

REVISION 1

South African Participation in the European Union's Sixth Framework Programme for Research



European - South African Science and Technology
Advancement Programme

LIFE SCIENCES, GENOMICS AND BIOTECHNOLOGY FOR HEALTH





HEALTH RELATED PROJECTS

Focussed on Priorities 1: “Life Sciences, Genomics and Biotechnology for Health”, 2: “Information Society Technologies”, and INCO: “International Cooperation”

BACKGROUND: Realisation of the maximum possible health is considered a basic human right. Good health consistently ranks as the number one desire of men and women around the world. Promoting public health, as a component of social development, is an integral element in overall sustainable development, with a healthy population seen as an important precondition for economic growth and competitiveness. Globally, health is seen as a key means towards eliminating poverty. The United Nations Millennium Development Goals focus on poverty reduction in general, and on several health goals in particular.

The World Health Organisation determined that for several important diseases of the poor, there is currently minimal industry R&D effort, despite the scientific promise of breakthroughs in new drugs, vaccines, and diagnostics. Areas recently identified as priorities include vaccines for malaria, TB, and AIDS; microbicides for AIDS; new pesticides to control vector-borne diseases; and combination therapies for malaria needed to slow the onset of drug resistance to anti-malaria medicines.

In response to the global emergency caused by HIV/AIDS, malaria and TB, the European Commission (EC) implemented a research strategy for the development of new drugs, vaccines and other effective interventions through:

- (i) support of research projects of promising new candidates through pre-clinical and early human testing and;
- (ii) establishment of a programme to support phases II and III clinical trials in Africa through the European & Developing Clinical Trials Partnership (EDCTP).

Included in the ongoing South African (SA) and European Union's (EU) 6th Framework Programme (FP6) activities in the health field are a number of initiatives to combat the scourges of these poverty-related diseases.



AIDS VACCINE INTEGRATED PROJECT

Starting year: 2004

FP6 instrument: Integrated Project

Why this research?

Vaccines based on viral structural products (Env/Gag/Pol) alone have failed to prevent infection by HIV/Simian Immunodeficiency Virus (SIV). More recently, vaccines based on viral regulatory gene products (Tat/Rev/Nef) have been shown to contain virus replication and to prevent disease onset. A vaccine combining both regulatory and structural viral antigens (combined vaccine) is likely to be superior to the former since it induces immune responses to both early and late viral products.

South African researchers:

The SA participants in AVIP are from the Perinatal HIV Research Unit of the Wits Health Consortium and Stellenbosch University's Medical Virology / Health Sciences. SA represents an acknowledged best practice in health information systems in Africa. The AVIP International School, which has been created by joining existing centres in the EU and SA, will be the main instrument for the training activity. As many of the assays and other aspects of the phase I trials will be used in future phase II and III trials in SA, the participation of SA researchers will promote continuity in the development of the vaccines.

What does the research hope to achieve?

The mission of AVIP is to develop novel combined vaccines to be tested in phase I preventive and therapeutic trials in Europe, that are suitable for future testing in phase II / III trials in developing countries (DC), and to foster training, technology transfer and community involvement among the EU and DC. To ensure completion of the programme, priority has been given to vaccine combinations containing single antigens for which efficacy has been demonstrated in animal models and phase I studies have been completed or are ongoing.

www.avip-eu.org



EMPRO

EUROPEAN MICROBICIDES PROJECT

Starting year: 2004

FP6 instrument: Integrated Project

Why this research?

In view of the increasing numbers of new HIV infections each year, particularly in the developing world, there is an urgent need for additional measures to prevent the transmission of HIV infection.

South African researchers:

SA scientists at the Faculty of Health Sciences, Stellenbosch University are

part of the EMPRO team. Leader of the Stellenbosch group of scientists and head of the University's Pharmacology Department, Professor Pieter van der Bijl, explains that the passage of drugs across biological membranes has been studied for almost a decade.

The project is looking at new ways of introducing drugs to the body, specifically through the mucosa or lining of the vagina and rectum. The work package of the Stellenbosch group relates specifically to the passage of HIV across vaginal and rectal membranes.

What does the research hope to achieve?

This project aims to develop new microbicide compounds to prevent HIV infection using technologies such as nanobodies, anticalins, peptide libraries and glyconanoparticles, in addition to more traditional approaches. Following a rigorous selection procedure, the most promising candidates will be tested in a phase I clinical trial.

www.empro.org.uk



NeutNet

STANDARDISATION OF HIV NEUTRALISATION ASSAYS TO BE USED IN VACCINE RESEARCH AND CLINICAL TRIALS

Starting year: 2005

FP6 instrument: Specific Support Action

Why this research?

