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EATRIS

Infrastructure bridges Basic Research and Medical Innovation

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The "**E**uropean **A**dvanced **T**ranslational **R**esearch **I**nfra**S**tructure in Medicine", EATRIS, is a new research infrastructure initiative which will help Europe to fulfil its potential in the strategically critical area of translational medical research. EATRIS is a unique framework linking European countries to accelerate the development of new medicinal products by facilitating access to a new pan-European infrastructure. EATRIS is one of the biomedical infrastructure projects initiated by the European Strategy Forum on Research Infrastructure (ESFRI) and is currently funded by the 7th Framework Programme of the European Commission.

Translational Medicine

"Translational medical research" or "translational medicine" is the crucial step between basic laboratory research and practical, clinical applications. At its best, translational medicine is a two-way street: the discoveries of basic research are developed into new tools for clinical care, and observations made in clinical care can inspire new approaches in basic research (Figure 1).

Everywhere in Europe basic researchers are hitting the same obstacles: they explore disease mechanisms, they find ways to influence these mechanisms and find new targets. They find ways to influence the target. All this contributes to the understanding of the biology of human disease. But the next step, the practical application of their basic work and the advancement into preclinical and clinical trials, is not available

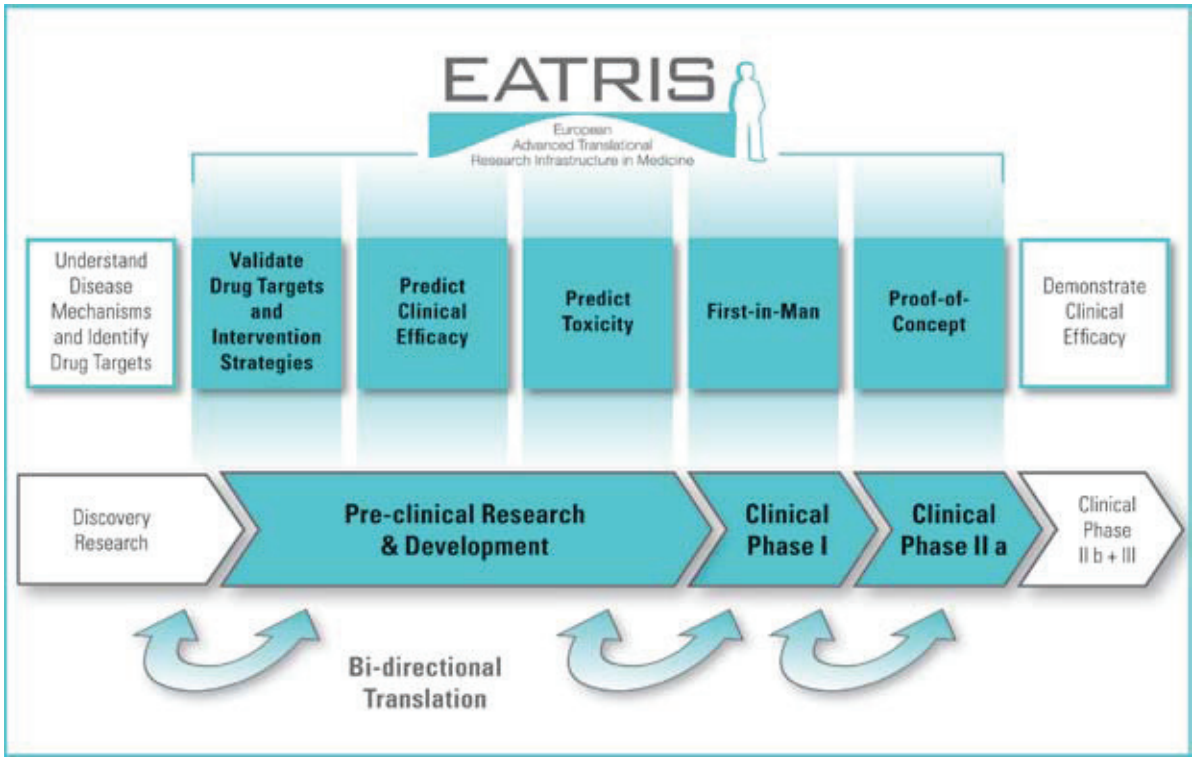

Figure 1. The infrastructure provided by EATRIS will cover the complete chain necessary to bring translational projects for which a first proof of principle has been established to the first proof of concept in human (clinical phase IIa).

to them. Despite this productive and strong biomedical research in Europe, the research stays in laboratories and journals and does not result in the groundbreaking new therapies and diagnostics that should follow from this work.

