

ANNUAL

REPORT

2014



EATRIS



European Infrastructure for
Translational Medicine

WWW.EATRIS.EU

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ACRONYMS

ADC	Antibody-Drug Conjugate
ATMP	Advanced Therapy Medicinal Products
BBMRI-ERIC	Biobanking and BioMolecular Resources Research Infrastructure
BMS RI	Biological and Medical Research Institutes
CDRD	Canadian Centre for Drug Research and Development
CBG-MEB	Netherlands Medicines Evaluation Board
CORBEL	Coordinated Research Infrastructure Building Enduring Life-Science Services
CVI	Central Veterinary Institute
EANM	European Association of Nuclear Medicine
EARL	EANM Research Ltd.
EATRIS	European Infrastructure for Translational Medicine
EATRIS-C&S	EATRIS Coordination and Support Office
EC	European Commission
ECRIN	European Clinical Research Infrastructure Network
EDRN	Early Detection Research Network
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EMBL	European Molecular Biology Laboratory
ERIC	European Research Infrastructure Consortium
ESFRI	The European Strategy Forum for Research Infrastructures
ETPN	European Technology Platform Nanomedicine
EURIPRED	European Infrastructure for Poverty-Related Diseases
EVI	European Vaccines Initiative
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
HTS	High-Throughput Screening
IMPD	Investigational Medicinal Product Dossier
IMTM	The Institute of Molecular Translational Medicine
IPROVE	Innovation Partnership for a Roadmap on Vaccines in Europe
MoU	Memorandum of Understanding
NIH-NCATS	US National Institutes of Health National Center for the Advancement of Translational Sciences
mAbs	Monoclonal Antibodies
NCI-US	The U.S National Cancer Institute
PAC	Patient Advisory Committee
PET	Positron Emission Tomography
PHC	Personalising Health and Care
RD	Rare Diseases
RI	Research Infrastructure
RIGHT	Research Infrastructure for Global Health and Treatments
RI-TRAIN	Research Infrastructure Training Programme
SMEs	Small and medium-sized enterprises
SOP	Standard Operation Procedure
SSI	Statens Serum Institute
SVA	The Sclavo Vaccines Association
TIA	Therapeutic Innovation Australia
TTO	Technology Transfer Office
UHF-MRI	Ultra High-Field MRI
VE	Vaccines Europe
WP	Work Packages
ZonMw	The Netherlands Organisation for Health Research & Development



1. FOREWORD



FOREWORD: SCIENTIFIC DIRECTOR



Giovanni Migliaccio, PhD

In 2014, we also explored and tested the needs and demands of our user/client groups. Throughout the year EATRIS assessed best practices for presenting and discussing policy, methodology, and technical requirements for each group. Requests and needs from charities and national funding agencies vary significantly from those of pharmaceutical companies and small and medium-sized enterprises (SMEs). As such, specific services and supporting materials were developed and tested to respond to these different requirements.

In light of these developments, we are looking forward to another promising year in 2015.

Dear Reader,

As the Scientific Director of EATRIS-ERIC, I want to warmly welcome you to the 2014 Annual Report. It has been another exciting year, in which we have validated our core processes and services.

The operational procedures granting access to the services of the EATRIS infrastructure have proven to be effective and transparent; a crucial step in our efforts and signalling our overall development towards a world-class research infrastructure.

To deal with the complexity of early-stage projects, additional scientific expertise was recruited in the areas of regulatory advice, Health Technology Assessments, and marketing authorisation – both from our own institutes and externally. With National Competent Authorities we continue to develop a network of supporting entities able to inform and sustain the regulatory choices for the future.

Sincerely,

Giovanni Migliaccio, PhD
Scientific Director, EATRIS

FOREWORD: CHAIR BOARD OF NATIONAL DIRECTORS



Marian Hajduch, MD, PhD

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 2014. In our first year of full-scale operations we achieved several important milestones in our growth, which are highlighted in this Annual Report.

The progress we have made in the past year towards realising our mission and vision gives us great confidence in the novel operating models that EATRIS has developed to serve the needs of our many stakeholders.

Our key accomplishments in 2014 include: the first public-private partnership initiated on the basis of our matchmaking role; the successful piloting of EATRIS-Inside with national and charity funders; facilitating client access to early-stage scientific advice from the Netherlands' Medicines Evaluation Board (CBG-MEB); and the initiation of a global collaboration with colleagues in the USA, Canada, and Australia. I invite you to peruse

this Annual Report to learn more about these and other varied activities undertaken this past year.

Following our work in 2014, we now have tangible evidence of the value that EATRIS adds to the complex realm of translational research. This gives us an extra stimulus and motivation to continue to dare to be different and seek real-world solutions to some of medical development's greatest challenges.

To this end, in 2015 we look forward to expanding our portfolio of exciting projects, and to continue developing the consortium as a world-class infrastructure serving the needs of the European Research Area.

Sincerely,

Marian Hajduch, MD, PhD
Chair, Board of National Directors



FOREWORD: CHAIR BOARD OF GOVERNORS



Maria Ferrantini, PhD

Dear Reader,

While Europe scores highly on the international publication lists in biomedical research, both in terms of output and impact, the translation of these research outcomes into innovation remains challenging. In parallel, the medicines and diagnostics development field is changing rapidly. Pharmaceutical companies are moving their investments downstream in the development pipeline, which exacerbates the gap between public and private funding.

Aside from the funding gap, we continue to see a misalignment between the requirements for scientific research by government and charity funders and the requirements set by regulators to deliver a complete dossier needed for product authorisation. Throughout 2014 EATRIS has worked to support clients to bridge these gaps and stimulate effective public-private collaboration. As a coherent effort in this field is both timely and needed, I am proud to be a part of the EATRIS family and what we have accomplished thus far.

In 2014, we turned our vision on translational medicine and the EATRIS mission into an operational strategy that makes the infrastructure available for users and clients. We focused on operations, and we actively supported principal investigators applying for calls by public and private funders. EATRIS, prior to selection, adds value by helping these academic researchers improve their project applications. We also assist with troubleshooting after selection rounds and during project execution. This year was also significant in that EATRIS also signed our first contracts for matchmaking and partnering with SMEs and pharmaceutical companies. Read more in Project Highlights on pages 14, 23, 37, and 40.

The EATRIS member states aim to build a successful, sustainable consortium. The establishment of EATRIS as a European Research Infrastructure Consortium (ERIC) in November 2013 was a key step in that direction. In 2014, we built on that key milestone in infrastructure development by:

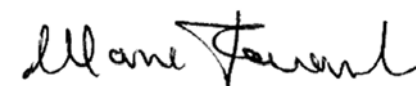
- Signing the EATRIS Framework Agreements, consolidating a consortium of 75+ academic institutions across Europe (ongoing);
- Approving the risk framework in order to better manage legal liabilities (April 2014);
- Accelerating the development of selected product platforms activities (ongoing);
- Formulating the marketing strategy (Q1 2014); and
- Holding the joint meeting of the Board of Governors and the Board of National Directors in November, which brought

government delegates and scientific leaders together to discuss scientific, strategic, and operational priorities. Based on preliminary results from 2014, key performance indicators for 2015 were discussed and approved by the Governors.

In 2014, the EATRIS operational model and services were validated by our clients, which means the focus of 2015 will remain on accelerating and scaling-up these operations. Additionally, we will strengthen collaboration with national scientific nodes and stimulate the utilisation of the infrastructure at the national level. Member States will continue to work together in 2015 to ensure growth and enable the use of the EATRIS infrastructure for European programmes.

As the Chair of the Board of Governors I am happy to present these results from 2014, and invite you to read more about our progress in this Annual Report.

Sincerely,



Maria Ferrantini, PhD
Chair Board of Governors

2. INTRODUCTION

2.1 About EATRIS



ABOUT EATRIS

Mission



To support researchers in developing their biomedical discoveries for novel preventive, diagnostic, or therapeutic products up to clinical proof of concept.

Vision



Making the translation of scientific discoveries into medical products more effective to improve human health and patients' quality of life.

Objectives



- Provide fast and professional access to academic services, such as facilities and expertise, and to help market these services.
- Develop long-term solutions to critical development challenges in the translational field through large-scale technical development projects and by engaging policy-makers, funders, regulators, and patient organisations.

The European Infrastructure for Translational Medicine (EATRIS), is a non-profit European Research Infrastructure Consortium (ERIC). EATRIS-ERIC's objective is to support clients involved in drug and diagnostics development by matching their needs with the unique services provided by top-level European academic research centres.

EATRIS focuses on supporting clients from industry and academia in advancing their medical discoveries, made in the laboratory or clinic, into novel products to be tested safely for the first time in humans and advanced to clinical proof of concept. In addition, EATRIS supports translational programmes initiated by governments and charity funders ('EATRIS-Inside'). The consortium is comprised of 75+ research institutions in eight European countries. Institutions are selected on the basis of their track record in public-private collaboration in drug development.

EATRIS centres are distinguished by their multidisciplinary teams of leading translational experts and their high-end research facilities, production laboratories, and licenses. Comprehensive support, services, and access to patient cohorts are provided in the fields of advanced therapy medicinal products, biomarkers, imaging and tracing, small molecules, and vaccines. By using standardised one-to-one contracting procedures between clients and EATRIS centres, lead times to start and execute projects are reduced to a minimum.

EXECUTIVE SUMMARY

Bridging Clinical Needs: Bench to Bedside & Bedside to Bench

EATRIS provides an effective development pathway – open to researchers, companies, funders, and charities – in need of support when advancing their biomedical translational innovations. EATRIS supports improving the development of high-potential medicines and diagnostics that meet patients' needs and positively impact their health outcomes.

We focus operations on two key activity areas:

- Functioning as a matchmaker for translational research capabilities by providing clients access to high-end academic infrastructure and expertise across Europe.
- Working on long-term solutions, operational and technical, to pressing bottlenecks in the translational research process.

2014 was another exciting year of growth, noteworthy for the validation of our operational model by successfully piloting select translational research services and infrastructure developments.

EATRIS-Inside

2014 marked the introduction and successful piloting of our EATRIS-Inside service in The Netherlands. EATRIS-Inside is a service for investigators, offered and paid for by public funders and charities, designed to improve the success rates of projects. As such, funding was provided by one public funder, ZonMw, and a Dutch rheumatology charity, Reumafonds.

The service was applied to 14 projects, representing approximately €15 million in research funding, and gives funders greater confidence in the translational feasibility of their shortlisted or already funded projects. Through EATRIS-Inside, we evaluate 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. This translational assessment helps identify potential gaps and bottlenecks that may arise during project execution.

Matchmaking

At the heart of EATRIS operations lies the matchmaking process. Any client's request for support can be matched to the specific capabilities and expertise of our 75+ EATRIS institutions. This simple and effective process allows EATRIS to serve clients quickly and professionally. In 2014, EATRIS facilitated its first public-private collaborations on the basis of our matchmaking model.

Infrastructure Development & Internationalisation

EATRIS and three other major translational health research organisations – US National Institutes of Health National Centre for the Advancement of Translational Sciences (NIH-NCATS), Therapeutic Innovation Australia (TIA), The Centre for Drug & Research Development (CDRD) in Canada – launched a global translational science collaboration in 2014. By signing a MoU these organisations seek to identify solutions to major bottlenecks in translational research, which will ultimately facilitate increased coordination on projects in 2015 and beyond.

Several other infrastructure development projects were initiated or continued in 2014, including the PET Zirconium-89 accreditation programme in collaboration with the European Association of Nuclear Medicine (EANM).

Legal & Regulatory Affairs

In 2014, EATRIS continued to ensure legal excellence in all areas of governance and operations, namely in the areas of:

- The legal entity - European Research Infrastructure Consortium (ERIC);
- Member States and governance;
- Operations – internal processes and Standard Operating Procedures (SOPs); and
- Contracting and collaboration – providing documentation for legal and financial processes.

The work of our Regulatory Knowledge & Support Centre continued, and in 2014 provided support to five Horizon 2020 projects and fourteen EATRIS-Inside projects. A collaboration with the European Clinical Research Infrastructure Network (ECRIN-ERIC) was initiated in 2014 to work together on the EATRIS database for European regulatory information.

Also in 2014, EATRIS began collaborating with CBG-MEB – The Netherlands drug evaluation agency – which granted our clients access to early-stage, informal advice from the agency. In the course of 2015, EATRIS will continue to expand this initiative to other countries' agencies.

Education & Training

Education & Training activities are strongly aligned with ongoing and planned activities across the organisation by supporting:

- Marketing & Communications in creating awareness;
- Product platforms harmonisation, exchange of best practices, and development activities; and
- EATRIS researchers by offering first-class services that contribute to overall quality assurance processes period

The Education & Training webpage now features seven courses relevant for product development that provide professionals with new skills and a knowledge base that can be transferred into the workplace.

Marketing & Communications

EATRIS reaches out to three client groups:

- Industry: both both SMEs and large pharmaceutical and biotechnology companies;
- Public funders and charities; and
- Academic researchers in biomedical sciences.

In the course of 2014, EATRIS stratified its marketing efforts. Marketing is now undertaken on the basis of unique technologies and/or expert capabilities, which are offered to specific user groups and clients based on their development needs.

