EATRIS Infrastructure Accelerates Translation

Developing a Pan-European Research Infrastructure

Efficient translation of research discoveries into clinical application is essential to improve human health and maintain Europe's competitiveness in biomedical research and in health industry. A major bottleneck is the lack and the fragmented nature of research infrastructure and know-how, leading to unacceptable delays or preventing of the development of new innovative medicines. The aim of EATRIS, European Advanced Translational Research InfraStructure in Medicine, is to fill this gap by developing a pan-European research infrastructure.

Basic biomedical research in Europe has traditionally been strong. If one compares the research budgets for biomedical research in the US to the EU, the output in publications and the citation index of European scientists is more than competitive. However, Europe lacks behind when it comes to bringing innovation into clinical practice.

EATRIS aims to improve the "translation" of research to new applications by giving researchers across Europe access to state-of-the-art facilities, training and supporting services to optimize the clinical outputs of both basic and clinical research. This initiative is one of the biomedical infrastructures identified on the roadmap of the European Strategy Forum on Research Infrastructure (ESFRI) and is currently funded by the 7th Framework Program of the European Commission.

Building on Excellence

EATRIS will operate through a pan-European network of leading biomedical translational research centers. Currently ten countries are partner in the EATRIS consortium (fig. 1). By gathering translational excellence and know-how across Europe the innovative momentum in Europe will be reinforced. At the same time a critical mass of state-of-the-art research facilities and experienced staff will be achieved.

The EATRIS Translational Centers build the core of the infrastructure. Each centre will be capable of handling the entire development chain for diagnostic, therapeutic
or preventive products up to a first proof of concept in human (fig. 2). All necessary disciplines are close together as a strong innovation core, and will be complemented with state-of-the-art facilities and patient cohorts from hospitals (fig. 3). The centers will specialize according to their core expertise in applications such as diagnostics, small molecule drugs, biologics, vaccines or advanced therapy medicinal products like cell therapies.

**The Scope of EATRIS Infrastructure**

The initial disease fields destined are the most pressing ones: cancer, infection, cardiovascular, metabolic and neurological diseases. The goal is to take up discoveries for which a proof of principle is established and develop them to a stage where a proof of concept in human subjects (clinical phase IIa) can be demonstrated. This infrastructure will consist of a number of physical components, including:

- State-of-the-art animal facilities for preclinical proof of principle and proof of concept studies
- Small molecule screening facilities to identify and characterize new drug targets
- Compound libraries
- High-resolution imaging facilities for preclinical and clinical validation
- Cyclotrons to produce tracers
- Disease-specific patient and population cohorts to develop and validate new innovative diagnostic and therapeutic strategies
- Centralized GMP facilities for bioprocess development and manufacturing
- Facilities for Clinical Phase I studies.
Further services for European scientists will be offered by providing expert knowledge in fields such as regulatory issues and product development as well as professional project management.

EATRIS will also contribute to the training and education of the next generation of translation researchers by creating true multidisciplinary research environments and by providing training programs for scientists as well as technicians and nurses. What is more: The supply of research support will be harmonized and facilities for research will be largely complementary. A central management will take care of quality management and technology transfer and will serve as an entrance portal for external scientists (fig. 4).

**Opening the Doors to Europe**

EATRIS will use the unique approach of opening the doors of its comprehensive translation centers to provide access for external users with promising discoveries. The users of the infrastructure will be mainly basic biomedical researchers and clinical scientists located at universities and research institutions. The aim is to drive innovative discoveries from academia further along the developmental path following high quality standards. Thus, EATRIS will "de-risk targets" for the industry as they can take up already advanced drug candidates. In addition access to academic know-how and specialized research facilities across Europe will be offered to industrial partners like SMEs or even big pharma.

**Time Frame**

In March 2008 the preparatory phase started in which the consortium will work out a master plan describing in detail the establishment and mode of operation of the planned pan-European infrastructure.

During the following Implementation Phase, the different EATRIS sites will expand their capacities and establish a full coverage of the necessary technological facilities. A limited number of user projects will already be conducted. By 2016, EATRIS will be fully operational and offer support on a regular basis. It will be an innovation core for new diagnostics and therapies. EATRIS is very open to accept partners from new countries. The philosophy of extension is driven by the fact that construction and operational support for new infrastructure has to be financed by the national governments of the hosting countries. Therefore the policy was set up that new partners can only join as a country which is represented both, scientifically by a partner who speaks for the national translational research community and politically by the relevant ministry or funding body of the country.
Conclusions

EATRIS will overcome the barriers to successful translational research in Europe, by:

- Overcoming fragmentation along the translational research pathway
- Improving performance and access to infrastructure for all scientists and researchers
- Fostering knowledge exchange and standardization
- Providing training programs for the next generation of translational researchers
- Improving exchange between academia and industry
- Facilitating a smooth and efficient handover of translational projects from academia to industry

The initiative is driven by innovation and medical need and thus will fill the pipeline of industry with innovative approaches. In the long run, EATRIS will improve population health by contributing to the development of new innovative diagnostics and therapies for the benefit of the patients.

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