EATRIS – the Mission

EATRIS serves the translation of both diagnostics and therapeutics with a three-way approach, focusing on: product, people and population. EATRIS provides the necessary means to the research community to further develop their research results into products, EATRIS trains scientists to think beyond their discipline and provides researchers with knowledge about clinical needs and regulatory requirements, and finally EATRIS contributes to public health by improving diagnostics and treatment for the population as a whole.

The EATRIS infrastructure will provide the following types of infrastructure: physical facilities, expert knowledge and training programmes. It uses the unique approach of opening the doors to the best comprehensive translation centres to provide access for external users with promising discoveries.

EATRIS will enable academic institutions to translate their research and gain greater control and greater returns on early research investments. EATRIS translational research centres are the instruments to fulfil this mission but EATRIS will be more than a network of centres. The supply of research support is harmonised, facilities for research built up in EATRIS are largely complementary and a central governance structure coordinates the internal management and serves at the same time as an entrance portal for external scientists.

The EATRIS Centres

Building on excellence

Each EATRIS centre will consist of one or more institutions which are excellent in translational research and will be capable of handling the entire development chain for one or more medicinal products. The EATRIS centres will specialise according to their core expertise in products such as diagnostics, small molecule drugs, biologics, vaccines or novel therapeutics. The initial disease fields envisaged are the most pressing

ones: cancer, infection, cardiovascular, metabolic and neurological diseases.

The strategic goal is to have all necessary disciplines, such as those needed in pre-clinical development labs and study centres, as a strong innovation core close together, and complementing them with large-scale technology facilities like screening platforms. Building on existing excellence and knowledge will avoid unnecessary duplication of research environments and limit the need for the construction of new research facilities.

Comprehensiveness

EATRIS centres comprise the technological facilities, expertise and the clinical environment needed for all aspects of translational research. In an integrated environment involving different disciplines, the following will all be part of EATRIS centres: GLP animal facilities, labs for medicinal chemistry, libraries and the associated screening facilities, 'omics'-screening platforms, imaging facilities, both pre-clinical and clinical, cyclotrons to produce tracers and GMP facilities, as well as hospitals and early clinical trial units. The EATRIS goal is to take up discoveries and develop them to a stage where a proof of concept in human (clinical phase IIa) can be demonstrated.

Professional Management

In each EATRIS centre, project managers experienced in medicinal product development will oversee and steer the translational projects. Their experience in product development ensures an optimal progress on the development chain and compliance with regulatory requirements. Another key success factor is the multidisciplinary team which will be assembled for each project in order to provide input for each stage of the development chain from the outset.

Capacity building

Education is another essential element of EATRIS to improve translational medicine. Training programmes such as PhD programmes and trainings for technicians in order to bring valuable knowledge about translation both back from the clinic into the basic research laboratory and in the other direction to train Europe's next generation of clinical scientists and basic translational researchers. This will lead to more flexible and open career paths and a better exchange between the still too separate worlds of the clinic and research labs.

