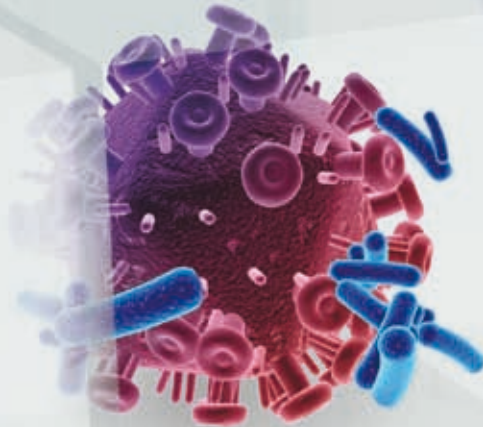
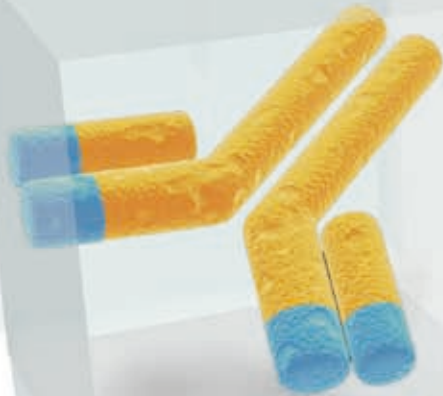




EUROPEAN
COMMISSION

European
Research Area



Infectious Diseases



COOPERATION

Introduction

The EU's Research programme on infectious diseases comprises Poverty Related Diseases (PRD), including the three main scourges HIV/AIDS, malaria and tuberculosis, Anti-microbial Drug Resistance (AMDR), Emerging Epidemics (EE) and Neglected Infectious Diseases (NID).


There are three main objectives for PRD research. The first one is to develop new promising candidate vaccines and therapies, covering the full spectrum from basic molecular research through preclinical tests and proof-of-principle on promising candidates. The second objective is to promote testing such new preventive and therapeutic tools in disease-endemic African settings, for which purpose the European and Developing Countries Clinical Trials Partnership (EDCTP) was established. The EDCTP is a unique European/African collaboration programme for phase II and III clinical evaluation of vaccines and drugs against HIV, malaria and tuberculosis and of HIV microbicides. The third objective is to organise the European Research Area in the field of PRD diseases such that pertinent European efforts for PRD research synergistically contribute to global research agendas in the respective fields.

Research on Antimicrobial Drug Resistance covers a broad range of multi-drug resistant pathogens and approaches. The aim is to address key pathogens and groups of pathogens causing major drug resistance problems through multi-disciplinary translational research, bringing basic research forward through clinical research to improved patient management and towards product oriented development of on new diagnostic tests, treatments and prevention strategies.

Emerging Epidemics is a novelty in the programme aimed to respond to the research needs related to the threat of emerging epidemics with pandemic potential and to help improving our preparedness to identify and control the unforeseen. With an initial focus on pandemic influenza in the calls of 2006 and 2007, the latest focus has been on reinforcing general pandemic preparedness and capacity building across a broader range of viral pathogens.

The work on Neglected Infectious Diseases focuses on capacity building in disease endemic countries, interventions and early discovery research on vaccines and therapies against diseases with a major impact on human health and with clearly defined unmet medical needs, as defined by the WHO Special Programme for Research and Training in Tropical Diseases.





The European Commission's Research Directorate General (DG RTD) is implementing translational research in infectious diseases within the Health Theme of the Seventh Framework Programme (FP7) with an emphasis on:

- 1) HIV/AIDS, Malaria, Tuberculosis
- 2) Antimicrobial drug resistance (AMDR),
- 3) Emerging epidemics (EE) and
- 4) Neglected infectious diseases (NIDs).

1 - HIV/AIDS, Malaria and Tuberculosis

The strategic objective of this area is to confront HIV/AIDS, malaria and tuberculosis in Europe and the rest of the world at broad fronts and in a multidisciplinary approach through the development of effective preventive and controlling strategies. Clinical evaluation of promising vaccine and drug candidates is facilitated through the European and Developing Countries Clinical Trials Partnership (EDCTP), which is a pioneer programme of the European Union specifically tailored to meet the needs of developing countries with focus on phase II and III clinical trials of vaccines and drugs against HIV, malaria and tuberculosis and of HIV microbicides and for capacity building in Africa.

