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Dear reader,

We proudly present to you our annual report for 2015. Just like all preceding years in the short history of EATRIS – and doubt

many more to come – 2015 was an exciting year for us. We continued on our journey towards better output of novel medicines, diagnostics and vaccines in Europe.

In our second year of operations, we focused heavily on increasing EATRIS’ profile, through active marketing of our excellent catalogue of translational research services, profession-

ally our communications efforts, and cul-

ti- vating the varied relationships so crucial to success in this multi-disciplinary field. We are happy to report that this is yielding results; we have seen growth in all relevant metrics – more and more researchers and small companies are approaching us for services, we have ongoing projects and explorations with several medium and large pharma companies, the competitive funding proportion of our operating budget is increasing steadily, and the feedback we are receiving from all stakeholders is very positive. And we remain committed to being a learning organisation, receptive to feedback and constantly inter-

acting with our stakeholders to learn of real needs on the work-floor of biomedical R&D.

Our long term innovation pipeline that will help us reach the main goal of a more pro-

ductive innovation pipeline. Notable examples include our interactions with the regulatory agencies, our continued development of EATRIS inside as a solution for public and

non-profit funders, and our global collaborations with infrastructures on several other continents. And finally, we welcomed with open arms Sweden into the EATRIS family of member countries. In the few short months that we have been working together, we already start to bear the fruits in the form of company interactions that may lead to projects, and are integrating the world class capabilities into our infrastructure offering.

All in all, we look back on 2015 as a year of building, learning and growing. I hope we continue in this vein, working closely with the committed individuals in our institutes, governments and client organisations.

Sincerely,

Anton Ussi

Operations & Finance Director, EATRIS
Dear Reader,

As the Chair of the Board of National Directors, it is with pleasure that I look back on the activities of EATRIS-ERIC in 2015, which represented our second year of full-scale operations and with a significant progress towards realizing the EATRIS vision and mission and serving the needs of our many stakeholders.

With the development of our services and opportunities, as well as the enhancement of our working program, EATRIS displayed its ongoing commitment to expanding our portfolio of exciting projects, and continued developing as a world-class infrastructure serving the needs of the European Research Area. 2015 had a continued focus on providing high-end services through our infrastructure, and increased networking to develop strategic projects to drive our goal of enhancing translational research and drug development. These goals have been made a reality by providing a promise of continued innovation in drug development through the development of our continually growing infrastructure with many stakeholders.

Some of our key accomplishments in 2015 include: a marked increase in matchmaking projects which saw EATRIS acquire and develop projects of high-translational merit and already contributing to EATRIS product管线 and the complex regulatory environment. This year saw a substantial increase in EATRIS participation in EU-funded projects including EATRIS involvement in a number of Horizon2020 projects, which will serve as key initiatives in the coming years. EATRIS continued to seek greater collaboration with the learned societies as we aim to combine resources and expertise in specific disease areas. With these initiatives and more, we also continued to develop our education and training portfolio, where 2015 saw EATRIS develop and foster the education and training infrastructure of now over 70 world-class institutions and industry stakeholders alike.

EATRIS remains dedicated to driving innovation and promoting the highest standards of quality and integrity in translational research and drug development. Our continued growth has been made real by offering a platform for continued innovation in drug development through the development of our continually growing infrastructure with a focus on beneficial collaboration, education and training and support for our network.

In May, the second EATRIS conference “Building Bridges in Translational Medicine” offered a unique forum for examining new ways for de-risking translation and drug development through effective collaboration with industry and with industry.

The EATRIS portfolio of public-private collaborations with companies from the diagnostics, biotech and pharmaceutical sectors continued to grow and related marketing activities have been included in the infrastructure. The EATRIS ERIC family has grown with Sweden joining as an observer member, while biotech and pharmaceutical sectors continued to work together in the future to support EATRIS meeting these expectations. Sincerely,

Marian Hajduch, Chair of the Board of National Directors
2. INTRODUCTION

EATRIS, the European infrastructure for translational medicine, strives to accelerate product development by utilizing cutting-edge enabling technologies. Academic researchers, companies and charities are provided access to the clinical expertise and high-end infrastructure that is available within the 75+ top academic centers across Europe that comprise EATRIS. We focus on preclinical and early clinical development of drugs, vaccines and diagnostics.

Solutions are provided in the fields of advanced therapy medicinal products, biomarkers, imaging and tracing, small molecules and vaccines. By providing tailored support in the collaboration process and using standardised one-to-one contracting procedures between researchers and EATRIS institutes, lead times to start and execute projects are reduced to a minimum.

As a result, EATRIS supported the exploration for a personalized medicine innovation pipeline, in collaboration with the BMJ Risk group.

Several other infrastructure development projects were continued in 2015, included formalisation of the steering committee for an early cancer detection initiative in Europe. In collaboration with the US NIH NCI and Cancer Research UK.

