year project time - to understand how patients with CRE infections are managed, with a focus on best available treatment and clinical outcomes. The project will develop new tools to detect CRE and conduct clinical trials with AstraZeneca's antibiotic combination product Aztreonam-avibactam (ATM-AVI), in development for the treatment of serious infections due to metallo- $\beta$ -lactamase producing Gram-negative pathogens, a difficult to treat sub-type of CRE infections.



### ACTIVITIES

COMBACTE-CARE will be the first concerted action in the ND4BB program to combat the rapidly growing threat of infections caused by carbapenamase-producing bacteria in Europe.

Concrete activities of the COMBACTE-CARE consortium include:

- Prospective observational studies to assess the risk factors, clinical management and outcomes of hospitalized patients with serious infections caused by MDR-GNB
- Microbiological studies to support the prospective observational, phase II and phase III studies
- Biomarker studies to optimize patient selection with poor outcome in future studies
- A Phase II prospective, multicenter study, to determine the pharmacokinetics (PK), safety and tolerability of ATM-AVI for the treatment of complicated Intra-abdominal Infections (cIAs) in hospitalized adults
- European component of a prospective, randomized, multicenter, assessor-blind, parallel group, comparative Phase III study to determine the efficacy, safety and tolerability of ATM-AVI for the treatment of serious infections due to metallo- $\beta$ -lactamase producing Gram-negative pathogens.

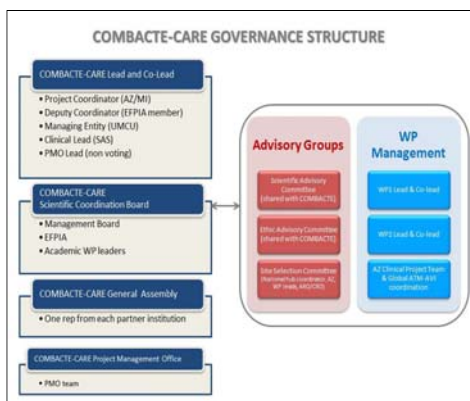
### COLLABORATION

This unique collaboration addresses the need for greater understanding of the clinical management and outcomes of CRE infections and also makes a significant contribution to the development of ATM-AVI for the treatment of patients with serious infections caused by Gram-negative bacteria for which currently there are limited or no treatment options.

The COMBACTE-CARE project will closely collaborate with and further strengthen the clinical and laboratory networks CLIN-Net and LAB-Net of COMBACTE-NET, one of the first projects within the ND4BB program, that started in January 2013. Also the project will be part of global collaboration with AZ and BARDA to deliver the global phase 3 ATM-AVI clinical trial.

Efforts to develop novel antibiotics are hampered by a number of scientific and regulatory hurdles that cannot be easily tackled by any individual organization. The COMBACTE-CARE consortium brings together 18 European academic partners, 3 European Federation of Pharmaceutical Industries and Associations (EFPIA) partners from 10 European countries to closely collaborate on combatting Carbapenem resistance.

COMBACTE-CARE researchers are widely considered to be global opinion leaders due to their expertise in executing clinical trials evaluating new (and established) antibiotics or anti-infective agents, antibiotic strategies and preventive measures against Healthcare-associated Infections (HAIs) as well as guiding antibiotic and infection prevention policies.



### LOCATION

All clinical and microbiological studies will be conducted in South-Eastern Europe, where infection rates with MDR-GNB are expected to be high. COMBACTE-CARE will also provide medical leadership and European sites to a global, phase III, clinical trial of aztreonam-avibactam (ATM-AVI). This global study will be carried out with AstraZeneca, and will be funded in part by the US Biomedical Advanced Research and Development Authority (BARDA).

### CONTACT INFORMATION

Unique in its scale, ambition, and its potential benefits for patients, public health and pharmaceutical research in Europe, the COMBACTE projects have the potential to become the powerhouse of anti microbial drug development in Europe that could serve as a standard for other groups. [Join us!](#)

Visit us at booth 37A in the exhibition hall.

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