Communications activities were focussed on supporting select marketing activities, including:

- Redesigning and launching the new website;
- Developing specific, product platform and technology service leaflets for clients;
- Focusing on communicating achievement-driven news via newsflashes; and
- Receiving initial coverage in key international media.

Patient Advisory Committee

A Letter of Intent was signed with the European patient organisation Patients Network for Medical Research and Health (EGAN) to establish the EATRIS Patient Advisory Committee (PAC). The EATRIS PAC will explore how patient outcomes can support our translational feasibility assessments. Collaboration on strategic projects is expected to begin in 2015.

Product Platforms

Our product platforms – Advanced Therapy Medicinal Products (ATMP); Biomarkers; Imaging & Tracing; Small Molecules; and Vaccines – are composed of academic and non-profit research institutions in biomedical translational research. All members exhibit well-established track records in:

- Entering clinical development;
- Hosting unique infrastructures;
- Expertise and licenses; and
- Access to a broad array of patient cohorts, including rare diseases.

Several new centres have joined EATRIS in 2014. Additionally, a new web-based reporting and maintenance tool was delivered for internal use and a system was put in place to assist with the managing team's overview of service capabilities in order to accelerate access and contracting.

By the end of the year, EATRIS was managing a total of 15 active projects and handling approximately 75 requests and contracts.

Financial

In the organisation's implementation phase (2011-2013), EATRIS functioned under the legal entity EATRIS Foundation (Stichting EATRIS). In this period, operational costs stayed substantially below agreed budgetary limits, enabling EATRIS to build up a comfortable level of financial reserves. According to the Transfer of Assets and Liabilities Agreement, all assets of EATRIS Foundation were transferred to EATRIS-ERIC per January 1, 2014. As in previous years, our 2014 operational costs stayed within agreed budgetary limits. All resource allocation was in line with budgets approved by the Board of Governors.



3. OPERATIONAL ACTIVITIES



OPERATIONAL ACTIVITIES



Anton Ussi, MSc
EATRIS Head of Operations

“In 2014, we successfully tested our novel operations model, with positive results in industry matchmaking and the use of EATRIS-Inside by funders and charities”

Core Process

EATRIS-ERIC's ('EATRIS') long-term goal is to improve the output of high-potential medicines and diagnostics that meet patients' needs and positively impact their health outcomes. This is operationalised by focusing on two areas of activity:

- Serving as a market-maker for academic translational research capabilities, and matching supply and demand in the European Research Area by providing access to high-end infrastructure and expertise;
- Developing long-term solutions to pressing bottlenecks in the translational research process, whether operational or technical.

Given that translational research is a multi-disciplinary, multi-stakeholder undertaking, each project requires access not only to technical expertise and infrastructure, but insight into to legal, intellectual property, regulatory, product development, and many other skill-sets. To simplify this, EATRIS

brings together access to these domains via its 'one-stop-shop' matchmaking process.

For public and charity research funders, we have also developed EATRIS-Inside. This initiative is designed to support funders with translational research portfolios. We support them by offering projects within their portfolio a translational assessment and potential use of the EATRIS infrastructure. This provides funders greater confidence in the aggregate value of the research being conducted, as explained in more detail below.

EATRIS-Inside

EATRIS-Inside is a service for investigators, offered and paid for by public funders and charities, to improve the success rates of projects. It provides funders with greater confidence in the translational feasibility of all shortlisted projects or already funded projects.

Through EATRIS-Inside, we evaluate the translational feasibility of projects on available non-scientific elements, such as

clinical need, intellectual property, regulatory pathway, and end-product definition. Furthermore, this translational assessment helps address potential gaps and bottlenecks that may be experienced during project execution.

Additionally, EATRIS offers non-binding advice on the best utilisation of high-end infrastructure and expertise. When appropriate, we also make recommendations regarding institutions that can provide additional expertise in translational medicine.

During the translational assessment, each project is gauged using the complementary background, knowledge, and experience of the EATRIS Coordination & Support Office (EATRIS C&S). These skills specifically pertain to: technology transfer; intellectual property; regulatory affairs; industry partnering; product development; and marketing.

EATRIS-Inside services include:

- Assessment of the translational strategy. This is conducted to ascertain whether the study goals, as defined in the proposal, can benefit from or be optimised through high-end academic infrastructure (e.g. molecular imaging, Good GMP-compliant tracer production, Ultra High-Field MRI capabilities, data analysis expertise), and when possible, give advice on GMP production and scale-up feasibility;
- Preliminary analysis of the intellectual property status. This is conducted in order to detect obvious issues concerning the protection of the invention;
- Assessment of the medical need and clear end-product definition. This is

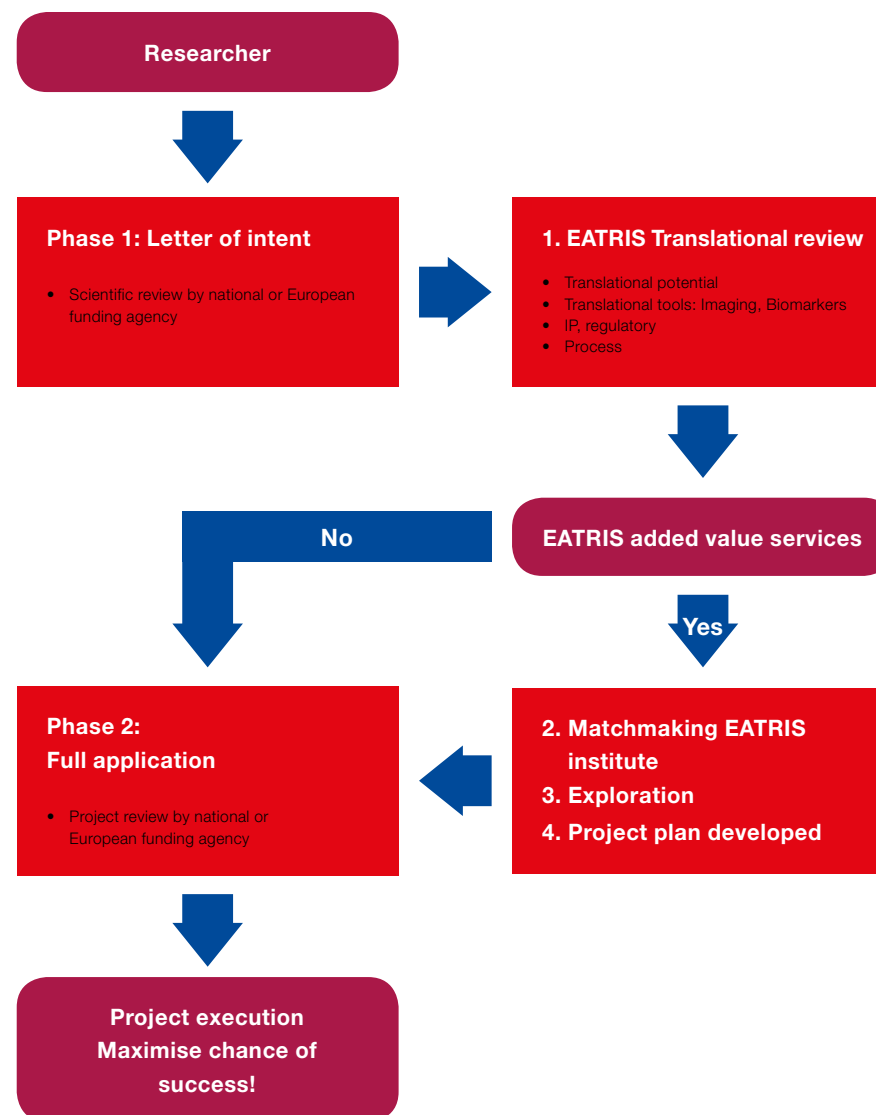
carried out in order to ascertain whether the proposal has a clear clinical goal, meaning that the proposed project sets out to serve a defined patient population who have a real, unmet medical need; and

- Preliminary analysis of the regulatory pathway. This serves to identify obvious potential conflicts with regulatory requirements for authorising a new product.

In 2014, EATRIS developed and piloted EATRIS-Inside through an agreement with ZonMw, a funding agency from The Netherlands. The pilot was carried out for the 2-TREAT programme, which after generating much success, was extended to ZonMw's MEMORABEL programme. For more information on these ZonMw projects, see page 14.

EATRIS also collaborated with Reumafonds – a charity dedicated to rheumatoid disease research in The Netherlands – in 2014. After a successful pilot project, EATRIS and Reumafonds are currently negotiating a long-term, mater collaboration agreement to provide the charity with EATRIS-Inside services on a permanent basis.

EATRIS Inside



EATRIS 4 Step Matchmaking Procedure



Matchmaking

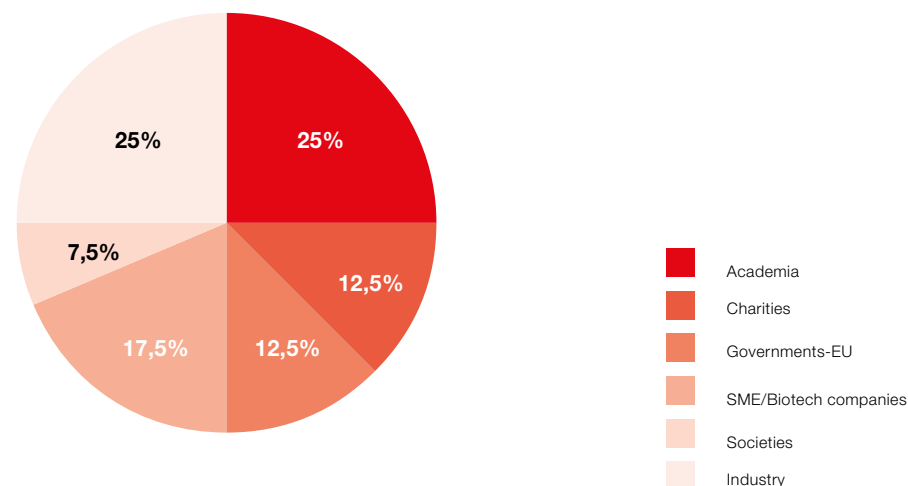
At the heart of the EATRIS operations lies the Through this service, we match clients' needs to the specific capabilities and expertise of our 75+ EATRIS institutions. This process is supported by our sophisticated and detailed database outlining our institutional capabilities, which facilitates objective yet speedy matches. Our approach to matchmaking entails a four-step procedure, which is outlined in the graphic to the left.

This simple yet effective process allows EATRIS to serve clients quickly and professionally, thereby increasing the utilisation of strategic European infrastructures and facilitating public-private partnerships.

The EATRIS operational model – in which a large consortium operates under harmonised conditions and a framework agreement – offers clients the same reach of a consortium, but with the safety and effectiveness of a bilateral relationship. How? Following matchmaking, project agreements are signed between an EATRIS institution and the client, which eliminates 'consortium risk' whereby legal liabilities flow to parties that have no functional control over events.

EATRIS 2014 Matchmaking Activities

Client groups



Infrastructure Development

Along with providing clients cutting-edge services for the biomedical innovation pipeline, EATRIS also focuses a great deal of energy on improving the effectiveness of the pipeline itself. Translational research is extremely challenging, costly, and time-consuming. It is characterised by frequent bottlenecks, which can be classified as:

- **Technical challenges** – Examples: ATMP manufacturing, nanomedicine characterisation, predictive models for safety, and toxicity; and
- **Operational challenges** – Examples: effective industry collaboration, multi-site (clinical) studies, regulatory affairs, and biomarker validation.

EATRIS relies on its extensive scientific and industrial network to identify these bottlenecks, devise possible solutions, and seek the funding to develop them. This results in projects and initiatives that:

- Lead to research projects for EATRIS institutes;
- Result in new and better services; and
- Improve productivity of the overall innovation pipeline.

The specific infrastructure development activities undertaken in 2014 for each of our five platforms can be found in the Scientific Services section on pages 26-39.

HIGHLIGHT ZONMW PROJECTS: THE VALUE OF EATRIS



EATRIS-Inside's Translational Optimisation

In the summer of 2014, EATRIS and ZonMw jointly piloted EATRIS-Inside under the ZonMW 2-TREAT programme. EATRIS-Inside for 2-TREAT was designed to promote a new form of collaboration within the field of translational research.

EATRIS-Inside is an initiative designed to assist funders with research portfolios by supporting selected projects with translational assessment. This way funders can be more confident about the aggregate value of the research being conducted.

2-TREAT is a funding scheme for public-private partnerships between businesses and research institutes that aims to realise translational and/or early clinical research in the fields of Regenerative Medicine, Molecular Diagnostics, and Pharmacotherapy.

Applicants advancing to the full proposal stage were invited by ZonMW to contact EATRIS for assistance with translational optimisation of their proposal before submission for selection by ZonMw. All applicants took advantage of this service. Subsequently, we evaluated the translational feasibility of each project on the available non-scientific elements (i.e. intellectual

property, regulatory pathway, end-product definition, potential use of infrastructure services), and helped identify potential gaps and bottlenecks that may be experienced during project execution.