HIV/AIDS

HIV/AIDS kills close to 3 million people each year. New interventions to combat this disease are therefore desperately needed. In the Sixth Framework Programme (FP6) the European Commission funded HIV/AIDS projects in different areas of research. In particular, support was given to projects dealing with a) therapeutic approaches of different types (drugs, RNA interference, therapeutic vaccines based on apoptotic T cells and others); b) vaccine research (mucosal vaccines, vaccines targeting on dendritic cells and DNA vaccines, new antigen design, delivery systems); c) Microbicides (design of new molecules and use of anti-retroviral drugs to inhibit HIV replication in vaginal mucosa); d) Studies on cohorts of HIV-infected adults and children to investigate insurgence of resistance to marketed anti-HIV drugs, mother to child virus transmission. Many of the FP6 translational research projects included Phase I clinical trials.

In the Seventh Framework Programme (FP7) the projects funded in the context of the first two calls deal with the study of a) vaccines, inducing broadly-reactive neutralizing antibodies; b) a platform to support harmonization of vaccine adjuvant testing; c) drug discovery and pre-clinical development; d) paediatric formulations of drugs. The third call of FP7, published in September 2008, includes topics on microbicides, mucosal and transcutaneous vaccines and translational vaccine research (allocating funds for phase I and IIa clinical trials).

In addition, in 2009 a call for an HIV/AIDS ERA-NET, was published. ERA (European Research Area)-NETs involve funding institutions from Member States, to promote further cooperation to combat HIV/AIDS.

MALARIA

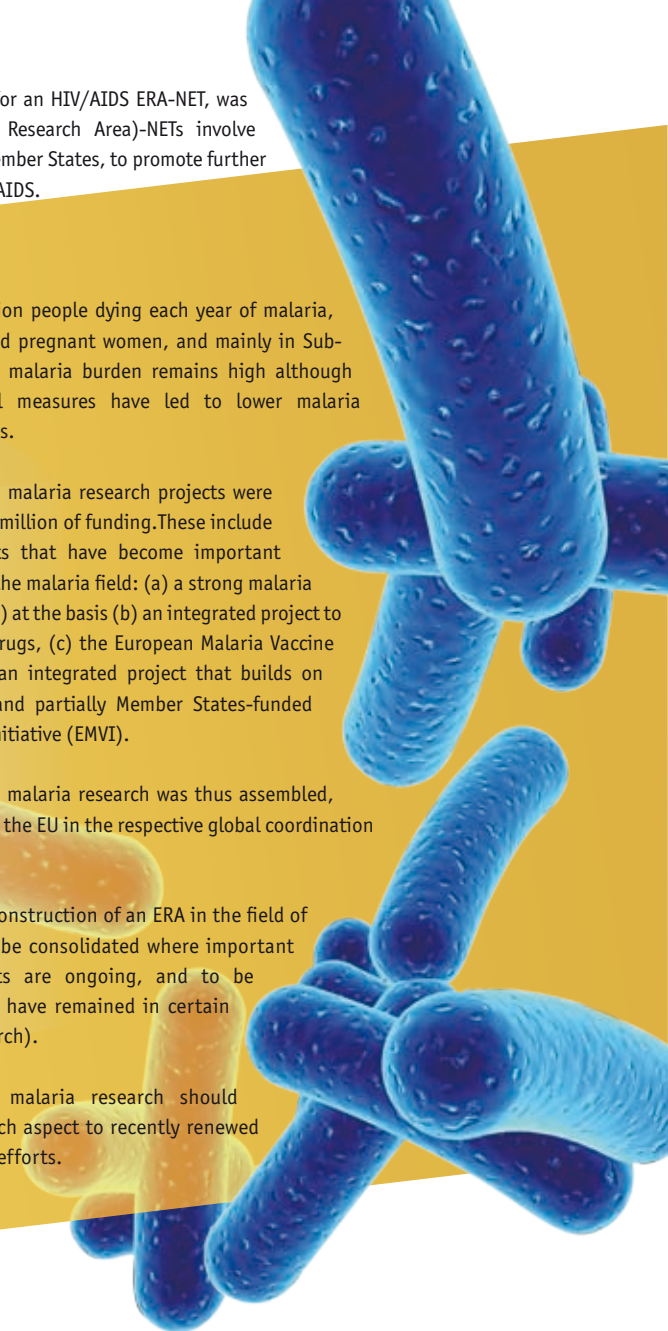
With still more than 1 million people dying each year of malaria, mainly children under 5 and pregnant women, and mainly in Sub-Saharan Africa, the global malaria burden remains high although successful malaria control measures have led to lower malaria transmission in certain areas.

