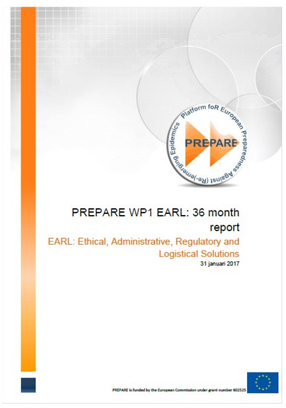
PREPARE

Platform foR European Preparedness Against (Re-)emerging Epidemics

What is PREPARE?

PREPARE is a clinical research network established with support of European Union funding running from 1 February 2014 to 31 January 2019.

The aim of **PREPARE** is to build Europe's capacity for harmonised large-scale clinical research studies on infectious diseases, prepared to rapidly respond to any severe infectious disease outbreak and providing real-time evidence for clinical management of patients and for informing public health responses.



ETHICAL, ADMINISTRATIVE, REGULATORY AND LOGISTICAL (EARL) processes

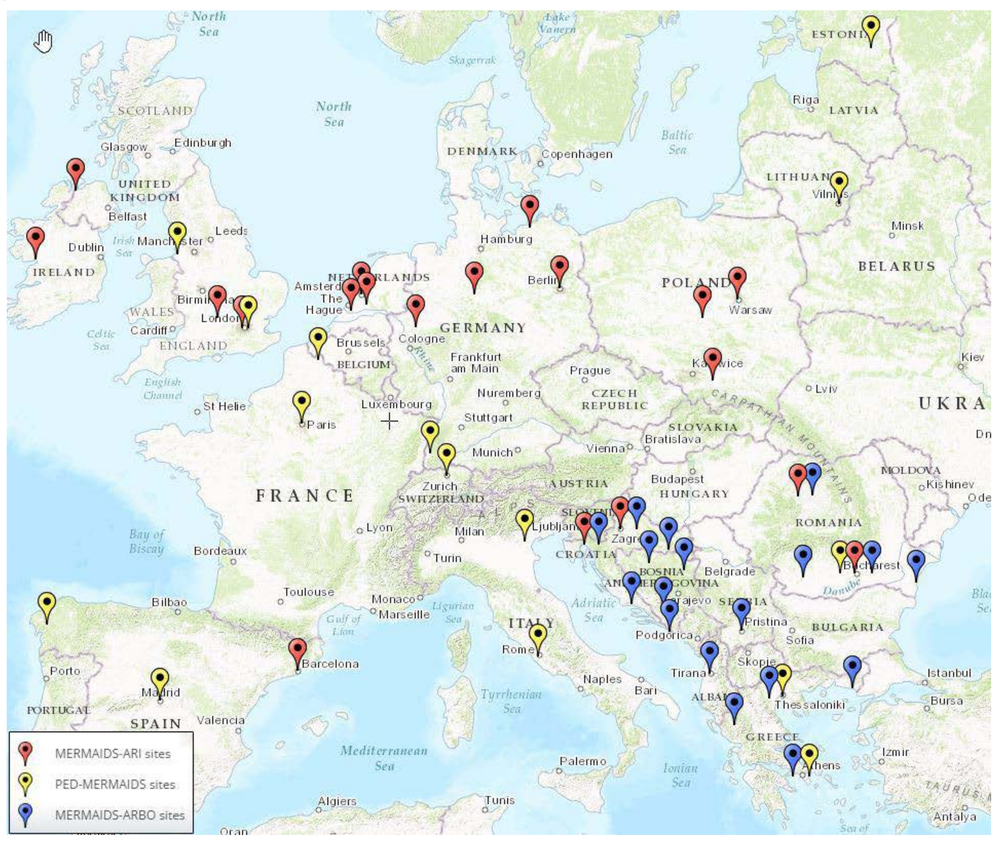
Current EARL and behavioural and cultural (BC) bottlenecks to the rapid implementation of large multi-site clinical studies in Europe in response to severe infectious disease outbreaks have been mapped in the report 'A provider and a user assessment of EARL hurdles for research in Europe'. The 'EARL barriers solutions report' incorporates aspects of preparedness planning and extends the mapping of barriers and solutions, building on primary empiric work from the PREPARE observational and intervention clinical studies MERMAIDS and ALIC^{4}E.