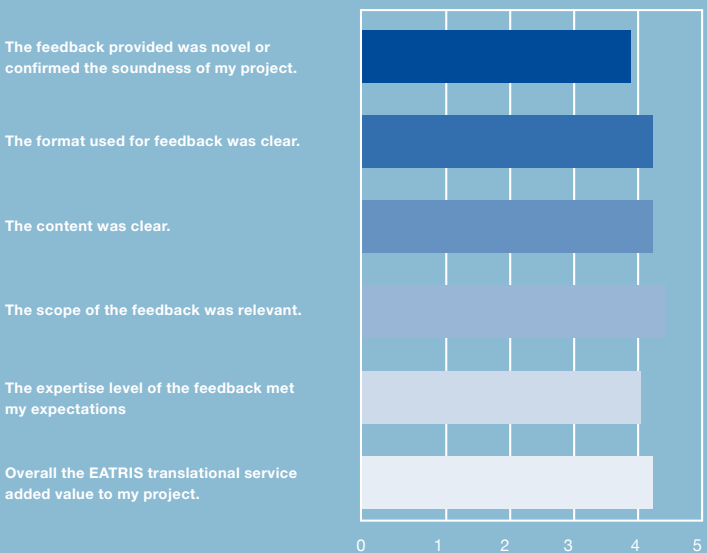
A feedback survey completed by five of the six 2-TREAT applicants indicated our translational assessment was very useful. Online survey responses indicated that the primary added value of this assessment pertained to the product development plan and regulatory affairs input. All five replied that they would use the EATRIS-Inside service again for future projects. For more on EATRIS-Inside, see page 11.

After the success of this first EATRIS-Inside project, ZonMw and EATRIS extended their collaboration to the MEMORABEL programme.

The MEMORABEL programme – part of the 'Deltaplan for Dementia' – focuses on dementia research, the improvement of health-care, and social innovation. This research is jointly funded by ZonMw and Alzheimer Netherlands. Within the MEMORABEL programme, 12 funded projects were invited by ZonMw to make use of our translational assessment services.

Of these 12 projects, 7 applicants contacted EATRIS. Even though most of the projects were discovery-focused medical research, the reports were well received. Preliminary feedback from the primary investigators clearly indicated the added value of our translational assessment. They emphasised that the strength of this process related to expertise and awareness-building in project planning and next translational phases. The feedback cited the need for strong collaboration agreements to adequately ensure an intellectual property strategy and our emphasis on goal-oriented, milestone-driven project management.

EATRIS-Inside ZonMw 2-TREAT Satisfaction Survey



INSTITUTIONS OVERVIEW

	Account Name	ATMP	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
Czech Republic	Brno Masaryk University					
	Central European Institute of Technologies (CEITEC)		●			
	Charles University Prague		●			
	Institut of microbiology of the AS CR, v.v.i					●
	Institute of Chemical Technologies Prague				●	
	Institute of Macromolecular Chemistry Prague (IMC ASCR)				●	
	Institute of Molecular and Translational Medicine (IMTM)		●	●	●	
	Institute of Organic Chemistry and Biochemistry, Czech Academy of Sciences				●	
	Nuclear Physics Institute of the ASCR/JUJF, v. v. i.			●		
	Århus University Hospital - Institut for Klinisk Medicin			●		
Denmark	Statens Serum Institute (SSI)					●
	The Hevesy Laboratory (DTU/Risø)			●		
	University of Copenhagen (UoC)			●		
Finland	Estonia: University of Tartu	●			●	
	Institute for Molecular Medicine Finland (FIMM)		●		●	
	Regea Cell and Tissue Center	●				
	University of Eastern Finland	●				
	University of Turku and Turku University Hospital		●	●		
France	VTT Technical Research Centre of Finland (VTT)		●			
	Neuratis-Albert Chevalier-Henri Mondor Hospital	●		●	●	
	Neuratis-Biotherapies Institute for Rare Diseases (BIRD)	●	●			
	Neuratis-Brain & Spine institute IHU-A-ICM		●	●	●	
	Neuratis-French Alternative Energies and Atomic Energy Commission (CEA)	●	●	●	●	
	Neuratis-Neurosciences Bicêtre - Paris Sud (NBPS)	●		●		
	Centro di Riferimento Oncologico di Aviano (CRO Aviano)	●	●			
	Centro Medicina Rigenerativa (CMR)	●				
	CNCCS - IRBM Science Park				●	
	Fondazione IRCCS CRIBT		●			
Italy	Fondazione IRCCS Fondazione Pascale	●	●	●	●	
	Fondazione IRCCS Giovanni Paolo II		●			
	Fondazione IRCCS Istituto Nazionale dei Tumori (INT-Milan)		●	●		
	Fondazione IRCCS Ospedale Pediatrico Bambino Gesù	●				
	Fondazione IRCCS SDN per la Ricerca e l'Alta Formazione in Diagnostica Nucleare			●		
	Italian Network for Molecular Imaging IMINET			●		

	Account Name	ATMP	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
Italy	ISMETT	●	●			●
	Istituti Fisioterapici Ospitalieri - Istituto Dermatologico "San Gallicano"					●
	Istituto Dermatopatico dell'Immacolata (IDI)	●				
	Mario Negri Institute				●	
	National Institute for Infectious Diseases Lazzaro Spallanzani		●			●
	Istituti Fisioterapici Ospitalieri - Regina Elena Tumor Research (IRE)	●			●	
	Rizzoli Orthopedic Institute (IOR)	●	●	●		
	Scientific Institute San Raffaele (HSR)	●		●		
	The Italian NIH (ISS)	●	●	●	●	●
	Academic Medical Centre (AMC)			●		
Netherlands	Biomedical Primate Research Centre (BPRC)					●
	Erasmus University Medical Centre			●		
	Intravacc					●
	Leiden University Medical Centre (LUMC)	●		●	●	●
	Maastricht University Medical Center (MUMC)			●		
	University Medical Center St Radboud (UMCN)	●	●	●		●
	University Medical Center Utrecht (UMCU)		●	●		
	University Medical Centre Groningen (UMCG)			●		
	University of Technology Eindhoven (TU/e)	●				
	VU Medical Center (Vumc)		●	●		
Spain	August Pi i Sunyer Biomedical Research institute (IDIBAPS)		●	●		
	Bellvitge Biomedical Research Institute (IDIBELL)	●	●			
	Fundacion Jimenez Diaz Institute for Medical Research (IIS-FJD)		●			
	Germans Trias i Pujol Foundation (IGTP)		●	●		
	Health Research Institute of Santiago de Compostela (IDIS)		●	●		
	Hospital de la Santa Creu i San Pau (IR-HSCSP)	●	●	●		
	Hospital La Fe (IIS-La Fe)	●	●	●		
	Hospital La Paz Institute for Health Research (IdiPAZ)	●	●			
	Institute of Biomedicine of Seville (IBIS)	●	●	●		●
	Instituto Ramón y Cajal (IRYCIS)		●			●
	University Hospital La Princesa (IIS-IP)	●	●	●		
	Vall d'Hebron Research Institute (VHIR)	●	●	●	●	
Total		27	33	33	16	12

COUNTRY OVERVIEW

CZ Czech Republic

Brno Masaryk University
Central European Institute of Technologies (CEITEC)
Charles University Prague
Institute of microbiology of the AS CR, v.v.i
Institute of Chemical Technologies Prague
Institute of Macromolecular Chemistry Prague (IMC ASCR)
Institute of Molecular and Translational Medicine (IMTM)
Institute of Organic Chemistry and Biochemistry,
Czech Academy of Sciences
Nuclear Physics Institute of the ASCR/UJF, v. v. i.

DK Denmark

Århus University Hospital - Institut for Klinisk Medicin
Statens Serum Institute (SSI)
The Hevesy Laboratory (DTU/Rise)
University of Copenhagen (UoC)

EE Estonia

University of Tartu

FI Finland

Institute for Molecular Medicine Finland (FIMM)
Regea Cell and Tissue Center
University of Eastern Finland
University of Turku and Turku University Hospital
VTT Technical Research Centre of Finland (VTT)

FR France

Neuratis-Albert Chevalier-Henri Mondor Hospital
Neuratis-Biotherapies Institute for Rare Diseases (BIRD)
Neuratis-Brain & Spine institute IHU-A-ICM
Neuratis-French Alternative Energies and Atomic
Energy Commission (CEA)
Neuratis-Neurosciences Bicêtre - Paris Sud (NBPS)

IT Italy

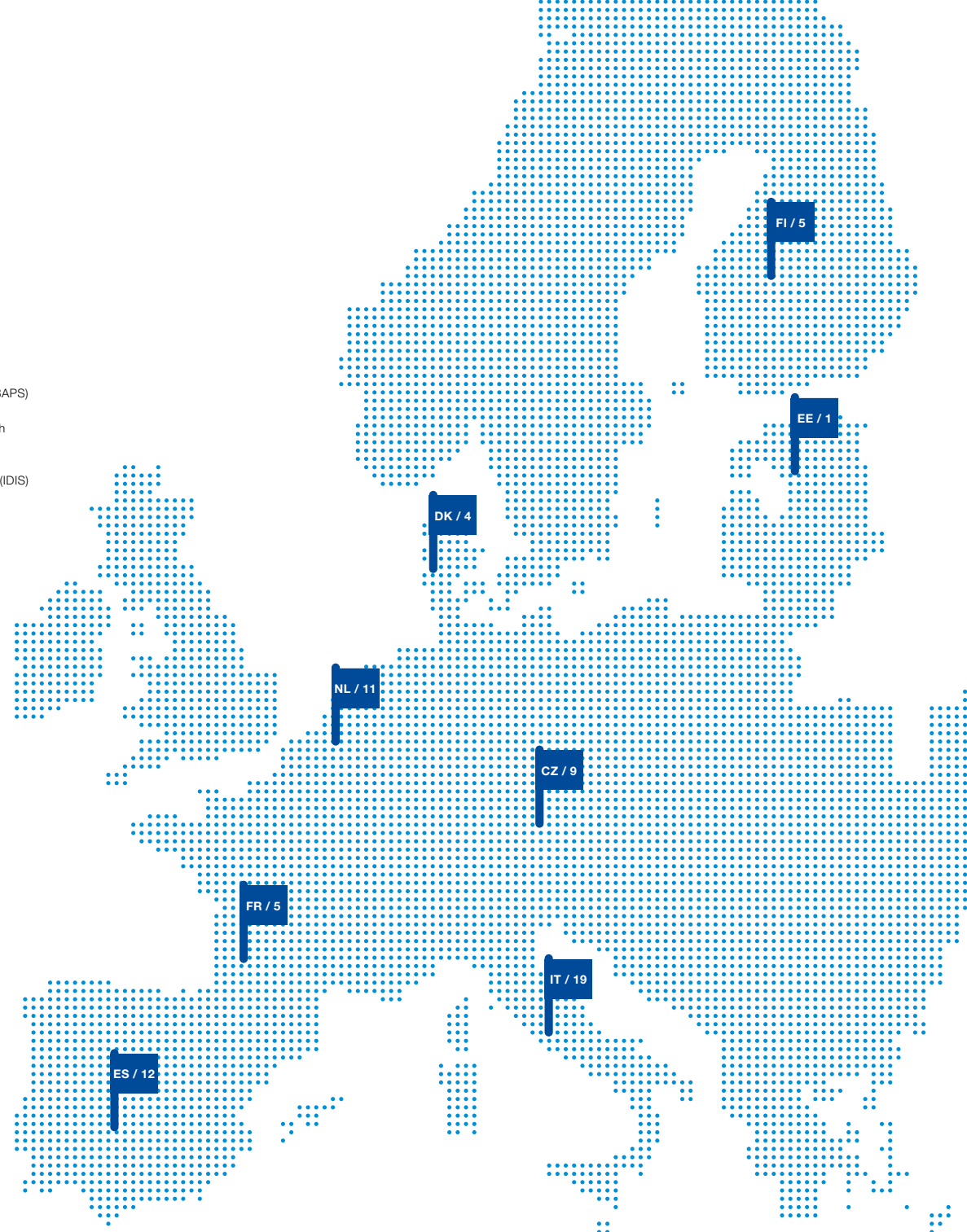
Centro di Riferimento Oncologico di Aviano (CRO Aviano)
Centro Medicina Rigenerativa (CMR)
CNCCS - IRBM Science Park
Fondazione IRCCS CRIBT
Fondazione IRCCS Fondazione Pascale
Fondazione IRCCS Giovanni Paolo II
Fondazione IRCCS Istituto Nazionale dei Tumori (INT-Milan)
Fondazione IRCCS Ospedale Pediatrico Bambino Gesù
Fondazione IRCCS SDN per la Ricerca e l'Alta Formazione
in Diagnostica Nucleare
Italian Network for Molecular Imaging (IMINET)
ISMETT
Istituti Fisioterapici Ospitalieri - Istituto Dermatologico
"San Gallicano"
Istituto Dermatologico dell'Immacolata (IDI)
Mario Negri Institute
National Institute for Infectious Diseases Lazzaro Spallanzani
Istituti Fisioterapici Ospitalieri - Regina Elena Tumor
Research (IRE)
Rizzoli Orthopedic Institute (IOR)
Scientific Institute San Raffaele (HSR)
The Italian NIH (ISS)

