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FOREWORD

Anton Ussi

Operations & Finance Director EATRIS Coordination & Support Office

2016 can be characterized as the continuation of an exciting journey on the path to growth and learning. Growth was reflected by a healthy increase in our project portfolio of both academic and public/private translational research projects utilising our technical and expert services. Growth was also seen in terms of our reach, by welcoming Norway, Slovenia and Luxembourg as new EATRIS members, whilst Latvia has become Observer country.

With regards to learning, we continue to evaluate and develop our ability to provide professional and effective access to those leading research institutes representing EATRIS. Via this process, we learn how to maximise the spillover and innovation potential of our varied technical domains, seeking how best to bring funder, regulator and researcher closer together for better, faster and more effective outcomes for both patients and society.

We look forward to more of the same and many new challenges in 2017!

Sincerely,

Anton Ussi

Marian Hajdúch

Chair of the Board of National Directors

With the continued development of the EATRIS infrastructure in 2016, we progressed our offering of the most innovative technologies for early de-risking of novel drugs and diagnostics, coupled with world class translational research expertise to a higher level. This growth provided an improved opportunity to all stakeholders to translate their scientific discoveries in more efficiently towards the patient EATRIS achieved this growth by continuing to add more top-tier institutions - including the addition of 3 more countries - with one main goal: to provide better therapies more efficiently which benefit our society as a whole. EATRIS' continued advancement this year in all fields (including an increased project portfolio) improved education and training opportunities such as its coordination of C-COMEND.and its driving of strategic initiatives which improve the translational research landscape, have all contributed successfully to this overarching goal. Therefore, we look forward to 2017 with great optimism as we continue our path to further establish this world class translational research community defined by the best possible development pipeline for new drug discoveries leading to the best possible clinical impact.

Sincerely,

Marian Hajdúch



Chair of the Board of Governors

To our great satisfaction, in the new 2016 ESFRI Roadmap, EATRIS was listed as a Landmark Research Infrastructure which has reached the implementation stage and is now established as a major element of competitiveness of the European Research Area.

Of relevance for the European and global translational medicine ecosystem is the translational science collaboration group comprising EATRIS, TIA Australia, NIH NCATS USA, MRC-Technology UK and CDRD Canada. Moreover, this appears to be the focus of the group on the development of models for de-risking early translational projects, as well as the need for innovative and predictive tools for early-decision-making, aimed at minimising early failure of translational medicine projects.

Overall, the performance shown by EATRIS in 2016 raises even higher expectations than before with regard to the potential of EATRIS of playing a pivotal role on a global level in filling the gaps which still exist in translational medicine. EATRIS' ERIC Members and Observers are fully committed to support EATRIS in reaching this goal.

Sincerely,

Maria Ferrantini





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INTRODUCTION

Academia driving productivity

The process of translating novel biological insights into effective interventions is a highly complex process, which requires significant dedicated expertise and infrastructure. The hope generated by the revolution in biology – stemming from the unravelling of the human genome and subsequent explosion of a variety of 'omics fields – was not matched by an increase in effective medical interventions. Failure rates in the development phase remain high, while paired with this reality is the continuing trend of industry reducing their investments in the early phases of discovery and translational research and development.

The field of translational science is a highly multi-disciplinary enterprise, tasked with gaining a fuller mechanistic understanding of both disease process and the mode of action by which a potential therapeutic works. This is a step beyond more empirical methods of development, and is in part the response to growing scrutiny from regulators, who increasingly require developers to show understanding of the mechanisms behind their investigational drugs.

Likewise, there is increasing focus on the ability to stratify potential responders from non-responders on the basis of companion diagnostic tests to improve response rates and thus the cost-effectiveness of prescribed drugs. This personalised medicine approach has far-reaching consequences on both the Research & Development (R&D) continuum as well as the healthcare sector.

Due to these ongoing developments, the R&D pipeline finds itself in a transitional stage. Developers are trying to validate tools which can support in discriminating early in the process which drug candidates possess a high potential versus those that will fail, as well as significant resources deployed to identify and validate potential biomarkers for patient stratification and prognostication. In this biology-driven, technology-rich area, academia is proving to be a significant driver of productivity, both in terms of novel tools for development as well as in the interventions that will ultimately be brought to patients.