We also welcomed Sweden to the EATRIS family of countries. The coordination team has made a flying start to developing the Swedish node and participation, and the first industry contacts have been made.
The long-term goal of EATRIS is to improve the output of high potential medicines and diagnostics that meet patients’ needs and impact their health outcomes positively. In 2015 we focused on two main areas of activity:

- Serving as a matchmaker for academic research projects, bringing together academic research and industry expertise.
- Developing long-term solutions to regulatory, product development, and many other areas of expertise. This has been for -malised into a set of services which EATRIS offers via its ‘one-stop shop’ matchmaking process or directly to funders via EATRIS-Inside.

In 2014, EATRIS initiated its marketing strategy and first approach to clients, especially with its first participation to Bio-Convention and Bio-Europe. In 2015 we implemented a more systematic approach and follow-up to strengthen the marketing and engagement with clients. Participation to partnering events increased together with the drafting and distribution of targeted communication materials (such as the platform technology leaflets, new pages 18, 21, 23, and 27). As a result, the number of leads doubled in 2015 and five new letters of engagement for matchmaking were signed. Among them was one project involving a statiplycoccus aureus challenge study for a novel SME which was successfully finalized and completed (page 14).

Another project involved regulatory support to apply for Orphan designation, which despite positive exploration is on hold, subject to financing green light.

The other projects are still under exploration. We expect, for at least two further requests, a signed agreement between institution and client by early 2016.

In addition, in 2015, EATRIS was approached by one big pharma company to help in the development of an academic hub for preclinical development. The initiative is currently under development, with a steering committee in place and first projects under exploration. The hub will focus, at first, on a series of experimental medicine pilot projects, with the consequent development of the hub’s logical and operational framework.

EATRIS kept offering fast-match-making using the EATRIS database. EATRIS fast matchmaking helps to quickly and objectively identify potential partners with the skills and facilities needed for any project and to build the optimal consortium to apply to national and international calls. Under its E-Round call (BMBF for Research Program on Rare Diseases) applicants were encouraged to use this service offered by EATRIS.

In 2015, EATRIS introduced the successful pilot of the EATRIS Inside service in The Netherlands. Through EATRIS-Inside, the translational feasibility of projects on elements like the best utilisation of high-end infrastructure and expertise, medical need, intellectual property, regulatory pathway, and end product definition is promoted.


3. SERVICES AND INFRASTRUCTURE

The services provided by the EATRIS institutions, while additional expertise is brought on board as needed, either provided centrally by CAS or from institutions, depending on the requirements.

Results
Partnering during the year 2015 reached an all-time high with the number of clients served and projects signed. Among them was one project involving biomarker validation initiated in the early 2016.

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evaluated. In 2015, the EATRIS coordination team visited at EATRIS member states to engage with national funding agencies for the implementation of EATRIS inside national funding and translational programmes. As a result of the country roadshows, and to answer to countries’ specific needs, EATRIS impact was developed. This service was designed to support the evaluation of the overall impact of biomedical research projects, based on the results available after a first round of funding. This service has not yet been piloted.

Marketing activities
In order to increase the number of users accessing the translational research services, marketing activities were established in 2015 as a dedicated program performed at three levels:
1. Establishment of relationships with the Biotech branch of industrial associations;
2. Visiting and sponsoring scientific and partnering events;
3. Direct contact with potential prospects.

Biotech organizations
In order to increase the visibility of EATRIS in the member country relationships were established with the following branch organisations:
- Denmark – Danish Biotech
- Finland – FinnBio Biotechs
- Italy – Asibiotech
- Netherlands – HollandBio
- Sweden – SwedBio
- Europe – EuBiopool

EuBiopool allowed to present EATRIS during their National Association Council, November 2015.

Additionally, in the Netherlands and in Finland relationships have been built with science parks and regional investment funds as a test case to explore opportunities for relationships with regional partners.

Partnering events
An important part of the marketing activities of EATRIS is its presence at scientific and partnering meetings and events. Platform chairs, other EATRIS key opinion leaders as well as EATRIS C&S staff visited numerous scientific meetings.

Some examples are:
- ISGT meeting (International Society for Cell Therapy), Spain: EATRIS had a booth at this event;
- EMFM 15 (European Association of Nuclear Medicine), Hamburg: EATRIS organised a workshop on translational molecular imaging to support drug development programme.

Apart from scientific meetings, we also visited various partnering and networking events:
- Innovation for Health (Feb 2015, The Netherlands – sponsored);
- Knows4life (May 2015, Belgium) Bio International Convention (June 2015, USA);
- Healbio (Aug 2015, Finland – sponsored by the Finnish node);
- Nordic Life Science Days (Sep 2015, Sweden);
- Biotechnology Partnering Conference, BIO-Europe (Oct 2015, Germany);
- Bio4Life academia-industry collaborations in Life Sciences (Dec 2015, France);

At these Partnering events over 70 1:1 partnering meetings were conducted with representatives of large pharma, SMEs, consultants and investors.

Based on the technology leaflets and backed up by platform chairs, scientific staff of over 30 companies were approached directly to seek their interest in the EATRIS services.

This approach was piloted for the Imaging & Tracing and the Vaccines platforms.