Under the previous FP6, 17 malaria research projects were supported with about € 64 million of funding. These include 3 larger structural projects that have become important cornerstones of the ERA in the malaria field: (a) a strong malaria basic research network (NoE) at the basis (b) an integrated project to develop new antimalarial drugs, (c) the European Malaria Vaccine Development Association, an integrated project that builds on the already FP4-initiated and partially Member States-funded European Malaria Vaccine Initiative (EMVI).

A critical mass of European malaria research was thus assembled, that can now participate for the EU in the respective global coordination of malaria research.

Under FP7, the successful construction of an ERA in the field of malaria research needs to be consolidated where important structural malaria projects are ongoing, and to be complemented where gaps have remained in certain subareas (e.g. vector research).

At the same time, FP7 malaria research should contribute from the research aspect to recently renewed global malaria eradication efforts.



TUBERCULOSIS

Approximately 1.7 million people die each year due to tuberculosis (TB) and up to two billion people are infected with the causative agent, *Mycobacterium tuberculosis*. We recognize the importance of TB and are building partnerships with the Member States, disease endemic countries and other stakeholders to integrate European efforts in the global TB research agenda.

Many of the European Commission-supported research projects aim to gain information about the mechanisms of pathogenesis and about the delicate balance which prevails between us humans and the pathogen. Host-pathogen interaction and latency is an important area for research when we want to elucidate the mechanisms underlying the complex life cycle of *M. tuberculosis*.

However, only translational research can lead to real applications. In TB control the BCG vaccination is not as effective as could be hoped for, and the spread of antimicrobial resistance has made most currently known drugs ineffective against some strains of TB. The strategy of utilizing large translational projects has proven useful in bridging the gap between discovery and application and even larger initiatives can be foreseen in the future.

Joining forces with other funders and stakeholders is important if we want to solve the global TB problem.

2 - Antimicrobial Drug Resistance

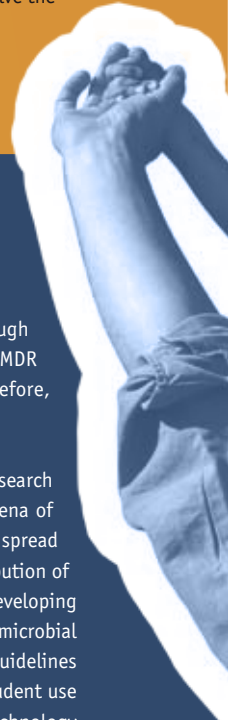
Once easily mastered through the administration of antibiotics, severe hospital- and community-acquired bacterial infections are on a sharp rise in Europe due to increasing resistance against available antibiotics. At the same time, the drug development pipeline for new antibiotics is virtually empty because of a lack of incentives for the pharmaceutical industry to invest in this field. In the longer term perspective, difficulties to effectively treat bacterial infections pose a threat to many modern diagnostic and treatment modalities.

Research to combat the growing problem of antimicrobial drug resistance (AMDR) has been a high priority on the agenda of the EU Framework Programmes ever since the Microbial Threat Conference in Copenhagen in 1998. Its goal is to generate scientific evidence for the policies, strategies and practices for countering AMDR in and beyond the EU. Ten years later and with more than € 200 million of EU support to research into antimicrobial resistance, Europe is in the lead to tackle AMDR at broad fronts.

In the 7th Framework Programme (2007-2013), AMDR research remains a high priority. In contrast to research on HIV/AIDS, malaria and tuberculosis, this pillar primarily


addresses a biological phenomenon rather than individual pathogens. Although drug resistance of viral, fungal and parasitic infections are not excluded from AMDR topics, the vast majority of the resistance problems are found in bacteria. Therefore, AMDR of bacterial infections is the major focus of EU-funded projects.

The Health Directorate of DG RTD supports multi-disciplinary collaborative research in several inter-dependent areas of AMDR problems. Studies of basic phenomena of drug resistance focus on molecular mechanisms that lead to the emergence and spread of resistance genes. Epidemiological studies unravel the dynamics of the distribution of multi-drug resistant strains of pathogens in human populations with the aim of developing control and preventive measures. Translational research merges basic science of microbial and human genomics with clinical and public health research for developing guidelines for evidence-based clinical practice and patient management, in particular, prudent use of antibiotics. To promote the rational use of antibiotics, the European biotechnology industry is mobilized to develop point-of-care diagnostic tests for early identification and differentiation of the disease-causing agents. Finally, anti-infective drug discovery seeks to identify novel molecular targets in pathogens and candidate drugs against them.