EATRIS ERIC

EATRIS is a European Research Infrastructure Consortium (ERIC) created to defragment the substantial European efforts in translational research. Its mission is to improve productivity of the translational R&D pipeline by providing high quality research services to public and private research entities. Comprising over 80 leading research institutions in twelve countries across Europe, EATRIS has established itself today as a key player in the biomedical innovation continuum. By bringing together multi-disciplinary expertise, facilities and patient resources to support the development of promising drugs and diagnostics, EATRIS accelerates and de-risks the path to clinical proof of concept and partners with key stakeholders for the validation and introduction of novel tools to support R&D.



EXECUTIVE SUMMARY

Infrastructure with impact

Introduction

Over the last years, EATRIS has gained momentum and positioned itself as a key player in the field of Translational Medicine. As failure rates in the development phase remain high and industry investments in early discovery continue to decline, the focus strengthens on understanding the mechanism underlying both disease and treatment as well as on a personalised medicine approach. Throughout these challenging developments, academia is proving to be a significant source of novel tools and expertise for the development of new interventions.

Services

Facilitating research collaborations is one of the main pillars of EATRIS. The portfolio of users is steadily growing, with a two-fold increase of industry requests and four-fold growth of academic requests compared to 2015. Academia accounted for approximately 60% of our users in 2016. Furthermore, the first collaboration for a globally active mid-size pharma company, with two EATRIS institutions, was initiated; the development of the immune-inflammation imaging hub for a large pharmaceutical company and seven EATRIS institutions progressed steadily towards launch.

Infrastructure

The EATRIS infrastructure expanded significantly in 2016 as a result of three new member states joining. Luxembourg, Norway and Slovenia joined as full members, and Latvia joined as an observer country. By doing so, several high-quality research institutes entered the EATRIS product platforms, adding valuable expertise and infrastructure.

Platforms

The EATRIS product platforms have been a hive of activity over 2016, initiating and contributing to several projects in various roles.

ATMP product platform

The advanced therapy medicinal products (ATMP) product platform participated in an Innovative Medicines Initiative (IMI) Consultation, co-organized the 2016 INFORMA Cell and Gene Therapy Congress and developed a white paper, discussing the issues of manufacturing and reimbursement in ATMP development.

Biomarkers

The Biomarker platform developed a position paper on the need for good biomarker practice in collaboration with two other research infrastructures, namely BBMRI and ELIXIR, to be published in Nature Reviews Drug Discovery in Q1 2017. The ECaDE (Early Cancer Detection Europe) initiative was developed further. The ECaDE steering committee wrote jointly a letter to the editor of the International Journal of Cancer published in December 2016. Thanks to EATRIS, the FDA-SEQC2 initiative was considerably expanded with European institutions as part of the EATRIS quality initiative.

Imaging & Tracing

Within the Imaging & Tracing platform, the first, cross-site project for a mid-cap pharmaceutical company was initiated involving two EATRIS institutions. The formation of the immune-inflammation hub for the delivery of imaging tools and methodologies made major achievement towards agreement and full operation is foreseen in 2017. Together with the European Association of Nuclear Medicine (EANM), the Imaging & Tracing platform remained dedicated to promoting nuclear medicine and drug development through harmonization of Zr-89 PET/CT.

Small Molecules

In 2016, the University of Ljubljana in Slovenia was added as a new member to the platform. Notable examples of successful project explorations encompass the integration of an emerging technique into a client's drug discovery platform and the preclinical profiling of lead candidates of a client. In addition, an increasing number of academic partners submitted requests to enrich their public drug candidate research and development programmes with academic expertise and capacity in Absorption, Distribution, Metabolism, and Excretion (ADME) profiling and academic medicinal chemistry capacity.

Vaccines

The 'Innovation Partnership for a Roadmap on Vaccines in Europe' was launched in March 2016 at a European parliament event. EATRIS was one of its partners, setting out a vision for vaccine research and innovation in Europe. EATRIS continued its functional role in the collaborative infrastructure program European Infrastructure for Poverty-Related Diseases (EURIPRED) throughout 2016, reinforcing the knowledge infrastructure across diseases.

Furthermore, the Vaccine platform set up the Vaccine Working Group to engage industry in exploring the pressing needs in vaccine development and to assess in which manner academic institutions can add value to the process.