Those first interactions confirmed the need for public/private efficient partnership and fast access to academia high-end facilities.
In 2015, Sweden joined EATRIS as a full-fee observing member, with first goals to establish a national node and to identify the most relevant Swedish infrastructure to complement the already established set of infrastructure services that exist within EATRIS. The Swedish Coordination Center is located in Uppsala and includes a National Director (Erik Ingelsson) and a National Coordinator (Ulrika Bäckman). During the past year, the Swedish node has inter alia achieved the following:

• Key persons responsible for infrastructures at all Swedish universities have been identified for presentation of EATRIS, in order to make the initiative national;
• A roadmap describing suitable infrastructures available at Swedish universities and how to approach them has been developed and has been contact for the Swedish Coordination Center, Coordination Unit, coordination.

HIGHLIGHT: SWEDEN NEW MEMBERSHIP
EATRIS is organised along five product platforms: Advanced Therapy Medicinal Products (ATMP); Biomarkers; Imaging & Tracing; Small Molecules; and Vaccines. Each platform offers a specific set of infrastructure services to be targeted at specific users, namely: academic and non-profit research institutions (including charities and small companies), industry; academia; charity funders and governments. These services are accompanied by infrastructure development projects designed to overcome the significant bottlenecks in translational medicine using cross-platform projects targeted to specific disease areas.

In addition, EATRIS scientists are developing innovative strategies to approach the bottlenecks in translational medicine using cross-platform technologies and innovation to accelerate the progress of novel drugs and diagnostics. The list of these can be found in the next section. These initiatives are important efforts to improve the overall efficiency of the translational pipeline.

In 2015, the EATRIS Imaging & Tracing platform consolidated its service offering for advanced translational molecular imaging to support drug development, with an increasing number of mediated requests. Interest from pharmaceutical and biotech companies has increased with the aim to develop novel imaging methodologies tailored around certain disease mechanisms. In addition, we received various requests, ranging from regulatory guidance for developing an imaging comparison diagnostic, certified PET imaging studies in non-human primates to fluorescent/PET labelling of biotherapeutics, PET imaging in animal models and small molecule tracer development (F-18, C-11). Imaging & Tracing and project initiation is ongoing for several projects. In addition, the formation of a central hub with tailored infrastructure and services to generate imaging methodologies to support the early clinical development of drugs for treatment of immuno-inflammatory disorders in order discussion with a major pharma company.

In 2015, the EATRIS Imaging & Tracing platform consolidated its service offering (PET imaging, tracers labelling of biologicals (antibodies, Fab fragments), new non-human primates to fluorescent/PET labelling of biotherapeutics, PET imaging in animal models and small molecule tracer development (F-18, C-11). Imaging & Tracing and project initiation is ongoing for several projects. In addition, the formation of a central hub with tailored infrastructure and services to generate imaging methodologies to support the early clinical development of drugs for treatment of immuno-inflammatory disorders in order discussion with a major pharma company.

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The Imaging and Tracing platform will continue to work on programs to make drug development more efficient through robust and harmonised translational (molecular) imaging and to optimise access for industry and academic clients through exchange of best practice.

EARL is the EANM Research Ltd initiative (earl.eanm.org) to promote multi-site nuclear medicine and research through harmonisation and standardisation of (PET) image acquisition and quantitative data analysis. EATRIS and EARL are jointly developing a novel pilot calibration programme for harmonisation of clinical/PET/CT imaging involving Zirconium-89 (Zr-89). The goal of the program is to enable clinical PET/CT imaging involving Zirconium-89 calibration programme for harmonisation of and quantitative data analysis. EATRIS and standardisation of (PET) image acquisition (earl.eanm.org) to promote multicentre nuclear practice.

Candidate Drug Benefit compounds tracking of eatris imaging & tracing Platform provides in vivo Better prediction of drug efficacy and validated targets Clinical imaging in cohorts Clinical de-risking drugs decrease risk, Improve Insights, and Increase value of disease specific in vivo and for outcome monitoring with the same techniques applicable can be used for initial diagnosis and prognosis, for treatment selection, effect of unlabelled pharmaceuticals on critical disease processes. Tracers the appropriate tracers, molecular imaging can be used to assess the in vivo labelling of these compounds/cells, molecular imaging can serve to: track agents’ in providing a wealth of information when it comes to novel

ULTRA-HIGH FIELD MRI: IMAGING BIOMARKERS FOR HIGH PRECISION MEDICINE

In the future more pilot phase is underway with 7 sites within the EATRIS network. In the future, more than 120 FDG-accredited sites will be eligible for the program. Prof. Ronald Bovill, chair of EARL, FDG PET/CT accreditation programme, presented an update of the accreditation programme development at the EAMM 15 meeting.

Example 1
Advanced Therapies are an increasingly important frontier in the development of novel therapeutic treatments in many disease areas. Gene transfer vectors are important tools of molecular medicine, and high-quality investigational medicinal products manufactured according to European Good Manufacturing Practice (GMP) and the guidelines of the European Medicinal Agency (EMA). EATRIS academic centres and hospital-based GMP facilities are major contributors to the development of ATMP, providing high-quality medicinal products combined with expertise. ATMP products and tissue-engineered products represent a new category of drugs that hold vast therapeutic potential for treating an extensive range of indications. Clinical trials employing ATMP require the application of innovative Advance Therapy Medicinal Products (ATMP), while cell therapy medicinal products, in addition to offering intense programs with academia, SMEs and pharma, consist of 9 speakers with 79 registrants from manufacturing standardisation of ATMP products across the EATRIS infrastructure.