3 - Emerging and Re-Emerging Infectious Diseases



Emerging and re-emerging Infectious Diseases (EIDs) are the result of a constantly evolving interplay between pathogens, their hosts and other environmental factors. Over the last decades, a number of new emerging diseases, such as HIV/AIDS and SARS, as well as re-emerging diseases that increase in incidence or whose geographic range is changing, such as chikungunya or dengue fever, continue to pose a significant threat to populations in Europe and world-wide.

Research on many of these diseases had already been funded in different areas of previous Framework Programmes. However it was events such as the SARS epidemic and the increasing awareness of the threat of a new human influenza pandemic that led in 2007 to the introduction of a new dedicated activity “Potentially new and re-emerging epidemics” in the “Cooperation – Health” theme of the 7th Framework Programme (FP7). The aim of this activity is to provide a constant funding stream to building a research capacity that prepares for potential emergencies, but also to allow for sufficient flexibility to cover newly emerging topics in this - by definition - rapidly moving field. Calls for proposals will cover the full “value

chain” of health research, from the underlying biologic processes of pathogens and hosts to the development of much needed better prevention, diagnostic and treatment options all the way to research on public health-relevant issues, such as novel surveillance methods or non-pharmaceutical interventions.

Taking into consideration that HIV/AIDS, malaria, tuberculosis, antimicrobial drug resistance and neglected bacterial, protozoal and helminthic diseases that are endemic in developing countries are covered in other areas of the FP7 infectious disease programme, “Emerging Epidemics” addresses in its current working definition emerging viral diseases of current or future relevance to Europe.

Influenza - into which subsequent FPs have invested more than € 100 million through more than 40 projects since 2001 - has a special importance because of the potential magnitude and likelihood of a new pandemic. However, other specific diseases (such as SARS or dengue) as well as groups of illnesses (such as vector-borne diseases in Europe), and generic aspects of preparedness (such as screening of blood products), have also been considered and will increasingly complement the influenza project portfolio. Many EIDs are of animal origin (called “zoonoses”), which highlights the importance of a close interdisciplinary collaboration between animal and human health research.

4 - Neglected Infectious Diseases

The European Commission has significantly increased its support to research in neglected infectious diseases.

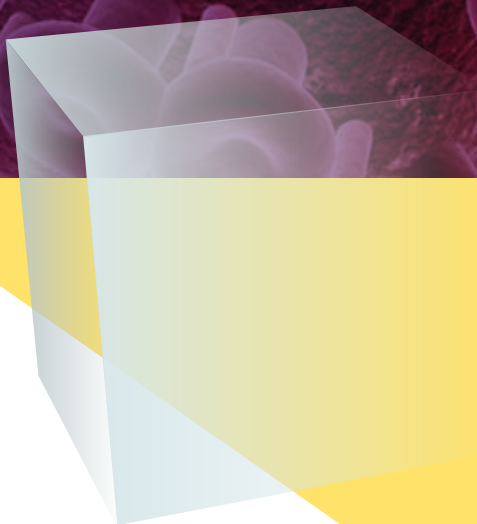
Over one billion people are infected by Neglected Infectious Diseases (NIDs) worldwide. NIDs impact on people and societies by promoting poverty, stigmatize, disable and inhibit individuals from being able to care for themselves or their families.

Urgent action is needed to develop new drugs, diagnostic tests and vaccines that are adapted to developing countries' needs, and to make them available at affordable prices.

The European Commission has supported research on neglected infectious diseases as part of the EU's international research cooperation since the early 1980s.

The objective of the European Commission (EC) in the area of NIDs is to support research and development to improve existing and develop new approaches for preventing, diagnosing, treating, and controlling neglected infectious diseases. These measures are intended to be applicable, acceptable and affordable in disease-endemic countries. The ambitious goal of the EC is to contribute to the long-term control of NIDs.

The main focus will be on NIDs with a major impact on human health, and with clearly defined unmet medical needs. These include diseases caused by protozoal, bacterial and helminth infections, whereas neglected viral diseases are covered by the area Emerging and Re-Emerging Infectious Diseases.



For more information please visit:

http://ec.europa.eu/research/health/infectious-diseases/poverty-diseases/index_en.html

http://ec.europa.eu/research/health/infectious-diseases/antimicrobial-drug-resistance/index_en.html

http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/index_en.html

http://ec.europa.eu/research/health/infectious-diseases/neglected-diseases/index_en.html



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