Impact

In 2016, EATRIS continued to support a portfolio of long-term initiatives which are intended to ultimately improve the effectiveness of the translational pipeline. These long-term initiatives result from the interaction with various stakeholders and international players in the field of translational medicine. In a position paper published in Nature Reviews Drug Discovery, EATRIS together with 4 other international players in the translational sciences field (NCATS, TIA, CDRD and MRCT) set-up a vision for collaboration.

Business development & marketing

In 2016, EATRIS attended several conferences and networking events such as BIO Europe and BioJapan to showcase its capabilities as well as raising brand awareness.

At the BIO International convention in San Francisco, EATRIS presented itself with a large booth and co-hosted a session entitled 'Models for de-risking early translational projects'. During Bio-Convention, EATRIS launched its new brand identity, followed by a full rebranding of all communication materials and the launch of a completely new website later that year.

Education & Training

As the coordinator of the C-COMEND project, EATRIS co-designed the e-learning course entitled 'The Landscape of Translational Medicine' covering biomarker development, target validation, and regulatory environment which has successfully been held in the autumn of 2016 EATRIS has also been involved in developing training activities in two European Community Horizon 2020 projects: RItrain (Training of management staff of Research Infrastructures) and CORBEL (Coordinated Research Infrastructures Building Enduring Life-science services).

SOLUTIONS

MATCHMAKING

Matchmaking refers to the process of matching client requests with the institutional capabilities that reside within EATRIS. We provide support to ensure that project agreements are reached efficiently, and facilitate partnerships (see page 18. Introduction Platforms), while the EATRIS institutes execute the resulting study plans in direct collaboration with the client.

Industry, big pharma, biotech companies, SMEs

FAST MATCHMAKING

Similar to matchmaking, Fast Matchmaking is a quick way to identify potential partners for consortium building for funding applications.

Academia and SMEs

EATRIS-INSIDE

With EATRIS-Inside, EATRIS assesses the translational feasibility of projects based on various elements such as intellectual property, regulatory pathway(s), and end-product definition.

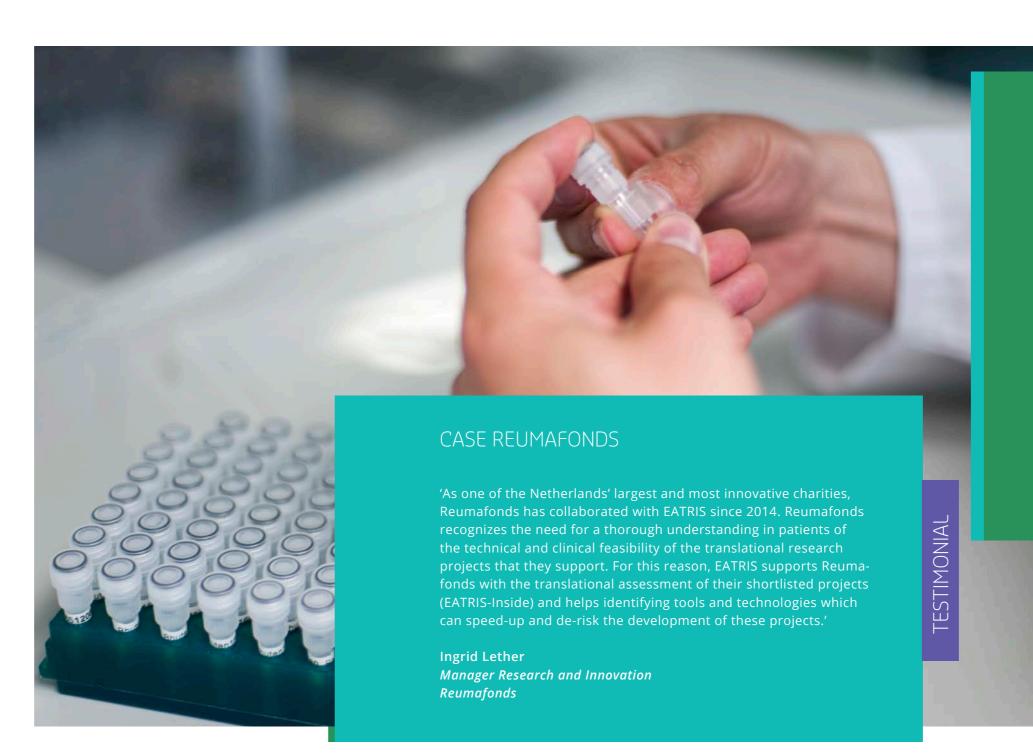
This translational assessment proactively aids identifying potential gaps and bottlenecks which may obstruct project execution, as well as identifying key enabling technologies to support robust data generation.