NL Netherlands

Academic Medical Centre (AMC)
Biomedical Primate Research Centre (BPRC)
Erasmus University Medical Centre
Intravacc
Leiden University Medical Centre (LUMC)
Maastricht University Medical Center (MUMC)
University Medical Center St Radboud (UMCN)
University Medical Center Utrecht (UMCU)
University Medical Centre Groningen (UMCG)
University of Technology Eindhoven (TU/e)
VU Medical Center (Vumc)

ES Spain

August Pi i Sunyer Biomedical Research institute (IDIBAPS)
Bellvitge Biomedical Research Institute (IDIBELL)
Fundacion Jimenez Diaz Institute for Medical Research
(IIS-FJD)
Germans Trias i Pujol Foundation (IGTP)
Health Research Institute of Santiago de Compostela (IDIS)
Hospital de la Santa Creu i San Pau (IR-HSCSP)
Hospital La Fe (IIS-La Fe)
Hospital La Paz Institute for Health Research (IdiPAZ)
Institute of Biomedicine of Seville (IBIS)
Instituto Ramón y Cajal (IRYCIS)
University Hospital La Princesa (IIS-IP)
Vall d'Hebron Research Institute (VHIR)



EATRIS COORDINATION & SUPPORT TEAM OVERVIEW



Giovanni Migliaccio, PhD
Scientific Director



Frank de Man, LL.M, PhD
Finance Director



Martin de Kort, PhD
Project Manager Imaging & Tracing and Small
Molecules



Anton Ussi, MSc
Head of Operations



Florence Bietrix, PhD
Project Manager Vaccines and Biomarkers



Oskar Uzun, LL.M
Legal Counsel



Rebecca Ludwig, PhD
Education & Training Manager



Apostolos Gkazepis, PhD, MBA
Project Manager ATMP



Anne-Charlotte Fauvel, MA
EU Coordinator



Josephine Sanders
Team Assistant



Petra van der Valk
Office Manager



Tim Moser, MSc, MBA
EATRIS Industry Partnering Specialist

SPOTLIGHT GLOBAL COLLABORATION

Global Collaboration Between European, Australian, American & Canadian Partners

EATRIS and three other major translational health research organisations – US National Institutes of Health National Centre for the Advancement of Translational Sciences (NIH-NCATS), Therapeutic Innovation Australia (TIA), The Centre for Drug & Research Development (CDRD) in Canada – launched a global collaboration in the field translational biomedical research in 2014. By signing a MoU these organisations seek to identify solutions to major bottlenecks in translational research, which will ultimately facilitate increased co-ordination on projects in 2015 and beyond.

Led by experts from each of the participating organisations, the initiative aims to drive research forward through a number of expert-led meetings. By identifying globally relevant issues, like those around the high rates of development failure and the reproducibility of data, the initiative will support a coherent approach that improves the output of novel drugs and diagnostics for patients and the wider public.

“By focusing on the major bottlenecks in the translational process, and having access to the expertise of these innovative organisations, we have an excellent opportunity to leverage each other’s strengths and resources in the battle to improve the output of new patient interventions”

Giovanni Migliaccio, PhD
EATRIS Scientific Director

The first expert meeting was hosted by NIH-NCATS December 9-10, 2014 in Bethesda, Maryland. Leading scientific representatives from all four partner organisations presented their organisations and reviewed some of their flagship initiatives. This meeting focused on four themes, namely: reproducibility, attrition rate, efficiency, and policy and funding.

Together we concluded that each organisation shares similar goals, faces similar bottlenecks, and tackles translational science with a common mindset. This promising start bodes well for our long-term collaboration in joint projects and international cooperation in the field of translational science.



THE THERAPEUTIC
INNOVATION
AUSTRALIA
QUEENSLAND



cdrd The Centre
for Drug Research
and Development
Transforming Discovery into Opportunity

5. LEGAL & REGULATORY



LEGAL & REGULATORY

Legal

EATRIS Legal is the starting point for ensuring our compliance with applicable governance and legislation, the management of our legal structure, providing legal advice to operations and scientific practice, providing legal templates, and supporting core process activities such as the administration of the contracts archive.

EATRIS Legal defines the blueprint for the EATRIS organisation and our activities, planning, and strategy by providing ongoing risk management and compliance with regulations.

EATRIS Legal work can be clustered in the following subject areas:

- The legal entity European Research Infrastructure Consortium (ERIC);
- Governance;
- Operations; and
- Contracting and collaboration.

Legal Entity EATRIS-ERIC

This area of work covers the legal status and the administration for the EATRIS legal entity and organisation. In November 2013, EATRIS became the first biomedical science infrastructure to receive European Research Infrastructure Consortium status, established by the European Commission. As of Q1 2014, EATRIS-ERIC became fully operational after the following actions were undertaken:

- The transfer of assets from EATRIS Foundation (Stichting EATRIS) to the EATRIS-ERIC legal entity was completed;
- In Q2 2014, all administration related to EATRIS-ERIC, such as accountancy, Chamber of Commerce registration, and so on, was completed; and

- Exchanges with The Netherlands and EC tax authorities – for confirmation of the tax exemption provided under ERIC status – were ongoing throughout 2014 and will extend into 2015.

Governance

Governance within EATRIS refers to the statutory Board structure and the interactions with our Member States, national nodes, affiliated institutions, and the European Commission (EC) and other governments. In 2014, we progressed in the following areas:

- Signing of the EATRIS Framework Agreements with EATRIS institutions reached 70% (+15% in 2014);
- EATRIS Tendering and Procurement Policy established in Q4 2014; and
- Development of EATRIS Confidentiality, Data and Privacy Policy initiated in Q2 2014.

Operations

EATRIS operations refers to our core activities, including interactions with clients and third parties, supporting the establishment of collaborations, and handling contracting between EATRIS institutions and clients. We have established procedures and contract templates to support the aforementioned tasks. In 2014, our operation finalised the following elements:

- Development of EATRIS support and services, which include: facilitating contract negotiations and signing between client and institution(s), fast-matchmaking for European framework consortium project applications, trouble shooting during project execution, and infrastructure development;

- Further implementation of the Legal Risk Management Framework, which manages legal liabilities during projects between clients and EATRIS institutions;
- Implemented workflow, archiving, and contracting SOPs; and
- Established an insurance policy for EATRIS C&S employees.

Contracting & Collaboration

Contracting and collaboration covers a wide spectrum of exchanges with various parties such as: letters of engagement with clients; contracting with EATRIS institutions; advisory contracts with funding bodies; and the establishment of strategic partnerships. Below is an overview of some of the established contracts and collaborations in 2014:

Completion and use of new contract templates, such as:

- Partnership agreements;
- Collaboration agreements;
- EC framework documentation;
- Consultancy agreements;
- Advisor agreements;
- Platform chair agreements; and
- Master Secrecy agreements.

Contracts signed for collaboration:

- The Netherlands funding agency ZonMw for a review of translational research projects (two contracts for 13 projects);
- European funding consortium agreements;
- Executive Committee of the European Association of Nuclear Medicine (EANM-EARL) partnership agreement;
- Rosetta Genomics collaboration;

- Roche EIN partnering agreement;
- Structural collaboration agreement with a large pharmaceutical company; and
- Ongoing discussions with other pharmaceutical companies and funding agencies.

EATRIS Regulatory

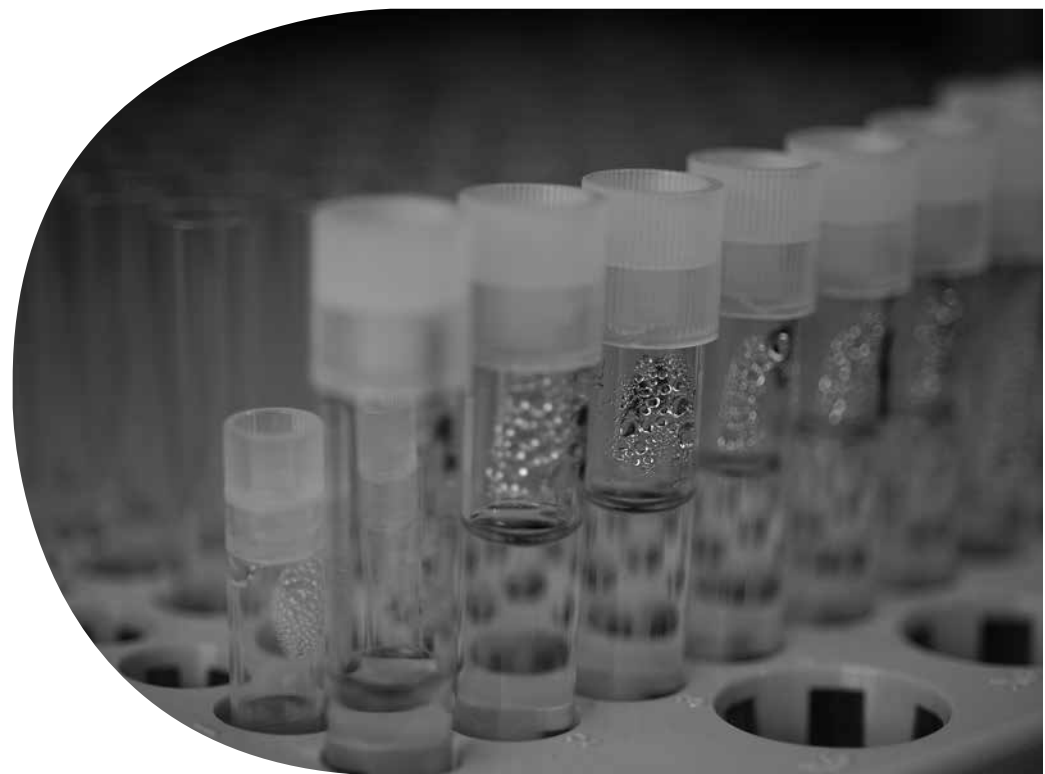
The EATRIS Regulatory Knowledge & Support Centre is a key component of our central offering to clients. Working in collaboration with current and former members of National Competent Authorities and the European Medicines Agency (EMA) – along with our regulatory experts residing within EATRIS institutions – we are able to offer clients the entire spectrum of regulatory support for new product development, as well as access to expertise in Health Technology Assessment and reimbursement.

Given that research decisions in the early development of new medicines can greatly impact their eligibility for later testing in humans, access to regulatory feedback and advice is essential at this stage.

In recognition of this, EATRIS has started working with National Competent Authorities to provide our clients with the possibility of engaging the relevant authorities in open dialogue about the regulatory requirements of their project.

In 2014, EATRIS signed a Memorandum of Understanding with The Netherlands Medicines Evaluation Board (CBG-MEB) for such a service. We will continue to expand this initiative to other countries.

In 2015, the focus of our Legal & Regulatory work aims to ensure ongoing compliance with applicable legislation, and the availability of thorough know-how and expertise on regulatory issues. We also aim to enable high-quality facilitation during EATRIS interactions with clients.



6. EDUCATION & TRAINING



EDUCATION & TRAINING

The Education & Training strategy is a crucial part of the EATRIS core process and is designed to allow the lasting transfer of new skills and knowledge into daily scientific activities.

Education & Training activities are strongly aligned with ongoing and planned activities across the organisation, supporting:

- Marketing & Communications operations in creating an external awareness of EATRIS;
- The product platforms regarding cohesion, harmonisation, exchange of best practices, and development activities; and
- EATRIS researchers in successfully executing development projects by offering first-class services and thereby contributing to the overall quality assurance process.

Activities & Results

This section of our website now features seven courses relevant for product development. They provide professionals with new skills and knowledge that can be transferred into the workplace.

These courses are open to all EATRIS partners, with associated course fees paid directly to the course provider. Four courses were offered by EATRIS partner institutes and three from external providers in 2014. For the external courses, EATRIS participants received a minimum 10% discount.

Throughout 2014 at least one training activity was performed in each platform:

Imaging & Tracing: A virtual training event, which aims to demonstrate the value of PET imaging in drug discovery and development, was integrated into two existing courses on drug discovery simulation and drug development simulation. Both courses have attracted professionals from SMEs and the pharmaceutical industry. By integrating PET imaging into this course, EATRIS not only raised awareness about the potential of PET imaging, but also positioned EATRIS as a potential provider of imaging services. Additionally, the platform performed an exchange of personnel to share best practices in GMP production. Read more about PET imaging on page 30).

Exome Sequencing	Analysis of Exome-Sequencing Data for Clinical Applications
Entrepreneurship	Problem-solving realising opportunities to maintain a competitive advantage
My Own Business	Creating a business plan
Biomarker Simulation	Biomarker development for test development to product marketing
Drug Discovery Simulation	Preclinical and clinical phases of drug development
Drug Development Simulation	Target identification, lead finding and development, candidate selection.
Master in ATMP manufacturing	Knowledge, skills, and hands-on technical expertise necessary to face the challenges of manufacturing ATMPs for clinical use

Vaccines: An Education & Training plan was developed for the H2020-TRANSVAC-2 proposal. Although the proposal was not selected, EATRIS plans to develop a two-day interactive training that enables participants to plan a regulatory strategy from the early phases of development. Participants will also prepare a well-organised Investigational Medicinal Product Dossier (IMPD) as part of the training.