PREPARE Observational Trials

Three large-scale prospective observational studies on infectious disease syndromes of epidemic relevance are currently recruiting across Europe: the 'Multi-centre EuRopean studies of MAjor Infectious Disease Syndromes (MERMAIDS)'. In addition to syndrome-specific objectives, all studies are addressing aetiologies, clinical management and outcomes across Europe.

ARI-MERMAIDS aims to identify host- and pathogen related determinants of severity of acute respiratory infections. With a target sample size of 2000 patients (500 primary care, 1500 hospitalized), this study is powered to identify differences in local and systemic host gene expression profiles, representing the primary outcome measure, across the most prevalent clinical comorbidities (including chronic cardio-vascular, pulmonary or metabolic disease) and respiratory pathogens (including influenza, RSV, human corona- and rhinovirus and *S. pneumoniae*). Analyses of the first nearly 100 patients recruited between January and April 2016 suggest that assumptions for our sample size calculation were appropriate with respect to expected prevalence of comorbidities and respiratory pathogens.

ARBO-MERMAIDS aims to describe the aetiology and epidemiology of suspected arboviral febrile illness, in 1500 hospitalized adults in South East Europe, with particular focus on the contribution of West Nile virus, Toscana virus, Tick borne encephalitis virus, Crimean Congo haemorrhagic fever virus and Zikavirus. First season recruitment was 162 patients (May – October 2016), interim analyses of the collected data are ongoing.



PED-MERMAIDS is a prospective case-control study aiming to understand the aetiology and epidemiology of sepsis-like syndrome (SLS) in infants, with particular focus on the attributable contribution of entero- and parechoviruses, and of ARI in children under 5 years old, with particular focus on the contribution of influenza, RSV, rhinovirus and *S. pneumoniae*. Targeted sample sizes are a minimum of 300 infants with SLS and 52 controls, and 320 children with ARI and 320 controls. The study will recruit from September 2016 till December 2018 in 11 European countries.

PREPARE Intervention Trials

ALIC^{4}E aims to answer a critical question about the clinical and cost effectiveness of oseltamivir for influenza like illness (ILI) in primary care. The trial has been specifically designed to determine effectiveness of antivirals (currently oseltamivir) overall, as well as in patient sub-groups defined by age bands, illness severity and co-morbidity. The study is recruiting across three flu seasons, and is being implemented by 21 primary care networks in 16 European countries. As of end February 2017 (second recruiting flu season), 1660 participants have been randomised. Based on season one data, 50% of those recruited with ILI were positive for the influenza virus when nasal and nasopharyngeal swabs were tested on the PCR-based, Idylla™ platform.

The **REMAP-CAP** trial aims to evaluate different treatment options for patients with community acquired pneumonia (CAP), who require invasive mechanical ventilation and are admitted to the Intensive Care Unit. This study will recruit globally with inclusion of the Australia/ New Zealand (ANZIC) network. Between 100 and 150 intensive care units (ICUs) are expected to include 2000-4000 patients in Europe until 2019. In comparison to a conventional trial, this "Randomized Embedded Multifactorial Adaptive Platform"(REMAP) uses an adaptive design evaluating multiple questions simultaneously. The primary outcome is the occurrence of death during the index hospital admission censored 60 days from the date of enrolment. Eligible participants will be randomized to receive one intervention in each of one or more domains. Currently, three domains are available in which the effect of different antibiotic strategies and immunomodulatory interventions are tested. ICUs treating at least 10 CAP patients per year are welcome to participate.

Connect

prepare@uantwerpen.be
www.prepare-europe.eu
Twitter.com/PREPARE-Europe
Coordinator: Herman Goossens - herman.goossens@uza.be
Deputy Coordinator: Menno de Jong - m.d.dejong@amc.uva.nl

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