The relevance of neutralising antibodies in protection against HIV infection and disease remains to be elucidated. Numerous *in vitro* neutralisation assays have been developed, each one with different variables and endpoints. NeutNet proposes to coordinate activities aimed at standardising methods for the measurement of neutralising antibodies to HIV-1 for use in human clinical trials of candidate AIDS vaccines. NeutNet will organise an initial study with the most relevant neutralisation methods and a panel of well-characterised and common reagents, to define appropriate reference controls for neutralisation assays.

South African researchers:

The SA partner in NeutNet is the AIDS Virus Research Unit, National Institute for Communicable Diseases (NICD).

HIV research carried out at the NICD is primarily focused on research into the virology and pathogenesis of HIV. The Institute has contributed significantly towards the immunological evaluation of candidate HIV vaccines, addressing issues of HIV drug resistance in mother-to-child prevention programmes, and understanding mechanisms of mother-to-child transmission.

What does the research hope to achieve?

The data from this study will serve as the basis for a subsequent study with polyclonal serologic reagents to gain an understanding of the prerequisites to measure accurately and reproducibly HIV-1 functional antibodies for HIV protection and pathogenesis. A workshop, jointly organised with the World Health Organization (WHO)/ Joint United Nations Programme on HIV/AIDS (UNAIDS), will provide an avenue to discuss the results of the actions of NeutNet with a larger body of researchers in the field and share the information at a global level. The results of NeutNet will benefit HIV vaccine research and clinical trials, making it possible to compare all vaccine efforts throughout Europe and beyond.



PHARMA-PLANTA

RECOMBINANT PHARMACEUTICALS FROM PLANTS FOR HUMAN HEALTH

Starting year: 2004

FP6 instrument: Integrated Project

Why this research?

The expression of recombinant pharmaceutical proteins in plants has been under investigation for over ten years. Plants are attractive for several reasons, but the primary advantages are that they represent an inexpensive and versatile expression system for a wide variety of recombinant proteins, and they offer the potential for rapid and economical scale-up.

South African researchers:

The CSIR is the SA participant in the Pharma-Planta project.

The CSIR's primary role and tasks relate to the genetic transformation of maize and tobacco with the experimental vaccines, to perform crossing into elite lines and to monitor stability of Mab expression, molecular analysis and growing the transgenic plants in a contained environment to produce seeds that will be used for downstream processing.

A CSIR representative will be a member of the Pharma-Planta environmental and medicines biosafety committee in order to provide expertise on regulatory and biosafety issues.

What does the research hope to achieve?

Pharma-Planta aims to move beyond proof-of-concept studies and develop candidate products for clinical evaluation in phase I human trials. This will include compliance with all regulatory requirements, good manufacturing practice (GMP) standards and pre-clinical toxicity testing. The consortium will also develop robust risk assessment practices for recombinant pharmaceutical molecules produced in plants, based on health and environmental impact, working closely with the appropriate regulatory authorities. Finally, the consortium will develop a coordinated programme for securing and managing intellectual property, which will facilitate the availability of high priority, plant-derived recombinant pharmaceuticals to the poor in developing countries.

www.pharma-planta.org



Coeur4Life

IMPROVING PROJECT & RESEARCH MANAGEMENT SKILLS IN THIRD COUNTRIES TO STIMULATE THEIR COOPERATION WITH EUROPE FOR LIFE SCIENCES

Starting year: 2005

FP6 instrument: Specific Support Action

Why this research?

Life science research is increasingly global. Much research potential outside Europe in this field remains untapped. Many excellent research teams in various third countries around the globe would like to cooperate with Europe, but are hindered by various constraints.

In order to participate in and fully benefit from European Framework Programmes, they will need to adopt management and administration standards and procedures matching those applied by their partners in Europe.

Much of the training currently provided in this field is fragmented, fails to address the appropriate target audiences and often does not address specific local conditions.

South African researchers:

The SA Research and Innovation Management Association.

What does the research hope to achieve?

Coeur4life aims to develop a unique programme to improve research project management skills through a combination of:

- fact finding on the local needs for professional development in the context of local research management and administration practices,
- interviews with high level staff to address different organisational contexts and develop a limited set of local case studies,
- delivering a customised programme of interactive workshops using those case studies, to provide a stimulating environment for sharing good practice,
- direct aid to meet potential partners in Europe and attend relevant conferences (for selected workshop trainees), and
- interaction with the National Contact Points (NCPs) or equivalent bodies in these countries to develop policy recommendations which will create maximum benefits from international collaboration and mobility of highly educated personnel to and from Europe.



THE ALTERNATE TRANSCRIPT DIVERSITY PROJECT

Starting year: 2004

FP6 instrument: Specific Targeted Research Project

Why this research?

Production of mature mRNA transcripts in vertebrates is regulated at three stages: transcription initiation, splicing and polyadenylation. The combinatorial arrangement of variations at each stage generates, from a single gene, a variety of mRNA isoforms with different start sites, exons or 3 UTRs.