Biomarkers: Education & Training was integrated into platform meetings activities in order to review and enrich projects using the combined expertise of the platform.

Small Molecules: This platform has been busy preparing a Marie-Curie ITN proposal submission for January 2015 and has been organising the exchange of personnel between EATRIS institutions.

ATMP: This platform started preparations for a training course on regulatory issues in ATMP development in 2014. Additionally, Education & Training activities have been included in the H2020 first-stage proposal (BIOEYE, H2020-PHC14 call) and preparations for a presentation for the PDA-ATMP meeting in Amsterdam in 2015 are underway.

To further raise awareness about the field of translational medicine, and better position EATRIS within this field, a 'Translational Thinking Quiz' was developed in 2014. The quiz will be published on the EATRIS website in 2015. The quiz is meant to stimulate participants, namely professionals and students interested in translational research, to think about and incorporate translational elements into their work.

In order to further extend the reach of training activities and training networks, EATRIS is currently preparing a strategic partnership with the Eureka Institute for Translational Medicine, a network of translational medicine professionals particularly dedicated to Education & Training with partners in Europe, North America, and Singapore.

The EATRIS Translational Thinking Quiz

Developed in 2014, Launching in 2015: The path from a promising lab discovery to its successful application in patients requires the integration of a range of in-depth expertise. Furthermore, this process requires awareness of the overall translational process and its potential pitfalls. With the 'Translational Thinking Quiz' we invite future participants to think along the development pipeline, even if it falls outside your core area of expertise.



HIGHLIGHT ROSETTA GENOMICS: EATRIS' FIRST PUBLIC-PRIVATE COLLABORATION



In 2014, EATRIS was successful in facilitating its first private-public collaboration. The partnership resulted from a partnering meeting with the diagnostic company Rosetta Genomics Ltd. at the BIO USA 2014 convention in San Diego, California. Rosetta Genomics Ltd. (NASDAQ: ROSG) is a leading developer and provider of microRNA-based molecular diagnostics.

After positive matchmaking with the Institute of Molecular Translational Medicine (IMTM) at Palacky University (Olomouc, Czech Republic), it took less than 6 weeks for EATRIS to facilitate a collaboration agreement between both parties.

“This partnership represents a good opportunity to work with distinguished partners on a high-value thyroid diagnostic. We have been pleased with our interactions with EATRIS and impressed with their smooth and efficient international collaboration process”.

Kenneth A. Berlin,
President and Chief Executive
Officer of Rosetta Genomics

“This collaboration with Rosetta Genomics is significant for IMTM and for the field of translational research. By utilising our translational expertise and clinical samples, in collaboration with Rosetta’s proven product development capabilities, we hope to expedite the development of a high-value thyroid cancer diagnostic. We are delighted to be a part of this novel way of working with industry through the EATRIS infrastructure”.

Prof. Marian Hajdуч, M.D.,
Director at the Institute of Molecular
Translational Medicine

7. MARKETING & COMMUNICATIONS



MARKETING & COMMUNICATIONS

We aim to make translational research more effective for clients with the ultimate goal of assuring better health outcomes for patients. EATRIS does not provide project funding; therefore, we offer core services to clients with funded projects or pre-selected, high-potential projects close to receiving funding.

Marketing

In the course of 2014, our marketing strategy was made more targeted and stratified:

- Each platform was stratified according to client group needs, meaning that not all platforms are marketed to all client groups. This is due to the fact that there is little demand for some platforms with certain stakeholders;
- Our marketing was increasingly targeted on the basis of unique technology and/or expertise offering. This ensures that specific services are offered to specific users on the basis of their needs. As such, a PET imaging technology service leaflet has been developed to describe how PET molecular imaging technology works as a pivotal technique in the rapidly expanding field of next generation monoclonal antibodies (mAbs) therapeutics. Related communications materials for all platforms will be completed in 2015. Read more about the PET imaging leaflet on page 30.

EATRIS reaches out to three primary client groups, namely:

- Industry, both SMEs and large pharmaceutical and biotechnology companies;
- Public funders and charities; and
- Academic researchers in biomedical sciences.

Academia, Public Funding & Charities

Academic researchers are primarily served through programmes and projects signed with research funders, governments, and charities. We support shortlisted principal investigators while the funder continues to use its existing selection procedure. EATRIS does not take part in the final selection process. Bringing EATRIS-Inside to such programmes and projects adds value to the funder's portfolio. The services are also available for troubleshooting during project execution. For more information on EATRIS-Inside, see page 11.

EATRIS-Inside was first piloted in the Netherlands and resulted in our first successfully signed contracts with two funding agencies from The Netherlands: ZonMw and The Netherlands Rheumatology Charity (Reumafonds). With our marketing model newly validated, in the coming years we will expand our collaboration with funders in other Member States and across the EU.

Industry

For industry, we organise public-private collaborations and matchmaking for:

- High-end infrastructure;
- Patient cohorts; and
- Clinical and other key translational medicine expertise.

SMEs are targeted through partnering activities with:

- BIO International Convention (USA) and BIO-Europe partnering events;
- National and European biotechnology associations;
- Technology Transfer Offices (TTO) within EATRIS institutions and others; and
- Venture capital firms.

With our Member States and the EC, we explored opportunities to utilise the EATRIS infrastructure to support SMEs and their participation in European funding programmes in 2014. Large pharmaceutical and biotechnology companies were approached primarily through our key opinion leaders and existing contacts. With the first contracts signed in 2014 – with Roche Expanding Innovation Network, Rosetta Genomics, and others – we expect to convert ongoing leads into more projects in 2015. We will also expand and accelerate business development activities.

Patient Advisory Committee

With a Letter of Intent signed in December 2013, EATRIS and the European Patients Network for Medical Research and Health (EGAN) started the formation of the EATRIS Patient Advisory Committee (PAC) in 2014. The EATRIS PAC will explore how patient involvement can support our translational potential assessment process and guide the strategic development of EATRIS. Further collaboration on projects is expected to begin in 2015.

Communications

Communications activities were focussed on supporting selected marketing activities targeted at specific client groups. In 2014, the following communications tasks were undertaken:

- Redesigning and launching the new EATRIS website;
- Developing specific product platform service leaflets for clients;
- Focusing on communicating achievement-driven news;
- Initiating and supporting preparations for the second EATRIS conference in May 2015;
- Contracting PR agency Rule 5 to assist with media and press relations; and
- Receiving initial coverage in key international media.



EATRIS International Media Coverage

8. SCIENTIFIC SERVICES

8.1 Product Platforms Overview



SCIENTIFIC SERVICES



“EATRIS scientists are focusing on the bottlenecks in translational medicine and the use of research infrastructure to solve them. This proactive attitude will help the infrastructure fulfill its mission in the coming years”

Giovanni Migliaccio, PhD
EATRIS Scientific Director

Product Platforms Overview

EATRIS is organised along five product platforms: Advanced Therapy Medicinal Products (ATMP); Biomarkers; Imaging & Tracing; Small Molecules; and Vaccines. Each platform offers a set of infrastructure services targeted at specific user/client groups, namely: industry; academia; charities and patient organisation; funders; and governments. In addition to our services, each platform also works on infrastructure development that makes use of collaboration and knowledge-sharing to overcome technical and operational bottlenecks in translational research.

The product platforms are composed of academic and non-profit research institutions in biomedical translational research. All members exhibit well-established track records in:

- Entering clinical development;
- Hosting unique, high-end infrastructure; and
- Clinical expertise with access to a broad array of patient cohorts, including rare diseases.

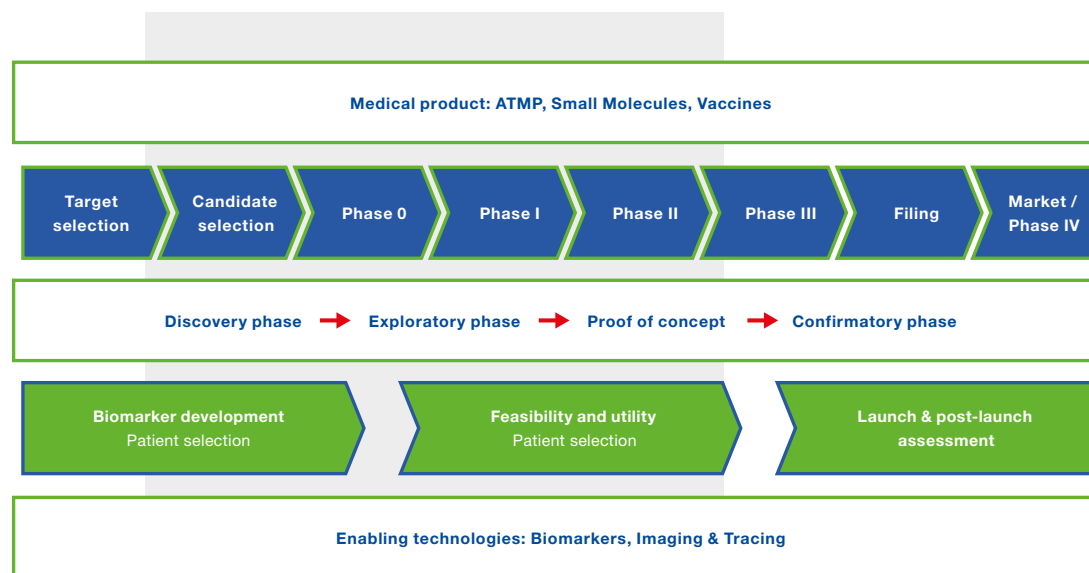
Members work to the highest quality, in accordance with all standards and certifications, in order to create a complete translational pipeline via a distributed infrastructure. Each of the EATRIS centres has signed legal framework agreements, which streamlines the process of time-consuming negotiations on IP and contract arrangements.

Our detailed capabilities database, developed in 2014, is one key element to quickly and objectively identify potential matchmaking partners with the skills and facilities needed to move any project into the next phase. This expertise is coupled with management experience to ensure the timely delivery of services.

In 2014, we welcomed several new members to EATRIS, all of whom enrich our overall service offering and each platform's capacity. Additionally, a new, web-based reporting and maintenance tool was put into place for internal use along with a system to assist the managing team's overview of service capabilities to accelerate access and contracting.

Throughout 2014 we worked to design and develop an expert database for legal, regulatory, and other advice, which we will continue to update and maintain in 2015 and beyond. Overall reporting was improved via meta-analyses and expertise documents created to showcase the capabilities of our institutions. Finally, internal communication and product platform cohesion was enhanced through the organisation of annual platform meetings. In the following product platform sections, our work in these area is elaborated further.

EATRIS Services



IMAGING & TRACING PLATFORM

Guus van Dongen, Chair
VU Medical Centre, The Netherlands

Martin de Kort
Product Platform Manager
EATRIS C&S, The Netherlands

Strategic Positioning & Client Groups

In 2014, the EATRIS Imaging & Tracing platform further developed its strategy to unlock access to high-end academic infrastructure and expertise and to address bottlenecks for imaging. Further development of the European-wide translational imaging infrastructure aims to play a key role in GMP manufacturing of radio pharmaceuticals, high-end (molecular) imaging facilities, regulatory and clinical expertise, and patient cohorts.

This platform is organised around three pillars:

- Positron Emission Tomography (PET) imaging of radio-labelled drugs;
- Tracers for *in vivo* translational molecular imaging; and
- Ultra high-field MRI to support drug development.

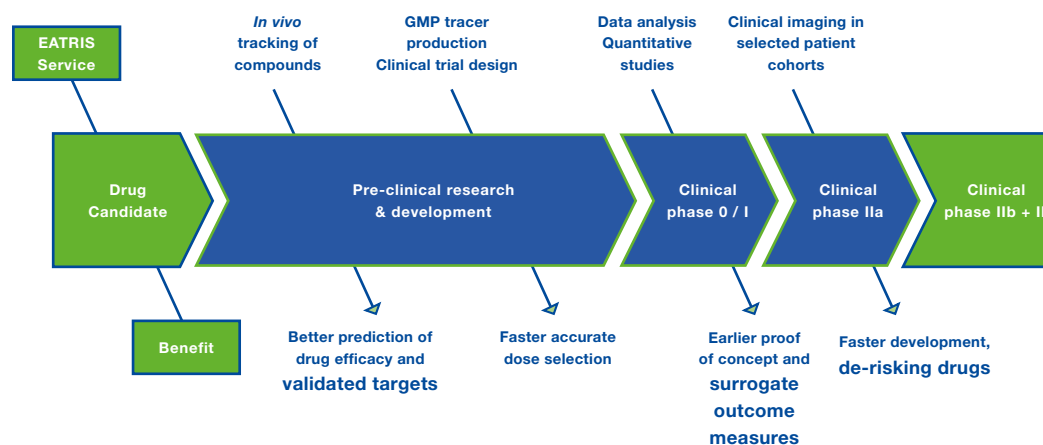
Throughout 2014, the Imaging & Tracing platform focused on optimising its use of capacity and expertise, along with setting quality standards and operating procedures for the field and GMP/GCP compliance, to further enable multicentre trials. We also focused on the harmonisation and standardisation of (PET) image acquisition and quantitative data analysis. Lastly, we prioritised sharing experiences and protocols such as Investigational Medicinal Product Dossier (IMPDs), GMP, and SOPs.