This partnership with ISCT was established to create a general framework of research agendas. In 2016, this partnership will be developed to promote mutual marketing, the establishment of Cell Therapy educational courses in Europe and the possible joint development of research agendas.

In 2015, the EATRIS ATMP platform continued to support development, from post-discovery to clinical proof of concept, of novel ATMP products, in addition to offering an entire spectrum of high end research infrastructure and patient cohorts. The ATMP platform continued to grow, with 31 state of the art centres forming the platform with the inclusion of the Institute of Experimental Medicine in Prague (Czech Republic), the IRCSS Institute Ortopedico Galeazzi from Italy and INCLIVA in Spain early 2016. In 2015 these institutions provided specialised GMP facilities, imaging facilities for in vivo animal studies, tailored animal models, and access to a broad range of clinical expertise patient cohorts.

The ATMP platform organized two educational workshops in 2015, the first being the “Introductory ATMP Development Regulatory Course” in Rome in September, which consisted of 28 speakers and 29 registrants from academia, SMEs and pharma. This was followed by an additional course in “Development of Advanced Therapy Medicinal Products” in collaboration with BiMaD in Pisa in November. This international workshop consisted of 18 speakers with 72 registrants, again from academia, SMEs and pharma. Both courses offered intense programs with key opinion leaders providing lectures and panel discussions on the ATMP development pipelines and the gaps that presently exist.

The EATRIS ATMP Reference Standard concept was initiated to develop ATMP standards and reference materials through collaboration with engineering, biology, regulatory & PPP collaboration. EATRIS will work in collaboration with EPSREC (LRC) in 2016 to develop a position paper on manufacturing standardisation of ATMP products across the EATRIS infrastructure.

The ATMP platform, with a view to establishing greater collaboration with the learned societies in the ATMP field, signed an MoU with the International Society for Cell Therapy (BCT). This Partnership with BCT was established to create a general framework to exchange ideas to better understand diagnostic and therapeutic development.

In 2015, the EATRIS ATMP platform continued to collaborate with EPSRC (UK) in 2016 to develop a position paper on manufacturing standardisation of ATMP products across the EATRIS infrastructure.

In 2016, this partnership will be developed to promote mutual marketing, the establishment of Cell Therapy educational courses in Europe and the possible joint development of research agendas.
In 2015, the EATRIS Biomarker platform continued to reinforce its long-term mission to validate biomarker targets and assays for the clinic by providing access to European biobanks, assay development knowledge, and clinical expertise. In 2015, the platform continued its positioning as a biomarker validation platform in Europe that will support drug and diagnostic development, with the participation of three new institutes: the National Cancer Institute in the United States, the KBCIS Istituto Ortopedico Galeazzi in Italy and INCLIVA in Spain - bringing the number of European EATRIS institutions managing research infrastructure operating under Good Biomarker Practice to 37.

To promote the biomarker platform capabilities and translational services, two technology leaflets were produced in 2015, namely Biomarkers: Genomics for Precision Medicine, with the contribution of 11 institutes, and Liquid Biopsies & Circulating Biomarkers, for which 6 institutes contributed. Both leaflets were actively distributed at various conferences and meetings, including during one-on-one partnering meetings with SME and industry during Bio-Convention (USA) and Bio-Europe. Moreover, the leaflets are available in English, French, and Spanish and will become available in 2016. In 2015, two matchmaking projects were under exploration with industry clients. An agreement for both projects should be signed Q1 2016.

In addition, the platform kept increasing its position on the international scene by organizing a series of meetings with international players. In October 2015, EATRIS organised together with Cancer Research UK (CRUK) and Dr. Suftli Sevalab, Chief Biomarkers Research Group, Early Detection Research Network (EDRN - NCI-US), a workshop in Brussels. The workshop consisted of an introduction of the NIH/EDRN - EDRN initiative to a group of European cancer funders and distinguished scientists to discuss the merits and challenges of a European initiative to a group of European cancer institutions.

How does EATRIS add value to your portfolio?

- Fast access to clinical samples and well-annotated data.
- Integration of clinical care and research.
- Validation of (Panel) biomarkers ready for qualification.
- Access leading academic expertise.
- Access head-to-head comparison platforms; technologies; specific diagnostic and prognostic applications.

BODILY FLUIDS

- Plasma-derived tumour DNA;
- Circulating tumour cells;
- Exosome-derived RNA and DNA;
- Circulating proteins and metabolites;
- Proximal tissue fluids expertise (exudates, etc.).

PERSPECTIVE TISSUE BIOPSIES

- Routine clinical diagnostics.
- Bone marrow biopsies.
- Tumour-free skin biopsies.
- Lymphocyte immortalisation and the establishment of primary cell cultures.
- Derived DNA.