Expression of Alternative Transcripts (ATs) has been observed to be specific to tissue-type or developmental stage. Disruptions in expression patterns have serious consequences for an organism and are associated with numerous diseases, including cancer, multiple sclerosis, heart failure and neurodegenerative disorders. Identifying disease-specific ATs can lead to development of novel drug targets or markers.

South African researchers:

University of the Western Cape.

What does the research hope to achieve?

The objective of ATD is to develop and integrate these independent approaches in order to derive a unified view of AT formation and create a genome-scale reference database for human ATs; such a database is envisaged to include alternate transcript structures, functional consequences of variations, phylogenetic conservation, and references to other major genome and proteome resources. In addition, the consortium seeks to identify tissue or disease-specificity of isoforms using bioinformatics approaches. This will potentially reveal co-regulated expression patterns and associated regulatory motifs involved in transcript maturation. Finally, a selection of alternative transcripts will be submitted to experimental validation using semi-quantitative RT-PCR.



BEANISH

BUILDING A EUROPEAN - AFRICAN COLLABORATIVE NETWORK FOR APPLYING IST IN THE HEALTH CARE SECTOR

Starting year: 2005

FP6 instrument: Coordination Action

Why this research?

The HIV/AIDS pandemic together with the generally poor health status in Africa have emphasised the need for appropriate IST in health care for strengthening various activities such as knowledge exchange between health care managers, providers and the community, optimal allocation of resources and monitoring the roll out of the HIV/AIDS programmes. Europe has a strong research base in eHealth and there can be mutual benefits arising through cooperation between Europe and Africa.

However, given the contextual differences, for example related to infrastructure, economy, and culture, European solutions and know-how need to be sensitively reworked and appropriately translated to the African context.

Furthermore, best practices, learning and workable ISTs need to be shared and further developed across African countries within a regional framework.

South African researchers:

University of the Western Cape.

What does the research hope to achieve?

The BEANISH initiative, which is formally a WITFOR (World Information Technology Forum) project, proposed by EU-African partners and IFIP (International Federation for Information Processing), builds upon an existing global RandD network called HISP (Health Information Systems Program). This initiative seeks to involve various institutional actors (government, universities, private sector and NGOs) to strengthen and extend an existing Europe-Africa collaborative network to support the application and sharing of IST application development so as to support cooperation, learning and innovation in mutually beneficial ways.

The WITFOR 2005 served as an important milestone in the BEANISH project. The project focus is on organisation of the WITFOR conference; strengthening of the HISP network by conducting case studies and sharing of best practices; establishing capacity building to enable sharing open source software development; and supporting eTraining. The BEANISH project will help create the basis for developing international cooperation related to IST applications.

www.ifi.uio.no/beanish



PROMISE

PROMOTING INFANT HEALTH AND NUTRITION IN SUB-SAHARAN AFRICA: SAFETY AND EFFICACY OF EXCLUSIVE BREASTFEEDING PROMOTION IN THE HIV NETWORK AREA FOR APPLYING IST IN THE HEALTH CARE SECTOR

Starting year: 2004

FP6 instrument: Specific Targeted Research Project

Why this research?

It has only recently been proven that it is possible in hot and even dry climates, that Exclusive Breastfeeding (EBF) without even offering water is still little appreciated by mothers or supported by health workers.

EBF rates are especially low in Africa but the potential for rapid implementation may be high. A few studies elsewhere suggest that peer counselling can often achieve dramatic increases.

South African researchers:

University of the Western Cape.

What does the research hope to achieve?

The objective of the project is to develop and test an intervention to promote EBF to assess its impact on infant health in African contexts where a high prevalence of HIV is a barrier and to strengthen the evidence base regarding the optimal duration for EBF. Promotion of EBF is the most effective child health intervention currently feasible for implementation at population level in low-income countries. It can lower infant mortality by 13%, and by an additional 2% were it not for the fact that breastfeeding transmits HIV. Thus the consortium proposes to run the first randomised trial to develop and test models for applying this approach in four African countries and to quantify health benefits, cost-effectiveness and implications for the health care system. While experts realise that the HIV threat ought not to present much of a biological constraint to promoting EBF, in heavily affected countries it does represent a cultural constraint. Overcoming this will require the development of a safe and effective means of promoting EBF that is HIV-sensitive by taking into account the need to minimise postnatal HIV transmission. Another scientific constraint to the promotion of EBF for six months, as recommended by WHO, is uncertainty about its impact on the micronutrient status of infants. In a sub-study, the consortium will carefully follow markers of infant micronutrient status to see how they vary by feeding pattern, including EBF, for a longer period than has been examined previously.

To discuss South African participation in the FP6 Life Sciences, Genomics and Biotechnology for Health thematic priority, or the upcoming FP7 Health theme, please contact:



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