The Imaging & Tracing platform's most important clients are the pharmaceutical industry, where they have ample expertise but still require clinical imaging infrastructure for first-in-man studies. Furthermore, we target SMEs and pharmaceutical companies who require support when exploiting the maximum potential of imaging for their drug development. Charities and foundations benefit from our services and expertise, which maximise the outcome of their drug discovery research and development programmes.

Service Offering

The EATRIS Imaging & Tracing platform is an integrated European infrastructure of more than 30 institutes residing across The Netherlands, Finland, Spain, Italy, France, Denmark, and The Czech Republic.

EATRIS provides support in the following translational domains:



In summary, EATRIS Imaging & Tracing institutions offer:

- Access to high-end imaging capabilities and expertise, which range from pre-clinical imaging to clinical proof of concept studies;
- Novel tracers (^{11}C , ^{18}F) for novel and established targets for various therapeutic areas are available for advanced imaging studies compliant for human studies;
- Quantitative imaging studies to select the optimal dose/dose range for novel drug candidates;
- Studies to support the selection and stratification of patient populations and monitoring drug exposure, drug effects, and disease progression; and
- Dedicated PET imaging studies using 89-Zirconium labelled antibodies (immuno PET) that allow for the study of the

pharmacodynamics and kinetics of antibodies as well as the level of specific targeting.

A PET imaging technology leaflet was developed to describe how PET molecular imaging technology serves as a pivotal technique in the rapidly-expanding field of next generation monoclonal antibodies (mAbs) therapeutics development. Needing fewer subjects, more detailed information can be acquired about precise targeting, which can guide early decision-making and the selection of optimal drug profiles in a cost-effective manner. For more on the PET imaging technology leaflet and services, see page 30.

Infrastructure Development

In July 2014, EATRIS signed a collaboration agreement with EANM-EARL, the European umbrella organisation for nuclear medicine. Together EATRIS and EANM-EARL are working on strategies of harmonisation and standardisation of (multimodal) PET imaging in order to improve the quality and speed of transnational access to multicentre clinical trial activities.

EATRIS and EANM-EARL share the joint goals of advancing scientific initiatives and clinical research projects, and together we will work towards establishing an 89-Zirconium PET/CT accreditation programme. Dedicated PET imaging studies using 89-Zirconium labelled antibodies (immuno PET) allow for the study of the pharmacodynamics and kinetics of antibodies as well as the level of specific targeting.



On October 18-22, 2014 in Gothenburg, Sweden, EATRIS and EANM-EARL organised a joint symposium entitled, "EANM/EARL/ EATRIS: Joining Forces to Improve Quality within Translational Research and Clinical Practice". The session included presentations from Prof. Ronald Boellaard, Chair of the EARL FDG PET/CT accreditation programme.

Prof. Boellaard presented the latest results and developments of the EARL FDG PET/CT accreditation programme. In addition, industry partners (GE-Healthcare, Siemens, and Philips) expressed interest by presenting their support for development programmes. Read more about what the EATRIS and EARL collaboration undertook in 2014 in the PET Imaging spotlight on page 30.

Annual Meeting

The Imaging & Tracing platform held its annual meeting May 27, 2014 in Amsterdam, The Netherlands in order to make an inventory of the current state-of-the art high precision medical imaging capabilities that support drug development. Thirty-nine participants from 10 countries attended, which was a further testament to the expertise and capabilities of this platform.

Annual Meeting key discussion points:

- Initial costs related to operating Ultra High-Field MRI (UHF MRI) infrastructures like 7 Tesla were identified and are very high. However, the equipment's long lifespan justifies the business case for sharing this technique as a research service;
- UHF MRI is already contributing to our understanding of patho-physiological mechanisms (e.g. in brain disorders, oncology, and bone diseases), with further potential for applications to improve staging, biopsy targeting, and therapy response monitoring;
- The technique holds great potential to support drug development programmes by studying therapeutic effects on tissue pathology in great detail through images

with superior spatiotemporal resolution and enhanced signal to noise ratios; and

- EATRIS offers excellent integrated facilities accessible for third-party usage, with state-of-the art equipment ranging from pre-clinical 17.2 Tesla MRI to clinical 7 Tesla, and plans for the first ever 11.7 Tesla for precision medical imaging.



SPOTLIGHT PET IMAGING

In 2014, the EATRIS Imaging & Tracing platform has further developed its strategy to unlock access to high-end academic infrastructure and expertise, particularly around Positron Emission Tomography (PET) imaging of radio-labelled drugs.

European Collaborations in Nuclear Imaging

In July 2014, EATRIS signed a collaboration agreement with EANM-EARL, the European umbrella organisation for nuclear medicine. Together EATRIS and EANM-EARL are working on strategies of harmonisation and standardisation of (multimodal) PET imaging in order to improve the quality and speed of transnational access to multicentre clinical trial activities. Together we will work towards establishing a 89-Zirconium PET/CET accreditation programme.

Throughout the remainder of 2014, the EARL team has worked on the preparation and validation phases of the programme to develop the database and SOPs. Thus far the calibration of the PET/CT at 3 sites is within -5% and satisfactory SUV (specific uptake value) recoveries. This lies well within the anticipated margin of 10% and within acceptable bounds for the uncertainty of the ⁸⁹Zr measurements.

PET Technology Leaflet: Shedding Light in the Dark

Our marketing is increasingly targeted on the basis of unique technology and/or expertise offering. This ensures that specific services are offered to specific users on the basis of their needs. As such, a PET imaging technology service leaflet has been developed

to describe how PET molecular imaging technology works as a pivotal technique in the rapidly expanding field of next generation monoclonal antibodies (mAbs) therapeutics.

This PET imaging technology service leaflet highlights the current state of the field and how the Imaging & Tracing platform – through our high-end academic infrastructure and expertise – can support collaborative drug development programmes with pharmaceutical companies. By requiring fewer subjects, more detailed information can be acquired about precise targeting. This, in turn, can guide early decision making and the selection of optimal drug profiles in a cost-effective manner.

The brochure has proven to be a successful tool in creating both awareness of the power of PET imaging molecular imaging and in promoting public-private interactions with the EATRIS-ERIC consortium. Similar communications materials for all platforms will be developed in 2015.

EATRIS PET Virtual Training

EATRIS Education & Training also focused on PET in 2014. A virtual training event, which aims to demonstrate the value of PET imaging in drug discovery and development, was integrated into two existing EATRIS courses on drug discovery simulation and drug development simulation. Both courses have attracted professionals from SMEs and the pharmaceutical industry. They have also helped to profile EATRIS and the Imaging & Tracing platform externally.

EATRIS
European Alliance for Translational Research

PET IMAGING OF NEW DRUGS: SHEDDING LIGHT IN THE DARK

DECREASE RISK, IMPROVE INSIGHTS, INCREASE VALUE

In a relatively short period of time, monoclonal antibodies (mAbs) have entered the mainstream of targeted drug development, but the industry faces challenges in the development of more effective, safer, and cheaper drugs. PET imaging of radiolabelled biologicals like mAbs (e.g. ⁸⁹Zr-immuno-PET), mAb-like scaffolds, small molecules or other targeting vehicles is crucial for efficiently steering your new drug development programme with fewer subjects. Confirmation of precise targeting is key, especially because next generation mAbs like antibody-drug conjugates (ADCs), glyco-engineered mAbs, immune checkpoint inhibiting mAbs, immunocytokines and multi-specific mAbs are designed to be highly potent. PET imaging has now become an indispensable tool to support the development of next generation targeted drugs.

How can PET imaging guide your drug development programme?

- Assessment of target expression, modulation and internalization
- Assessment of drug pharmacokinetics and biodegradation
- Confirmation of selective disease targeting
- Assessment of uptake in normal organs to anticipate toxicity
- Selection of optimal drug candidate and therapeutic payload (e.g. for ADCs)
- Proof of concept studies for novel platform technologies
- Optimization of drug dose scheduling
- Optimization of combination therapy
- Early assessment of drug efficacy
- Assessment of inter-patient variability, patient selection
- Elucidating the distinguished properties of a drug: mechanism of action

"PET imaging studies allow accurate judgement of go/no-go decisions in preclinical drug development programmes, reducing risks and maximizing chances that investments return clinical and financial benefits"

"Imaging studies, when conducted by leading translational centres, fit with development timelines and can be conducted in a cost-effective manner"

ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP) PLATFORM

Filippo Belardelli, Chair
ISS, Italy

Maria Cristina Galli, Co-Chair
ISS, Italy

Apostolos Gkazepis
Product Platform Manager
EATRIS C&S, The Netherlands

Strategic Positioning & Client Groups

The long-term vision of the ATMP platform is to support clients from discovery to clinical proof of concept for novel ATMP. Offering the entire spectrum of high-end research infrastructures and patient cohorts, EATRIS ATMP is proud to be an official interested party at the Committee for Advanced Therapies of the EMA.

In 2014, EATRIS ATMP platform offered the most state-of-the-art technologies and clinical facilities to address critical issues in ATMP development in our focus areas:

- Specialised GMP facilities;
- Imaging facilities for *in vivo* animal studies;
- Availability of dedicated/tailored animal models;
- Access to patients for high-prevalence and/or rare diseases; and
- Clinical expertise to orchestrate and carry out research.

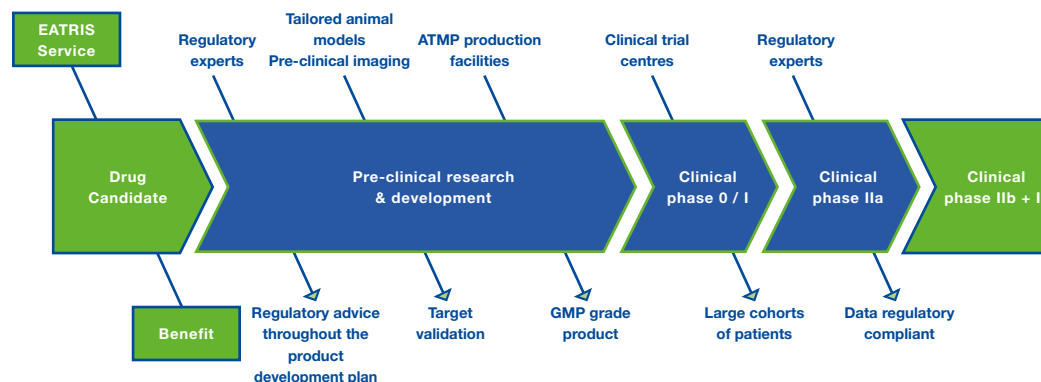
The platform includes a network of experts for regulatory affairs specialised in the ATMP field so as to ensure compliance with all pre-clinical and clinical development guidelines in Europe. Our services facilitate project

advancement in the shortest amount of time, and with the most efficient use of resources. The platform's primary client groups consist of academia and SMEs, because large pharmaceutical industries are not yet active in the field of ATMP development. We focused our efforts in 2014 on strengthening the regulatory support for ATMP development and our overall service offering.

Service Offering

The EATRIS ATMP centres demonstrate experience in the production and development of ATMP in the pre-clinical and clinical contexts. This platform is an integrated European infrastructure residing in 5 countries: The Netherlands; Finland; France; Estonia; and Italy. All facilities have the required on-site quality systems corresponding to the services offered, such as on-site QC/QA conforming with EU and EMA guidelines, and all clinical studies are performed in accordance with Good Clinical Practice (GCP).

EATRIS provides support in the following translational domains:



In summary, EATRIS ATMP institutions offer:

- Key opinion leaders in cell and gene therapy, as well as in tissue engineering, provide their expertise in disease-specific areas;
- Technical and regulatory expertise to guide clients throughout the development of ATMP;
- Target revalidation and pre-clinical development;
- GMP production of ATMP; and
- Clinical development.

Infrastructure Development

EATRIS ATMP Infrastructure development in 2014 can be summarised in five main points:

- **Initiation of a 'standardisation project' which aims to develop a benchmark or standard for comparability and scalability of an ATMP.** While ATMP hold great promise for personalised therapies and regenerative medicine, a lack of standardisation and

consolidated models hinders market access for new therapies. A solution to such bottlenecks requires strong public-private partnerships between key stakeholders, like academic infrastructures, pharmaceutical and medical device companies, regulators, and reimbursement agencies. In 2014, partners were approached and a concept paper was drafted outlining the main challenges to be addressed by this project. In 2015, the consortium will build on these activities.

- **Development of an introductory course on regulatory issues in ATMP development.** The course will highlight major regulatory differences between ATMP and classical drugs of a chemical nature or biological nature, as well as identify regulatory pathways applicable in the translational development of ATMP. The course has been planned in 2014 and will be delivered in Q3 2015.

- **Exploring synergies with the imaging and vaccines product platforms.**

A promising development in the field of ATMP is the use of imaging techniques for non-invasive follow-up of ATMP use in clinical settings. Together with imaging experts, the ATMP platform seeks to couple mature ATMP technologies with promising imaging cell tracking techniques. Interactions between the ATMP and Vaccines platforms also aimed to identify overlapping bottlenecks in regulatory and production aspects (e.g. therapeutic vaccines considered as ATMP from a regulatory point of view).