How does EATRIS add value to your 'therapies'?

- Data stewardship;
- Access multiple sites for clinical validation;
- Access to multisite clinical trials;
- Fast access to clinical samples and well-annotated data;
- Available biosamples;
- Development plan;
- For the development of biomarkers and diagnostics.

In an effort to reduce cost and complexity of validating biomarkers and improve biomarker development practices, several meetings have been organized with EDRN, ELI4S and others throughout the year. The concept of an integrated biomarker development infrastructure operating under Good Biomarker Practice has been further developed. The group has been engaging with several funders including EU (Innovative Medicine Initiative).
VACCINES PLATFORM

Dr. Jan Langermans, Chair
Biomedical Primate Research Centre
The Netherlands
Product Platform Manager
EATRIS CAS, The Netherlands

The vaccine platform continued to move forward in providing cutting edge service for the next generation of vaccinology by adopting a multidisciplinary approach. The platform, which comprises 19 advanced vaccine development centres, provides state-of-the-art technologies and expertise including antigen characterization, specialized GMP-manufacturing facilities covering USP and GMP formulation and adjuvantaion; animal facilities up to BSL3; animal models including non-human primates and GMP-toxicology; and immunomonitoring and clinical capacity. The vaccine platform welcomed two additional institutions in 2015: the Statens Serum Institute (SSI) in Denmark and the Central Veterinary Institute (CVI) from the Netherlands. In 2015 the Vaccine platform continued to support European HIV, Hepatitis and Hepatita B/C virus studies including repository for archiving and storage of clinical specimens, research biological materials and reference reagents accessible via (Transnational Access).

EATRIS, together with key European players, engaged in the drafting of the TRANSVAC 2 proposal to be submitted at the end of March 2016. 2015 saw EATRIS explore a partnership with TBVI as a joint undertaking in TB vaccine R&D. Possible areas were identified where both EATRIS and TBVI could collaborate, including workshops on optimising the vaccine development pipeline. A Memorandum of Understanding (MoU) will be signed in early 2016.

EATRIS facilitates a new partnership between IMAXIO, an integrated vaccine focused biotech company based in France, and the Infectious Disease group of the Institute of Biomedicine of Seville (IBiS), Spain. The initial contact with the company was initiated at the BIO USA 2014 convention in San Diego, California. The final objective of this study was to determine the efficacy of different S. aureus vaccines in a sepsis preclinical model of infection due to S. aureus.

About IMAXIO SA: IMAXIO is a small biotechnology company focused on immunology, with products ranging from commercial stage to clinical and preclinical R&D stages. Its clinical stage R&D pipeline is focused on vaccines for infectious diseases and immunotherapies in oncology (www.imaxio.com).

HIGHLIGHT: IBIS-IMAXIO PARTNERSHIP

EATRIS supported the European Vaccine Availability Roadmap for the next generation of vaccines by adopting a multidisciplinary approach. The platform, which comprises 19 advanced vaccine development centres, provides state-of-the-art technologies and expertise including antigen characterization, specialized GMP-manufacturing facilities covering USP and GMP formulation and adjuvantaion; animal facilities up to BSL3; animal models including non-human primates and GMP-toxicology; and immunomonitoring and clinical capacity. The vaccine platform welcomed two additional institutions in 2015: the Statens Serum Institute (SSI) in Denmark and the Central Veterinary Institute (CVI) from the Netherlands. There were 3 matchmaking projects in 2015 comprising a challenge study, a request for regulatory support and an on-going project in protein configuration analysis. Key Vaccine platform infrastructure development achievements centered on identifying and affiliating with new institutions, fostering collaborations, and implementing EU-funded projects. The latter included:

- The development of the Innovation Partnership for a Roadmap for Vaccines in Europe (IPROVE) project continued through 2015. This represents a collaborative effort of the leading vaccine experts in Europe to develop a roadmap on how the future of vaccines and vaccinology-related research in the EU should look over the coming decade. The objective carried out was the organization of key public and private stakeholders from across academia, public health institutes, regulators, industry, and SMEs to build a critical stakeholder consensus on the priority gaps and challenges that must be addressed to bolster vaccine innovation.

At the end of 2015 the final version of the roadmap was produced with the final summit planned for March 10th-11th 2016 at the European Parliament in Brussels.

The FP7 EURIFRED Project (European Research Infrastructures for Poverty Related Diseases) progressed through 2015 and will be on-going through 2016. This project promoted the integration of international resources into a single specialised infrastructure to support European HIV, Hepatitis and Hepatita B/C virus studies including repository for archiving and storage of clinical specimens, research biological materials and reference reagents accessible via (Transnational Access).

EATRIS, together with key European players, engaged in the drafting of the TRANSVAC 2 proposal to be submitted at the end of March 2016.

2015 saw EATRIS explore a partnership with TBVI as a joint undertaking in TB vaccine R&D. Possible areas were identified where both EATRIS and TBVI could collaborate, including workshops on optimising the vaccine development pipeline. A Memorandum of Understanding (MoU) will be signed in early 2016.

