ARTICLE

REFLECTIONS ON RUNNING A START-UP INFRASTRUCTURE

A RETROSPECTIVE LOOK AT EATRIS DURING ITS FIRST 5 YEARS.

BY FRANK DE MAN,
Governance & Finance, EATRIS

eatris

European infrastructure
for translational medicine

Building a European Research Infrastructure, to improve human health and quality of life. Over the last two decades European scientists, EU Member States and the European Commission (EC) have worked together to strengthen scientific research in Europe and advance their position globally.

EATRIS is part of that story.

What is a European Infrastructure?

In 2002 the European Strategy Forum for Research Infrastructures (ESFRI) was established to:

a) Support a coherent and strategic approach to policy making in Research Infrastructures in Europe.
b) Facilitate multilateral initiatives leading to the better use and development of Research Infrastructures (RI).

The concept of establishing European Scientific Centres of Excellence existed long before 2002.

CERN (European Organisation for Nuclear Research) and EMBL (European Molecular Biology Laboratory) are both examples of European scientists and Member States working together to focus and accelerate their scientific research efforts by sharing knowledge, expertise, and investment capacity to maximise utilisation and avoid duplication.

CERN for example, recognised that it did not make sense, in the context of its purpose, to build a number of small CERN's across Europe. Therefore, it was decided to build a state of the art, single site installation to facilitate European scientists in small particles and nuclear research instead.

As of 2002, the ESFRI Forum discussed the feasibility of extending the number of RIs in biomedical science. Biomedical science is performed among hundreds of academic hospitals and biomedical research Centres of Excellence across Europe, all with their own scientific focus and disease expertise. One of the areas explored was translational research: scientific research that translates the outcomes of basic biomedical research into the development of pharmaceutical products and diagnostics for patients.

Why translational research?

Development of new medicines is stagnating globally. Though new discoveries occur at an increasingly rapid rate, new products for patients do not.
The main reasons for this are:

1. Biomedical scientific research primarily focuses on discoveries and technologies measured by original publications, with the consequence that there is little incentive to perform the confirmatory type of research that is necessary to advance a discovery towards the clinic.
2. Basic biomedical research is mostly funded by public money, while product development is funded by companies and investors. However, there is a substantial funding gap between these two worlds, and public private collaboration remains a complex undertaking.

Varying objectives and outcomes for basic science versus product development, lead to substantial knowledge and funding gaps and consequently a high attrition rate in this translational phase. Therefore in 2005 – 2006 the ESFRI Forum, together with eight EU countries and a collection of scientists, decided to investigate the feasibility of developing a European infrastructure to improve the effectiveness of translational medicine.

EATRIS HOPED TO:

- Support scientists and funders to develop more effective project proposals and de-risk projects.
- Facilitate collaboration between academia and industry among others by matching the right expertise to the right resources, to build collaborative projects.
- Help solve systemic hurdles in translational research, to make the development of therapies and diagnostics more effective.

"If we do not hang in there together, we will definitely hang separately."

THOMAS JEFFERSON

How to build an RI

In the first phase of this project, the so-called preparatory phase (2007-2010), they worked together according to a mutually approved work plan. Their objective was to find out whether establishing a European RI for translational research could create added value for the European biomedical research community.

That RI was called EATRIS.

EATRIS' mission was to provide services to the scientific research community to improve, accelerate and de-risk their translational projects in order to bring pharmaceutical products and diagnostics to patients efficiently and effectively.

Structure follows strategy follows function

When designing a new RI defining the right functional model is one of the leading issues. To help discover our direction and the key factors that would drive our services and operations, a gap analysis was performed to determine how and where we could add value.

The areas we identified were:

- Multiple misalignments in the process, including the varying requirements and projected outcomes for basic scientific research versus those for product development.
- Access to key technologies and expertise, that allow researchers to decrease project risks and increase funding opportunities.
- Reverse project planning, with the user group and a clear end goal in mind including regulatory requirements.

These multiple misalignments, together with the lack of access to relevant technologies and expertise create substantial failure risks for researchers and projects, as well as funders. This stage of the translation process is often referred to as the "valley of death".

We hoped to breathe life into the valley of death.

Following the outcome of the gap analysis, the preparatory group decided to design the functional model around the technologies required for translational research and not, for instance, per disease area. As these technologies are distributed among hundreds of scientific biomedical centres across Europe it was decided to structure the RI as a distributed consortium of participating scientific institutions, in contrast to a large, single site RI like CERN.

Patient driven & multidisciplinary

The next question to be answered was, which organisational model and legal entity best serves the objectives and functional model of the new organisation?

As mandated by the 2009 EU Directive, a European Research Infrastructure Consortium (ERIC) was established by governments with the objective to deliver services. Was an ERIC the appropriate legal entity to support EATRIS' objectives and functions or would another legal structure be a more effective framework?