- **Identification and affiliation with new institutes that offer additional capabilities for the ATMP platform.**

In 2014, the Ospedale Pediatrico Bambino Gesù joined the platform.

Annual Meeting

The ATMP platform's annual meeting took place October 8, 2014 in Rome, Italy in order to prioritise challenges facing the ATMP platform development and to specify the ATMP service offering based on market feedback. Industry representatives also attended the meeting and were valuable participants in shaping the platform's priorities.

At this meeting, ATMP platform members agreed to develop a proposal on the 'standardisation of ATMP development' and to form a T-cell based gene therapy working group. This working group will identify systemic issues in the field to help further develop ATMP platform services. In regards to regulatory priorities, different aspects concerning the setup of educational courses on ATMP development, manufacturing, and regulation were defined.



SPOTLIGHT H2020 FUNDING PROPOSALS

In 2014, EATRIS was invited to participate in the preparation of multiple H2020 funding proposals under calls for both RIs and Personalising Health and Care (PHC). By the end of 2014, EATRIS had partnered in five RI proposals and three PHC proposals, of which two have been approved.

H2020 Research Infrastructures Work Programme

TRANSVAC2 (Call: H2020-INFRA-1A)

Lead partner: European Vaccine Initiative (EVI)
EATRIS Role: Partner
Status: Declined

The overall objective of TRANSVAC2 – European Vaccine Research & Development Infrastructure – is to support innovation for both prophylactic and therapeutic vaccine development based on a disease-overarching and one-health approach.

This approach would optimise the knowledge and expertise gained during the development of both human and animal vaccines. This would have been achieved by bridging the translational gap in biomedical research, and by supporting cooperation between public vaccine R&D institutions, related initiatives and networks in Europe, and industrial partners.

CORBEL (Call: H2020-INFRADEV-4)

Lead partner: European Molecular Biology Laboratory
EATRIS Role: Partner & WP leader
Duration: 4 years
Status: Expected to start September 2015

CORBEL – Coordinated Research Infrastructures Building Enduring Life-Science Services – aims to establish a collaborative and sustained framework of shared services between the European Strategy Forum for Research Infrastructures (ESFRI) and Biological and Medical RI (BMS RI). 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;
- Joint data management;
- Unified ethical and legal support; and
- Coordinated user access to advanced research instruments, facilities, and samples.

EATRIS applied to lead Work Package (WP) 8 “Accelerating Innovation”, the purpose of which was to provide access to real-time expertise in public-private collaborations by actively sharing best practices and developing innovative tools for all BMS RI.

RI-TRAIN (Call: H2020-INFRA-SUPP-3)

Lead partner: Biobanking and Bio-Molecular Resources Research Infrastructure (BBMRI-ERIC)
EATRIS Role: Partner
Duration: 4 years
Status: Expected to start September 2015

The RI-TRAIN – Research Infrastructures Training Programme – strives to identify competencies required for the professional management of European RI. Additionally, it works to design a training programme to fulfil these requirements.

Professionals already working in research infrastructures – like directors, project managers, HR heads, legal representatives, and communications experts – will be specifically targeted when developing training materials. In designing a flexible, modular programme, the project will also provide a new qualification aimed at future RI managers: the Master’s Degree in Research Infrastructure Management.

EATRIS proposed to contribute towards defining the competencies required by RIs at each phase of their lifecycle in WP 2. Furthermore, we committed to participating in WP 5, which targeted providing continuing professional development to the current generation of RI managers via staff exchanges and webinars.

RIGHT (Call: H2020-INFRA-SUPP-6)

Lead partner: European Clinical Research Infrastructure Network (ECRIN-ERIC)
 EATRIS Role: Partner & WP leader
 Status: Declined

RIGHT (Research Infrastructures for Global Health and Treatments) project was designed to foster international collaboration along the pipeline covering the three major steps of therapeutic innovation, namely: drug discovery (led by EU-OPENSOURCE); translational research (led by EATRIS); and clinical development (led by ECRIN), together with their international partners in Australia (Therapeutic Innovation, Australia) and in the USA (National Institutes of Health).

INNORARE (Call: H2020-INFRA-1A)

Lead Partner: Newcastle University
 EATRIS role: partner and WP leader
 Status: Declined

For more information, please read page 40.

Personalising Health and Care Work Programme

EATRIS was involved as a partner in three second-stage proposals:

- EURODIAL – PHC-01
 Lead Partner: Vall d'Hebron Research Institute (Spain)
 Status: Declined after second stage
- OncoMapDx - PHC-10
 Lead Partner: Stockholm University (Sweden)
 Status: Reserve list after second stage
- BioEye – PHC-14
 Lead Partner: Università degli studi di Modena e Reggio Emilia (Italy)
 Status: Evaluation ongoing

EATRIS also acted as a fast matchmaker in three PHC proposals. In this role, we helped to identify an EATRIS institution, which joined the proposal's consortium.

- CureWhim – PHC-14
 Lead Partner: Assistance Publique Hopitaux de Paris (France)
 Status: Evaluation ongoing
- Vision-DMD - PHC-14
 Lead Partner: Newcastle University (United Kingdom)
 Status: Evaluation ongoing
- Braingaze - PHC-12 (SME Instrument)
 Lead Partner: Braingaze (Spain)
 Status: Declined



BIOMARKERS PLATFORM

Olli Kallioniemi, Chair

FIMM, Finland

Florence Beatrix

Product Platform Manager

EATRIS C&S, The Netherlands

Strategic Positioning & Client Groups

The EATRIS Biomarkers platform's long-term mission strives to validate biomarker targets and assays for the clinic. As such, the Biomarkers platform focuses on: providing access to European biobanks and technology platforms and assay development know-how and clinical expertise.

In 2014, the platform continued defining building blocks for a biomarker validation and development platform in Europe that will support drug and diagnostics development. Furthermore, the platform built cohesion among partners within the EATRIS network and international players, such as the European Infrastructure for Biobanking (BBMRI) and The US National Cancer Institute (NCI-US).

Strategic clients for the Biomarkers platform include the pharmaceutical industry, mid-size pharmaceutical companies, and SMES. Additional contacts with SMEs and the pharmaceutical industry demonstrate a high level of demand for collaborations that facilitate access to high-quality, clinically annotated patient cohorts and materials.

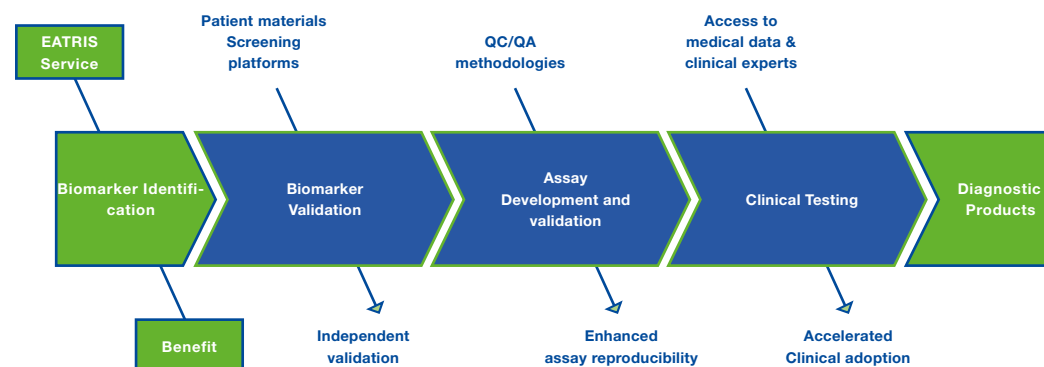
Service Offering

The EATRIS Biomarkers platform is an integrated European infrastructure of more than 30 institutes residing across The Netherlands, Finland, Spain, Italy, France, and The Czech Republic. All facilities have the required on-site quality systems corresponding to the services offered, such as on-site QC/QA conforming with EU and EMA guidelines, and all clinical studies are performed in accordance with Good Clinical Practice (GCP).

In summary, EATRIS Biomarkers institutions offer:

- Access to a wide variety of samples of tissues and bodily fluids;
- Support in key biomarker technologies such as molecular pathology, genomics, and immunoassays;
- Clinical expertise across a wide variety of diseases such as oncology, rare diseases, cardiovascular diseases, etc.;
- Access to multi-site clinical trials; and
- Access to multiple sites for the clinical validation of diagnostics.

EATRIS provides support in the following translational domains:



Infrastructure Development

In 2014, effort was placed on further exploring patient collections and access criteria, patient cohorts, and ongoing clinical trials within the EATRIS network. As a result, the EATRIS database was expanded to facilitate efficient matchmaking and easy collaboration. By the end of 2014, the EATRIS network consisted of 19 biobanks ready to deliver based on projects' needs for biological samples.

Special emphasis was placed on strengthening collaborations outside of the EU in order to further exchange expertise and learn about existing initiatives. In September 2014, EATRIS C&S participated in the Early Detection Research Network's (EDRN) annual workshop. The EDRN is an effective research and development funding initiative run by the National Cancer Institute (NCI) since 2000.

At this event, EATRIS C&S participated in a side-meeting organised by Dr. Sudhir Srivastava, Chief of Cancer Biomarkers

Research Group, to discuss opportunities for additional collaboration in 2015. A workshop with Dr. Sudhir Srivastava to discuss needs and opportunities for a detection network in Europe will take place October 2015 in Brussels with European cancer charities and other key opinion leaders in the field of oncology.

Annual Meeting

The Biomarkers platform annual meeting took place November 26-27, 2014 in Amsterdam, The Netherlands in order to refine services and technology offerings. The first aim of the meeting was to further define the services and technologies offered towards industry. Furthermore, by analysing case studies provided by EATRIS institutions, the platform used this opportunity to develop a strategy for reviewing biomarker development projects. In total, 16 EATRIS institutions were represented by 30 people.

VACCINES PLATFORM

Jan Langermans, Chair

BPRC, The Netherlands

Florence Bietrix

Product Platform Manager

EATRIS C&S, The Netherlands

Strategic Positioning & Client Groups

The long-term mission of the EATRIS Vaccines platform is to support the development of novel preventive and therapeutic vaccines up to clinical proof of concept. To this effect, the platform offers state-of-the-art resources including:

- Specialised GMP provision with accompanying formulation and adjuvantation;
- Disease-specific animal models with facilities up to BSL3 containment;
- Access to clinical facilities with relevant patient groups up to phase IIa trials; and
- Immunomonitoring.

In 2014, the platform strengthened its service offering and marketing of the platform by focusing its services towards SMEs involved in developing therapeutic and prophylactic vaccines. In order to identify the main gaps in the field, two SMEs – Curevac (Germany) and Bird-C (Austria) – were invited to the annual vaccines platform meeting (June 2014) to discuss their expectations, critical needs, and how the Vaccines platform might advance their product development.

Service Offering

The EATRIS Vaccines platform is an integrated European infrastructure of 11 institutes residing in four countries: The Netherlands; Spain; Italy; and The Czech Republic. Each vaccine development centre has broad

expertise in the production and development of vaccines in both pre-clinical and clinical contexts. These institutes, along with other EATRIS services, provide our clients with the management experience to ensure timely delivery of their high-end services.

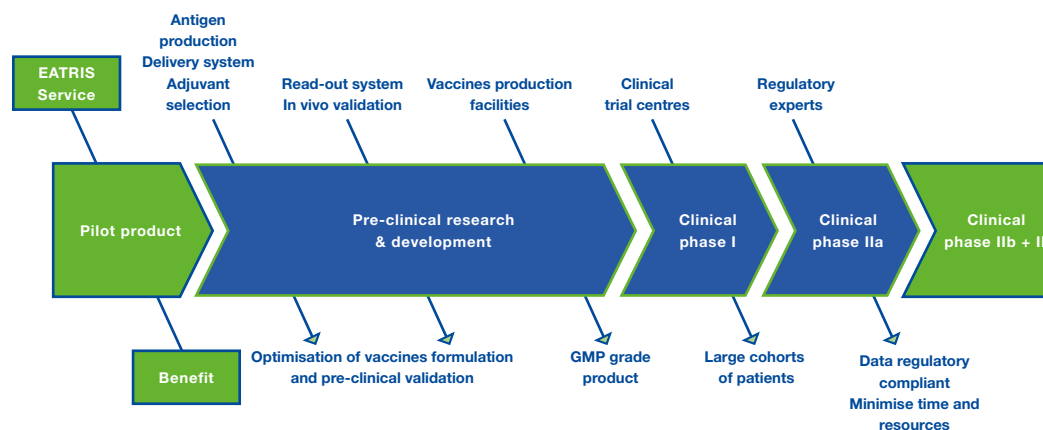
In summary, EATRIS Vaccines institutions offer:

- Antigen characterisation;
- Formulation and adjuvantation;
- Specialised GMP manufacturing facilities covering upstream and downstream process; formulation & adjuvantation;
- Animal facilities up to BSL3;
- Animal models including non-human primates and GLP-toxicology; and
- Immunomonitoring and clinical capacity.