EATRIS encouraged a new partnership between IMAXIO, an integrated vaccine focused biotech company based in France, and the Infectious Disease group of the Institute of Biomedicine of Seville (IBiS), Spain. The initial contact with the company was initiated at the BIO USA 2014 convention in San Diego, California. The final objective of this study was to determine the efficacy of different S. aureus vaccines in a sepsis preclinical model of infection due to S. aureus.

About IMAXIO SA: IMAXIO is a small biotechnology company focused on immunology, with products ranging from commercial stage to clinical and preclinical R&D stages. Its clinical stage R&D pipeline is focused on vaccines for infectious diseases and immunotherapies in oncology (www.imaxio.com).

ABDOUT IBIS: The Institute of Biomedicine of Seville (Instituto de Biomedicina de Sevilla, IBS) is a multidisciplinary biomedical research centre to undertake competitive research at an international level on the causes of the most prevalent pathologies in the population, and to develop new methods for their diagnosis and treatment. IMAXIO contributes to the EATRIS Product Platforms, namely ATMP Biomarkers, Imaging and Tracing and Small Molecules, (www.ibis-sevilla.es).
In 2015, the small molecules platform continued to work on its long-term mission to enhance the efficiency of clinical translation of novel chemical entities using cutting-edge technologies with access to patient materials and pre-clinical and clinical expertise. The strategic focus areas of the 24 European translational centres involved are advanced drug screening in 3D cultures and primary cells, peptide drugs and the pre-clinical and clinical validation of nanomedicines and -formulations. Several (best) matching requests have been handed to date which have resulted in the identification of suitable collaborations with a wide range of experts, including rare diseases (e.g. Wolfram Syndrome), drug repurposing (opioid drug abuse support), GLP-tox studies, re-formulation for immuno-inflammatory diseases, requiring medicinal chemistry expertise for the development of novel imaging probes for drug sensitivity and resistance testing in a-HTS setting, including organoid production, for tumor heterogeneity analysis, target validation and study of SFRF effect and tyrosine kinase inhibition; 4) ADME profiling of innovative drugs including repositioning, de-risking, combination therapies; 5) Production, characterisation and pre-optimisation of biopolymer nanoparticles for delivery of chelating agents, including advanced biodistribution assays. The platform welcomed institution INCLIVA (Prof. María Jesús Sanz, ES), to complement EATRIS expertise available, such as chemical analytical capabilities available at the Institute of Macromolecular Medicine (Prague, CZ) or GLP certified safety and efficacy testing at Tartu University (Tartu, EE). The further development of the institutions’ joint translational research to some academic institutions and biotech companies seeking infrastructure for their projects is expanding in the following focused areas: 1) Translational animal models involving patient-derived xenografts (xenografts) models for the development of personalized treatment strategies; 2) Advanced screening using 3D cultures and primary cells, peptide drugs and the pre-clinical and clinical validation of nanomedicines and -formulations. Several (best) matching requests have been handed to date which have resulted in the identification of suitable collaborations with a wide range of experts, including rare diseases (e.g. Wolfram Syndrome), drug repurposing (opioid drug abuse support), GLP-tox studies, re-formulation for immuno-inflammatory diseases, requiring medicinal chemistry expertise for the development of novel imaging probes for drug sensitivity and resistance testing in a-HTS setting, including organoid production, for tumor heterogeneity analysis, target validation and study of SFRF effect and tyrosine kinase inhibition; 4) ADME profiling of innovative drugs including repositioning, de-risking, combination therapies; 5) Production, characterisation and pre-optimisation of biopolymer nanoparticles for delivery of chelating agents, including advanced biodistribution assays. The platform welcomed institution INCLIVA (Prof. María Jesús Sanz, ES), to complement EATRIS expertise available, such as chemical analytical capabilities available at the Institute of Macromolecular Medicine (Prague, CZ) or GLP certified safety and efficacy testing at Tartu University (Tartu, EE).
### Pipeline Development Projects

**European Diagnostics**
- Portfolio REA evaluation: diakines, in vitro diagnostic kits.
- **Virtual Development**
  - Provides a view in one dashboard and tools for the translation of research.
  - **Operational Development Projects**
    - Personalised medicines; collaboration with other partners.
    - Collaborative programs and clinical trials.
    - CBG-MEB – The Netherlands drug evaluation.

### Operational Development Projects

**National Innovation**
- Collaborate with CEPSA to possibly review and surgical setting.
- **EATRIS – PAC**
  - EATRIS-Patient Advisory Committee is actively developing the project.

### Technological Interactions

**EATRIS**
- **Concepts Finalised**
  - Biomarker for Good Cancer Therapy.
  - Therapies medicinal products (ATMP).
  - Imaging and Therapies.

### Global Collaborations

**Operational Development Projects**
- Investigating new projects with EU-ETRIS and collaboration with other partners.
- Strategies for the organisation.

### Results

In 2014, EATRIS began collaborating with CBG-AB – The Netherlands drug evaluation agency. EATRIS will engage clients to identify the bottlenecks that are particularly acute challenges for academic researchers and their funders. The first contacts with industry have already been made.