For many biomedical scientists, Translational Medicine, as well as delivering scientific services, are new concepts. Scientific merit is still mainly measured in publications, which is closely linked to a scientist's ability to acquire new funding for new research. Patients have different needs. They do not read or need scientific articles, they want new products to manage and cure disease.

In translational research, multidisciplinary collaboration with a goal-oriented patient focus is a prerequisite for success. Scientific researchers, clinicians, regulatory experts, other experts and industry all play a role in getting a new product to the patient effectively. Aiming to implement new scientific concepts requires fundamental decisions about what is needed to make academic institutions and scientists adapt to these new concepts and enable them to work together. Such decisions will also drive subsequent considerations leading to the choice of legal entity.

At the end of the preparatory phase in 2010, participating Member States decided to continue the process and build the infrastructure. The Netherlands was chosen as the host country and it was confirmed ERIC was our preferred legal framework. So in 2011 the preparations for an operational plan started, in parallel with the formal application for EATRIS to be granted ERIC status. In November 2013, that application was approved by the European Commission and EATRIS became the first ERIC in biomedical sciences!

The RI as a start-up

Building EATRIS as a research infrastructure in Translational Medicine was a greenfield operation. Though in various parts of the world like Australia, US and Canada, service and development models in translational research existed, none of these were applicable to address the objectives identified via the gap analysis performed in Europe.

In contrast to other European initiatives in bioscience, that were built on existing collaboration networks, the EATRIS services model was developed from scratch and tested with potential users: academics, science funders and those with matchmaking needs, for projects among scientific institutions and industry.

Though now established as an international organisation and driven by 90+ leading scientific institutions across Europe, EATRIS is, in essence, a start-up that must continue to explore and define its position in the scientific and drug development markets.

Effective operations and sustainability

Being a start-up has pros and cons.
On the one hand established governments and large scientific organisations are not used to working with a small organisation that is still finding its equilibrium and position in the field. Building trust and support among clients and stakeholders is key, so it is important to continuously explain and clarify our position, our mission and manage expectations together with realistic timelines.

On the other hand, from a managerial point of view, building an organisation from scratch provides ample opportunity to build a bespoke staff team, with organisational flexibility, that enable us to thoroughly explore our users' needs and preferences while adjusting our services as necessary in response to an ever-changing environment. As mentioned, translational research is a relatively new concept in biomedical science that carries enormous potential to improve and accelerate drug development. Providing the scientific community and industry with the right tools and models, to not only improve but accelerate this development too, requires an ultra-flexible organisation that continuously (re-) assesses its added value against the needs of clients, in order to grow into a leading European RI. Moreover, the global collaboration with partners from Australia, USA, Canada, UK and Japan is an indispensable asset that helps us to stay up to speed with innovation in translational research.

Governance

Managing an organisation in a multidisciplinary, ever-changing environment requires tailored leadership and management skills. In the negotiations leading to the establishment of the ERIC legal entity, the governments followed the recommendations made by the Directors of the EATRIS transition organisation; to choose for a dual leadership model.

The EATRIS ERIC Executive Board consists of a Scientific Director and an Operations and Finance Director. It is a model that facilitates maximum steering power towards our key user groups. For us, it offers twice the insight and double the perspective. When it comes to negotiations these two Directors may sometimes have different opinions but that only leads to more considered outcomes. This twin leadership model ensure that the interests of clients and stakeholders are addressed equally. Should the two Directors ever disagree, the Chair and Vice-Chair of our Governing Board offer their counsel and support so that a unanimous decision may be reached.

The future

In 2016, EATRIS was awarded the status of a landmark European RI by the ESFRI Committee. More importantly, the impact of its operations show considerable progress in translational project support, research services and structural activities aimed at systemic improvements in translational research. The newly branded global alliance 'Translation Together' ensures alignment with global community and maximises knowledge sharing in the future.

Looking ahead, EATRIS aims to work towards a funding model that balances government support, service fees and participation in European projects, over the next five years.

Recent interactions and collaboration with the European Medicines Agency (EMA) and the European Patients' Forum (EPF), respectively, point to the recognition EATRIS has gained as Europe's leading RI in Translational Medicine. These connections provide significant opportunities to work together with key European authorities and organisations to improve human health and quality of life for patients.

ABOUT EATRIS

The European Infrastructure for Translational Medicine (EATRIS) is a non-profit, permanent European research infrastructure consortium (ERIC) that comprises more than 90 research institutions in 12 European countries. EATRIS focuses on accelerating medical discoveries to clinical development through innovative use of infrastructure and scientific expertise provided by top-level European academic research centres. EATRIS is active in the fields of ATMP, biomarkers, imaging and tracing, small molecules and vaccines.

WWW.EATRIS.EU

Mail
info@eatris.eu

Website
www.eatris.eu

Phone
+ 31 (0)20 44 422 54

Twitter
twitter.com/EatrisEric

Address
De Boelelaan 1118, 1081 HZ
Amsterdam The Netherlands

Linkedin
linkedin.com/company/eatris-eric