Infrastructure Development

The Vaccines platform focused its 2014 activities on identifying and affiliating new institutes, fostering synergies, and implementing EU-funded projects. Key achievements from 2014 include:

EATRIS provides support in the following translational domains:



- The Statens Serum Institute (SSI, Denmark), a key institute in the vaccines field, was approached in 2014 for official participation to the platform.
- CVI (Central Veterinary Institute, The Netherlands) was invited to join the annual platform meeting to further explore interaction with the veterinary vaccines field and strengthen the knowledge of the platform.
- The platform has been involved in two FP7 funded projects EURIPRED (European Research Infrastructures for Poverty Related Diseases, grant agreement 312661) and IPROVE (Innovation Partnership for a Roadmap on Vaccines in Europe, grant agreement 602167), which we continued to deliver on in 2014.
- Cross-platform synergies were also identified and discussed in relation to biomarkers, imaging, and ATMP in the platform's annual meeting.

Annual Meeting

The annual platform meeting was held in Amsterdam, The Netherlands on June 16, 2014. Nine of the platform institutes attended and helped further define our interactions with industry and a strategic marketing approach targeted at SMEs.

Two regulatory experts – Maria Christina Galli (ISS, Italy) and Irena Babilonova (Masaryk University, Czech Republic) – contributed to a better understanding of regulatory constraints related to therapeutic and prophylactic vaccines. They also helped to define opportunities for cross-platform interaction with the EATRIS ATMP platform, such as the development of a regulatory training course on ATMP development. Additionally, interactions with the Biomarkers platform and Imaging & Tracing platforms were also identified and explored (e.g. personalised vaccines).

HIGHLIGHT IPROVE: THE FUTURE OF EUROPEAN VACCINOLOGY



The “Innovation Partnership for a Roadmap on Vaccines in Europe” (IPROVE) – financed under the EU 7th Framework Programme (FP7 grant agreement 602167) – aims to establish a clear vision for priority innovations and technologies needed to boost research in the field of European vaccines and vaccinology. Issues under advisement include SMEs and R&D vaccine development needs, training in vaccines and vaccinology, vaccines research infrastructures, and therapeutic vaccines. The project looks at the entire innovation chain – from discovery to delivery – including interventions necessary to improve education curricula and public health perception and awareness.

IPROVE is supported by four renowned European organisations working in the field of vaccines. They include:

- **Vaccines Europe (VE)** – a specialised group within the European Federation of Pharmaceutical Industries and Associations (EFPIA) representing all major research-based vaccine global companies and SMEs operating in Europe;
- **The European Vaccine Initiative (EVI)** – a leading European Product Development Partnership supporting the development of effective, accessible, and affordable vaccines against diseases of poverty;
- **The Sclavo Vaccines Association (SVA)** – a non-profit association whose

main objective is to promote vaccine research targeted towards the discovery and study of advanced immunisation technologies; and

- **EATRIS.**

For IPROVE, EATRIS leads Work Package 5, relating to IPROVE communications. Throughout 2014, EATRIS experts from consortium institutions contributed to a series of IPROVE workshops related to SMEs needs and Education & Training that will continue until the final IPROVE summit in November, 2015. EATRIS is responsible for the organisation of the final IPROVE summit together with the publication and dissemination of the final roadmap for this event. These activities are crucial for shaping strategic decisions regarding the priorities of future vaccine investment at the EU-level, as well as at the level of individual Member States.



SMALL MOLECULES PLATFORM

Mario Salmons, Chair

Mario Negri Institution, Italy

Martin de Kort, Product

Product Platform Manager

EATRIS C&S, The Netherlands

Strategic Positioning & Client Groups

The EATRIS Small Molecules platform's long-term vision aims to enhance efficiency in the clinical translation of novel chemical entities for clinical use. The platform supports this vision by providing access to cutting-edge technologies, access to patient materials, and pre-clinical and clinical expertise. The institutions' activities are driven by medical need (e.g. drug (re)purposing activities for rare diseases) and the platform continued to define its strategic focus in 2014. In order to support the academic development of small molecule drugs, the platform focuses on the following fields of expertise:

- Advanced drug screening in 3D cultures or primary cells;
- Generation of peptide drug candidates;
- ADME-tox profiling of small molecules; and
- Pre-clinical and clinical validation of nanomedicines and nanoformulations

Throughout 2014, the Small Molecules platform focused on enhanced target validation and clinical translation, ensuring quality, reproducibility, and the sharing of expertise in such as way as to foster collaboration. As part of the larger objective to link clinical facilities with patient information, our work also focused on securing broad access to clinical samples and patient cohorts including

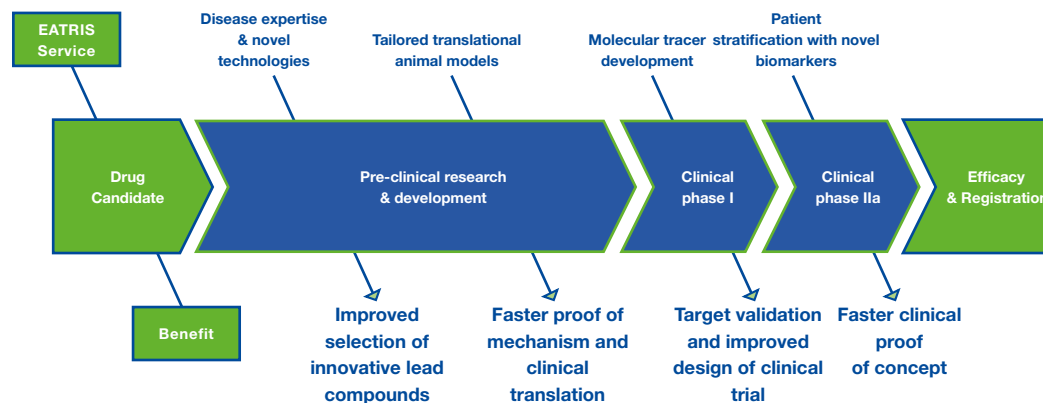
critical mass for rare disease studies. Furthermore, in 2014 cohesion was built among partners within the EATRIS consortium and with international players such as the European Technology Platform Nanomedicine (ETPN) and EU-OPENSREEN.

Client groups for the platform include academic institutions and SMEs seeking support from a translational infrastructure. This often takes the form of animal models, patient samples, and advanced screening (ADME, target validation). Charities and foundations benefit from our services and expertise that support their drug discovery research and development programmes.

Service Offering

The EATRIS Small Molecules platform is an integrated European infrastructure of more than 25 institutes residing across The Czech Republic, Italy, The Netherlands, Finland, Spain, and France.

EATRIS provides support in the following translational domains:



In summary, EATRIS Small Molecules institutions offer:

- Testing compounds in 3D spheroids for the selection of suitable tumour types, target validation, study of EPR effect for nanomedicines, hypoxia, and ADME screening;
- Supporting application filing to obtain orphan drug designation;
- Biomaterial/nanomaterial production, characterisation, and preclinical testing (e.g. bio-distribution assays);
- Characterisation and formulation of (polymer) nanoparticles for delivery of cytostatic agents;
- GMP peptide production and formulations; and
- Drug sensitivity and resistance testing in a High-Throughput Screening (HTS) setting using primary cells.

Infrastructure Development

The platform participated in the thematic EuroNanomed2 workshop in Düsseldorf, Germany, which focused on regulatory

affairs in nanomedicine. Potential synergies, complementary expertise, and overlap were explored between the European Technology Platform Nanomedicine (ETPN), the European Clinical Research Infrastructure Network (ECRIN), and EATRIS. When compared to ECRIN and EATRIS, ETPN focuses on an upstream approach that involves the (physico) chemical characterisation of nanoparticles.

Annual Meeting

The platform's annual meeting took place November 7, 2014. The meeting was hosted by the Vall d'Hebron Institution in Barcelona, Spain. In the spirit of true collaboration, 29 participants from eight countries joined together to discuss key strategic directions.

As such, several key points were identified for the future of the platform:

- Drug screening using 3D Spheroids was identified as a key service area;
- A focus on pre-clinical and clinical validation of nanomedicines in order to generate and unlock GLP/GMP capabilities in

- the production of nanomedicines;
- A focus on ensuring capacity and expertise in preclinical safety and efficacy testing of nanomedicines and first-in-man clinical testing;
- Drug repositioning (novel targets), drug rescuing (anti-shelving), and drug re-formulation (for novel dosing regimens, routes of administration or formulations) driven by medical need must be an important focus area;
- To continue collaborations with EU-OPENSOURCE regarding the transfer of hits for formulation and validation by *in vivo* efficacy profiling to support the INNORARE concept.



HIGHLIGHT INNORARE: RESEARCH INFRASTRUCTURES SUPPORT RARE DISEASES



Since August 2013, EATRIS and three Research Infrastructures (RI) involved in discovery, preclinical, and clinical development of innovative diagnostics and therapeutics – BBMRI-ERIC (Biobanking and Biomolecular Resources Research Infrastructure), ECRIN (European Clinical Research Infrastructure Network), and EU-OPENSREEN – have had a Memorandum of Understanding (MoU) in place. This collaboration aims to create a complete research and development innovation chain for Rare Diseases (RD) therapeutic and diagnostic development.

In 2014, the INNORARE partners joined together with Newcastle University and Prof. Dr. Kate Bushby – who is a RD expert and specialist in neuromuscular genetics – to coordinate a funding proposal Horizon 2020 for INNORARE. The INNORARE proposal aimed to develop new links between the rare disease community and the biomedical sciences RI on the European Strategy Forum for Research Infrastructures (ESFRI) Roadmap.

Our participation in the submitted proposal focused predominately on two Work Packages (WP):

- **WP2 (“Establishing INNORARE structure and user community: tools for communications, training, and ethics”):** As the task leader, EATRIS had to plan and model the creation of an easily accessible, highly integrated RI-based

RD development pipeline based on RI partner and other project criteria.

- **WP4 (“Innovation to accelerate the RD translational pipeline through novel de-risking strategies and industry engagement”):** EATRIS also led the design of WP4, which involved reinforcing industry partnerships, promoting the coordination of actions between projects, and spreading good practices between the RD and RI communities. The work plan also involved developing novel funding models based on industry partnerships.

The proposal was submitted in September 2014, but funding was declined. Despite the evaluation outcome, EATRIS, the three signatories of the MoU, Newcastle University, and other consortium partners continue to work together to seek ways to implement INNORARE. All involved parties seek to maintain a long-term, sustainable collaboration. EATRIS has invited Prof. Dr. Kate Bushby (Newcastle University, UK), as well as Dr. Mathieu Boudes (EURORDIS), to speak at the second EATRIS conference planned for May 27-28, 2015.

The INNORARE consortium included 30 European, Australian, and Canadian partners, for example:

- Patient organisations: EURORDIS
- Foundations and charities: Findacur and the French Foundation for Rare Diseases
- Research infrastructures: EATRIS-ERIC, BBMRI-ERIC, ECRIN, INFRAFRONTIER, EU-OPENSREEN; and
- Research institutes and universities: McGill University and Instituto de Salud Carlos III.



9. FINANCIAL SUMMARY



FINANCIAL SUMMARY



Frank de Man, LLM, PhD
EATRIS Finance Director

“As in previous years of the preparatory phase, EATRIS-ERIC’s operational costs stayed within budgetary limits as approved by the Board of Governors; the total resource allocation for 2014 was in line with the agreed budget”

Income & Expense Developments

Compared to 2013, the EATRIS contribution income dropped while the operating expenses increased. As in previous years, our operational costs stayed within agreed budgetary limits. Resource allocation was also in line with the budget approved by the Board of Governors. In accordance with the Board’s decision, the negative operating result was covered by EATRIS-ERIC’s reserves. Personnel expenses increased in 2014 primarily as a result of hiring more personnel and/or increases in employment hours. Regarding the sub-total of staff expenses, these expenses were lower than budgeted due to several factors like lower than estimated social security and pension costs.

Financial Year & Analysis of the Balance Sheet

The figures in this chapter are derived from EATRIS-ERIC’s 2014 audited financial statements. These financial statements were also accompanied by an auditor’s unqualified opinion dated April 7, 2015; this means there were no additional comments to the accounts.

Developments in Income and Expenses

Amounts in EURO's	2014	Budget 2014	2013
Contributions income	1,300,000	1,300,000	1,429,996
Subsidy income IPROVE and EURIPRED	30,628	40,000	-
Total income	1,330,628	1,340,000	1,429,996
Salaries and wages	698,639	682,500	599,533
Sub-total staff	257,612	385,600	302,236
Depreciation	7,391	-	5,466
Other expenses	672,261	621,900	543,911
Total expenses	1,635,903	1,690,000	1,451,146
Total operating result	305,275	350,000	21,150

Financial Year & Analysis of the Balance Sheet

	Dec. 31, 2014	Dec. 31, 2013	Analysis
Activa	€'000	€'000	
Tangible fixed assets	23	24	The book value of these assets did not materially change. The investment value was set off by the depreciation of acquired assets.
Current receivables	462	166	This increase was due to the outstanding contributions of two members.
Cash at banks	614	1,241	This decrease was primarily caused by an increase in current receivables, as well as the budgeted and approved operating loss.
	1,100	1,431	
Equity & Liabilities			
Reserves	794	1,174	The reserve was adjusted, with €75K less contributed from the Foundation into ERIC 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.
	1,100	1,431	





EATRIS-ERIC

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