In 2015, EATRIS welcomed Sweden as full member. Sweden is represented at the Board of National Director by Erik Ingelsson, University of Uppsala University and Ulrika Backman as national coordinator. Sweden will contribute to the EATRIS effort and product platforms.

EATRIS will continue dialogue with the EMA, National Competent Authorities. Both agencies expressed positive interest to expand the collaboration. Agreements are under completion.

In Q4 of 2015, EATRIS started working as lead representative on a concept for a personalized medicine innovation fund in 2016. EATRIS-C&S and EATRIS Patient Advisory Committee (PAC) met in May 2015 for a kick-off meeting. The EATRIS-PAC is organized under the patronage of EQAM. The Patients Network for Medical Research and Innovation can improve and accelerate outcomes of clinical trials and research projects. During the meeting the collaborative framework was defined together with the scope of activities and strategic projects the EATRIS-PAC will undertake. In addition to developing long-term operational plans, EATRIS is focusing in the translational research process. EATRIS sees research-based solutions for technical bottlenecks. Such initiatives are an integral part of the translational research process. Further descriptions of the various initiatives undertaken by EATRIS are described within the platforms section.
<table>
<thead>
<tr>
<th>Projects</th>
<th>Funding Programme</th>
<th>Start/End Year</th>
<th>Coordinator</th>
<th>Main topic of activities</th>
<th>EATRIS main role</th>
<th>EATRIS institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>HI-THREE</td>
<td>FP7</td>
<td>2013-2016</td>
<td>Istituto Superiore di Sanita (Italy)</td>
<td>Viruses, virology, virology</td>
<td>EATRIS participation in Wp2 (networking with other groups)</td>
<td>Medical University of Vienna, Austria, Karolinska Institutet, Sweden</td>
</tr>
<tr>
<td>HELIX</td>
<td>FP7</td>
<td>2013-2016</td>
<td>Helmholtz Centre for Infection Research (Germany)*</td>
<td>Biomechanics, systems biology</td>
<td>EATRIS participation in Wp2 (networking with other groups)</td>
<td>Elevated Health, The Netherlands</td>
</tr>
<tr>
<td>NN-TRAIN</td>
<td>FZK</td>
<td>2013-2016</td>
<td>Biomedical Primate Research Centre (Netherlands)</td>
<td>Medical sciences</td>
<td>EATRIS participation in Wp8 (accelerating innovation)</td>
<td>Primate Centre Brussels, Institute for Primate Research, Belgium, Karolinska Institutet, Sweden</td>
</tr>
<tr>
<td>eUIPreD</td>
<td>FP7</td>
<td>2013-2016</td>
<td>Istituto Superiore di Sanita (Italy)</td>
<td>Immunology &amp; immunochemistry</td>
<td>EATRIS participation in Wp5 (continuing access to essential technologies)</td>
<td>Istituto Superiore di Sanita (Italy), Karolinska Institutet, Sweden</td>
</tr>
</tbody>
</table>

C-COMEND is a two-year European training project supported by EATRIS and supported by the Erasmus plus funding programme. C-COMEND Compe- lency-based course on Translational Research and Medicines Development for PhDs and Post-docs. The project aims to develop an e-learning module and a face-to-face course in medicines development for PhD students and Post-docs, with the help of four other partners.

For more information on this particular project, please read page 31.
Since September 2015, EATRIS is participating in the 4-year CORBEL project (Coordinated Research Infrastructures Building Enduring Life-Science Services), supported by the Research Infrastructures Work Programme of Horizon 2020. CORBEL will establish a collaborative and sustained framework of shared services between the ESFRI Biological and Medical Sciences Research Infrastructures (MS RIs). This aims to transform biomedical research in Europe - from the discovery of basic biological mechanisms to applied medical translation – through the provisioning of harmonised services, including:

• Accession processes;
• Unified ethical and legal support;
• Joint data management; and
• Coordinated user access to advanced research instruments, facilities and samples.

EATRIS is the leader of the WP8 “Accelerating Innovation”. The aim of this WP is to support effective innovation from the MS RIs by facilitating and simplifying interaction and collaboration between RIs and industry. To achieve this goal, the WP will provide easy access to a shared and semi-centralised “Innovation Support Office”, managed by the EATRIS team, which will offer real-time legal support and partnering advice to RIs, as well as an online expertise centre providing access to essential tools and resources for collaboration, such as guidelines on Intellectual Property Rights, Open Innovation and legal templates.

EATRIS and the other WP partners will be responsible for creating and disseminating legal templates, which are key in the collaboration process (for instance material transfer agreements, collaboration agreements and confidential disclosure agreements). Additional WP tasks include the organisation of three workshops dedicated to industry-academia collaboration and the dissemination of an operational concept for joint MS RIs Expert Centres.

For more information, please visit CORBEL’s website: www.corbel-project.eu

This project receives funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 654248.

5. EDUCATION & TRAINING

Education and training activities are strongly aligned with other EATRIS activities with a special focus on:

• Supporting marketing & communication in creating an external awareness of EATRIS;
• Supporting platform initiated activities regarding cohesion, harmonisation, exchange of best practices, and development activities.

