

Combatting Bacterial Resistance in Europe (COMBACTE)

 consortiapedia.fastercures.org/consortia/combacte/

Research Areas



Tool Development

Clinical Trial



Basic Research



Data-Sharing Enabler



Product Development

At a Glance

- Status: **Active Consortium**
- Year Launched: **2013**
- Initiating Organization: **Innovative Medicines Initiative**
- Initiator Type: **Government**
- Location: **Europe**

Abstract

Antimicrobial resistance (AMR) is a growing problem worldwide, and with few new drugs making it to the market, there is an urgent need for new medicines to treat resistant infections. The Innovative Medicines Initiative (IMI)-funded Combatting Bacterial Resistance in Europe (COMBACTE) project aims to give antibiotic drug development a much-needed boost by pioneering new ways of designing and implementing efficient clinical trials for novel antibiotics. COMBACTE forms part of the New Drugs for Bad Bugs (ND4BB) initiative, IMI's wider program to tackle AMR.

Mission

The COMBACTE project focuses on addressing the barriers to clinical development. A key outcome of the project will be a high quality, pan-European clinical trial network. Dubbed COMBACTE CLIN-Net, it will be capable of recruiting sufficient patients into multinational trials at all stages of development.

Alongside this, the project will also establish a pan-European laboratory network (COMBACTE LAB-Net), which will deliver epidemiological information and data from microbial surveillance work to guide the selection of clinical trial sites. Crucially, the COMBACTE team aims to generate innovative trial designs to facilitate the registration of novel antibacterial agents. It will also design and validate tests to support the diagnosis of patients, identify the most appropriate treatments, and monitor the patient's response.

A large part of the project will be devoted to the performance of clinical trials of drugs under development in the pharmaceutical companies involved in the project. The first antibiotic to undergo clinical trials under COMBACTE is GSK1322322, which inhibits the action of a bacterial enzyme called peptide deformylase (PDF) and appears to be effective against multidrug-resistant respiratory and skin pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA). Most importantly, GSK1322322 represents a new class of antibiotics with a novel mode of action. In COMBACTE, experts will run clinical trials to evaluate GSK1322322's efficacy at treating acute bacterial skin and skin structure infections and community-acquired bacterial pneumonia.

The second compound to be tested will be MEDI4893, which is designed to prevent *S. aureus* disease by neutralizing a specific toxin produced by the bug, which is behind much of the tissue and organ damage associated with *S. aureus* infections. Considering the importance of *S. aureus* as a human pathogen and the extensive problems with antibiotic resistance, MEDI4893 represents an attractive preventive measure for patients at high risk of *S. aureus* infections. Early clinical trials will evaluate the efficacy and safety of MEDI4893 at preventing infections in patients at risk of *S. aureus* surgical site infections and mechanically ventilated patients at risk for *S. aureus* pneumonia. Finally, to support more broadly the clinical development of new treatments for *S. aureus*, the consortium will gather new data on hospital-associated infections by carrying out epidemiological surveillance among surgical and intensive care unit (ICU) patients across Europe. This will help to assess the impact of patient-related and other factors on the incidence of surgical site infections and ICU pneumonia to identify the patient subgroups that are at an increased risk of these infections.

The challenge of antimicrobial development is so great that no organization can take it on alone. By bringing together leading experts from universities, hospitals, and pharmaceutical companies who are skilled in microbiology, epidemiology, drug development, and clinical trial design, COMBACTE is set to give antibiotic development in Europe a major boost.

Unique in its scale, ambition, and its potential benefits for patients, public health, and pharmaceutical research in Europe, COMBACTE has the potential to become the powerhouse of antimicrobial drug

development in Europe that could serve as a standard for other groups. Ultimately, the hope is that COMBACTE will provide a framework for the rapid and efficient development of new treatments as well as diagnostic tests that can be speedily commercialized for use on the patients that so urgently need them.

Financing

The project is funded by the IMI (€109.4 million), European Federation of Pharmaceutical Industries and Associations in-kind contributions (€133.9 million), and other sources (€7.1 million) for a total cost of €250.4 million.

Links/Social Media Feed

Homepage www.combacte.com

Points of Contact

Project Coordinator

Helen Steel

GlaxoSmithKline Research and Development Ltd.

email: Helen.m.steel@gsk.com

Managing Entity

Marc J.M. Bonten

University Medical Center Utrecht

phone: +31 88 7557394

email: mbonten@umcutrecht.nl

Clinical Trials Lead

Bruno François

Centre Hospitalier Universitaire de Limoges

phone: +33 5 55 05 69 84

email: b.francois@unilim.fr and bruno.francois@chu-limoges.fr

Sponsors & Partners

Arbeitsgemeinschaft für Osteosynthesefragen
Documentation and Publishing Foundation
AstraZeneca
Centre Hospitalier Régional Pointe-à- Pitre
Centre Hospitalier Universitaire de Limoges
Cliniques Universitaires Saint Luc
Eberhard Karls Universität Tuebingen
Erasmus Universitair Medisch Centrum
Rotterdam
Fondazione IRCCS Ca' Granda Ospedale
Maggiore Policlinico
Fundacio Centre de Recerca en Salut
International de Barcelona
Fundacio Clinic Per a La Recerca Biomedica
GlaxoSmithKline
Helmholtz-Zentrum für Infektionsforschung
GmbH
Hospices Cantonaux CHUV
Institut National de la Santé et de la Recherche
Médicale
Instituto Nacional de Saúde
Janssen Infectious Diseases Diagnostics
Julius Clinical Research BV
Linköping Universitet
North Bristol National Health Service Trust
Servicio Andaluz de Salud
Servicio Madrileño de Salud
Stichting Katholieke Universiteit/Radboud
University Nijmegen Medical Centre
Tel-Aviv Sourasky Medical Center
Universitätsklinikum Freiburg
Universitätsklinikum Köln, AöR (University

Hospital of Cologne)
Université Claude Bernard Lyon 1
Université de Genève
Université Joseph Fourier
University Medical Center Utrecht
University Medicine of the Ernst Moritz Arndt
University of Greifswald
University of Antwerp
University of Athens Medical School

Updated: **04/14/2016**