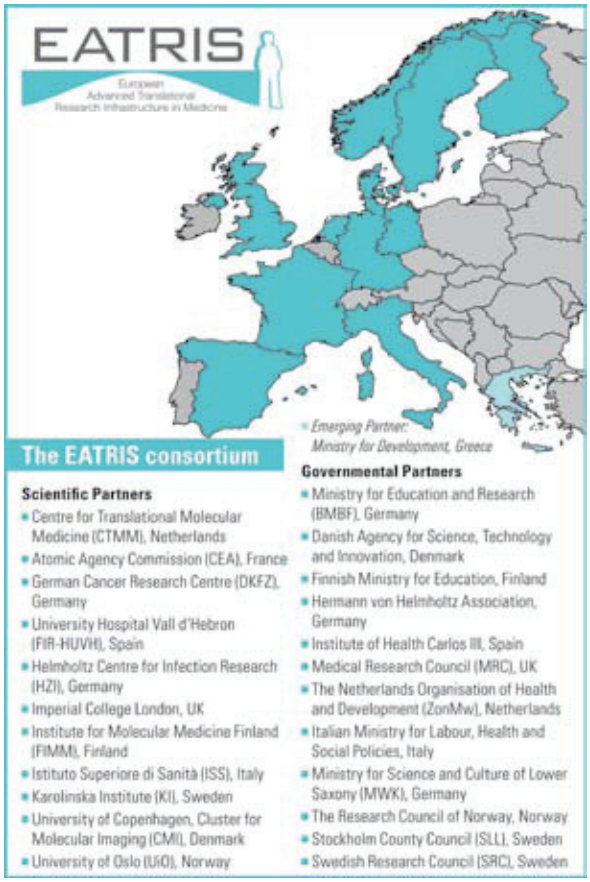

Figure 2. EATRIS is a new research infrastructure initiative consisting of a network of well-renowned biomedical translation research centres across Europe. Currently ten European countries are partner countries in the EATRIS consortium (turquoise).

Uniqueness of EATRIS

- The variety of platform technologies which EATRIS engages in will be unrivalled in any other framework. EATRIS closely intertwines development and basic research to provide a deeper understanding of the underlying biology and thus facilitates innovative solutions.
- The operational connection of hospitals and technology centres will encourage the development of a more personalised medicine. Carried out alongside therapeutics development, the development of novel and robust biomarkers will make therapies both more specific and less toxic.
- Combining technology and therapy development will lead to a faster drug development: Labelling therapeutic agents so that they can be traced *in vivo* with imaging methods can

speed up the assessment of the success of the therapeutic approach.

- Biomedical researchers and clinical scientists located at universities, research institutions or SMEs will be attracted to EATRIS for the support it offers to their research projects. EATRIS will act like a funnel drawing in a multitude of excellent discoveries, select the top ones and translate them for the benefit of the patient.

Let the EATRIS vision come true

The Preparatory Phase (2008-2010)

A strong consortium of excellent research centres in the area of translational biomedical research and relevant national and regional research policy makers has gathered to work on this vision of flourishing translational biomedical research in Europe (Figure 2).

The current Preparatory Phase of EATRIS aims at defining the benchmarks to establish a cutting-edge infrastructure for translational medical research, comprehensive training programmes and the requirements for implementation. A business plan will present the financing strategy and the governance scheme of EATRIS. Access conditions, a legal framework and a competitive IP management regime are being drawn up during this phase. The results of the Preparatory Phase will form the basis for the next implementation stage.

Construction Phase (2011-2015)

During a Construction Phase the different EATRIS sites will see their capacities expanded and a full coverage of the necessary technological facilities established. During this phase will already support a limited number of user projects within the framework of the existing infrastructure in the centres. By the end the EATRIS will be fully operational and offer support on a regular basis.

ECRIN

Integrating clinical research in Europe: the European Clinical Research Infrastructures Network

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Summary

ECRIN consists of integrating national clinical research facilities into a EU-wide network, able to provide support to clinical research in any medical field, and for any type of clinical research through information and consulting, and through a set of flexible services for the conduct of multinational clinical studies. This distributed infrastructure, based on the integration of competence centres, provides access to clinical research projects after assessment by its scientific board. A team of European correspondents working in the coordinating centre of each national network is the key actor in the provision of consulting and decentralised services. These services are particularly relevant for academic clinical research, especially under circumstances where international cooperation is required (ie. in rare diseases), or for clinical trials sponsored by biotechnology SMEs who often lack the capacity to act as a sponsor in EU-wide studies.

Introduction

Development of diagnostic and therapeutic innovation, and delivery of improved health care to EU citizens requires clinical research during the whole process extending from understanding the mechanism of disease, genetic studies or identification of biomarkers, clinical development and evaluation, and to post-marketing strategy trials.