Activities & Results

Projects:

- Since November 2015, EATRIS has coordinated the C-COMEND project, which will develop and deliver face-to-face and e-learning training on translational research and medicine development for PhDs and early postdocs (see page 31). EATRIS is also contributing to the project RI-TRAIN on the training of management staff of research infrastructures.

Service activities:

- EATRIS was contracted by the Ri.MED foundation to design and deliver a workshop on ATMP development in Palermo, Sicily in November 2015 (see page 20).

Platform activities:

- ATMP: EATRIS & ISS organised an introductory course on “Regulatory Aspects of ATMP Development” under the scientific direction of Maria Cristina Galli (ISS) (see page 20).

imaging & tracking:

- An outline for an introductory e-learning package on PET imaging to support decision making in medicine discovery & development was initiated with the EATRIS Platform chair and co-chair.

Bioremain: An educational session on “Bioremain: development and biomarkers as tools in ATMP development” was incorporated in the ATMP course in Palermo.

Vaccine: Contribution to Roadmap on Education & Training of the PRIDE project. Small molecules: A Marie-Curie ITN on nanomedicines was prepared for submission in January 2016.

The first episode of the “Translational Thinking Quiz” was published in 2015. Joan Jordan, a blogger for the Multiple Sclerosis Society of Ireland and EUPATI trainee, was our first lucky winner of a €100 gift voucher.

EATRIS ANNUAL REPORT 2015

EATRIS ANNUAL REPORT 2015

EATRIS ANNUAL REPORT 2015

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6. FINANCIAL SUMMARY

Result financial year and analysis of balance sheet

The figures in this chapter are derived from the audited financial statements 2015 of EATRIS ERIC, accompanied by the auditor’s report dated March 31, 2016.

Developments in income and expenses result

Contribution and projects incomes increased compared to the previous year, as well as the operating expenses. As in previous years, EATRIS’ operational costs stayed within agreed budget limits. Resource allocation was in line with the budget approved by the Board of Governors. In accordance with the Board’s decision, the negative operating result is covered by the reserves of EATRIS.

Amounts in EURO’s 2015 Budget 2015 2014 Analysis

Contributions income 1,578,052 1,839,741 1,300,000
Subsidy income IPROVE and EURIPRED 147,014 50,000 30,628
Total income 1,725,066 1,889,741 1,330,628
Salaries and wages 808,155 765,300 698,639
Sub-total staff 239,374 474,660 257,612
Depreciation 7,112 - 7,391
Other expenses 769,586 649,781 672,261
Total expenses 1,824,227 1,889,741 1,635,903
Total operating result - 99,161 - 305,275

The figures in this chapter are derived from the audited financial statements 2015 of EATRIS ERIC, accompanied by the auditor’s report dated March 31, 2016.

Development in income and expenses

2015 2014 Analysis

Tangible fixed assets 16 23 The book value of the tangible fixed assets decreased as a result of the depreciation of prior years acquired assets.
Current receivables 192 462 The decrease is due to receipt in 2015 of two outstanding contributions at year-end 2014. This year only one contribution receivable was outstanding at year end.
Cash at banks 1,231 614 The increase is caused by the decrease in current receivables, increase in contribution and subsidy income.
Equity & Liabilities

Reserves 794 1,174 The reserve was adjusted, with €75K less contributed from the Foundation into EATRIS in 2014. The operating result was negative €305K.
Current liabilities 306 257 This increase was primarily caused by the wage tax of €41K, as personnel are now employed by EATRIS-ERIC per 2014.

Financial year & Analysis of the Balance Sheet

<table>
<thead>
<tr>
<th>Items</th>
<th>2015</th>
<th>2014</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tangible fixed assets</td>
<td>16</td>
<td>23</td>
<td>The book value of the tangible fixed assets decreased as a result of the depreciation of prior years acquired assets.</td>
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</tr>
<tr>
<td>Current liabilities</td>
<td>306</td>
<td>257</td>
<td>This increase was primarily caused by the wage tax of €41K, as personnel are now employed by EATRIS-ERIC per 2014.</td>
</tr>
</tbody>
</table>
In May 2015, EATRIS held its second conference, entitled ‘Building Bridges in Translational Medicine’. This two-day conference, attended by approx. 250 stakeholders and key opinion leaders in the field of translational medicine, focused on how to access and mobilise the proper expertise in such a way that mitigates project risk and optimises translation and drug development.

The ‘Building Bridges in Translational Medicine’ conference examined how to reduce risk in projects through effective collaboration with industry, while leading industry experts shared viewpoints on industry-academia collaboration in public-private partnerships. National funding agencies and charities discussed resources and opportunities to optimise their portfolios and increase R&D productivity.

The conference was the occasion to bring together world’s leading minds in the field of translational medicine including: Dr. Christopher P. Austin, Director NIH-NCATS (USA); Prof. Dr. Graziella Pellegrini, Head of Cell Therapy Program, University of Modena e Reggio Emilia (Italy); and Dr. Gregorio Aversa - Senior Vice President, Drug Development, Centre for Drug Research and Development (Canada).