Funding agencies, charities, academia

REGULATORY SUPPORT

Regulatory Support offers early assessment of the requirements needed for successful translational projects. It also provides the necessary information to drive development plans for innovative technologies and products, which is also an essential part of the EATRIS-Inside service. The regulatory experts working with EATRIS provide a range of services, including facilitating early dialogue with national competent authorities, Orphan Drug Designation applications and more.

Any researcher or research-funding organization



UCB

"We engaged with EATRIS to support our experimental medicines activities by exploring the use of novel technologies outside the scope of our internal capabilities and knowledge, with the aim of enhancing the predictive value of proof-of-concept clinical studies.

Thanks to the support of the EATRIS team, we were able to identify leading experts within the EATRIS network. We collaborated with these experts to develop a plan for this highly technically challenging project, which will be executed in a multisite setting and which leverages each team's specific expertise towards a common goal."

Jay Tibbitts
Senior Director, DMPK Strategy Group
UCB

Serving as a matchmaker for academic

translational research capabilities, matching supply and demand in the European Research Area (ERA) by providing access to high end infrastructure and expertise forms the cornerstone of EATRIS.

In 2016, the first project for a mid-cap pharmaceutical company was initiated after a year of exploration and project plan finalisation. The project plan finalisation, an agreement. The project budget exceeds € 1 million euro and will be executed in 2017. During 2016, more projects were initiated across the EATRIS product platforms from collaborations for biomarker validation to profiling and validation of small molecule lead candidates or antiviral candidates efficacy against multiple strains of viruses. Each project involves complex timelines, numerous interdependencies and – in most cases – more than one EATRIS institution. In addition, EATRIS further developed its portfolio of clients in 2016 by nine signed Letters of Engagement (LoE) including one with a large Japanese pharmaceutical company. For at least two further requests, we expect a project agreement to be signed between EATRIS institutions and clients in early 2017.

Our Fast Matchmaking requests received extra attention in 2016 as a result of mailing campaigns and active scrutiny of Horizon 2020 and Innovative Medicines Initiative (IMI) calls. EATRIS aided eighteen Principal Investigators (PI) with consortium building for grant application. In addition to Fast Matchmaking and general matchmaking activities, EATRIS provided regulatory support to two projects to apply for orphan designation.

In 2016, EATRIS further developed the academic hub for immuno-inflammation imaging for a large pharmaceutical company.

The initiative is currently progressing with a Master Research Collaboration Agreement (MRCA) under negotiation which will provide the legal framework needed to operate.

The MRCA is expected to be signed by the eight collaborating parties in Q1 2017.

A steering committee is already in place as are the first projects under exploration for initiation in Q2 2017. The hub will focus on a series of experimental pilot medicine projects to validate and deploy molecular imaging tools to support drug development.

CORE ACTIVITIES	2014	2015	2016
FAST MATCHMAKING	9		18
MATCHMAKING	8	5	9
EXPERT ADVICE	13		
HUB PARTNERING			
INCOME TO C&S OFFICE	2014	2015	2016
INVOICING FOR C&S SERVICES		€ 50.000,00	€ 100.150,00
H2020	€ 30.628,00	€ 147.014,00	€ 219.039,00
INCOME INSTUTIONS (BUDGET NEGOTIATED)	2014	2015	2016
INDUSTRY	€ 33.302,00	€ 23.474,00	€ 1.609.931,00
H2020	€ 187.287,00	€ 203.966,00	€ 388.859,00
USERS DIRECT TO EATRIS FACILITIES 2014-1	6: 1400		

ONCODESIGN 'At Oncodesign we apply a "Probe based Drug Discovery Process" that starts from our proprietary Nanocyclix® medicinal chemical platform that generates small macrocycles with outstanding selectivity and potency against unexplored kinases. It led us to recently identify inhibitors of a kinase regulating Tau phosphorylation. Tau protein is involved in neurological diseases like Alzheimer's disease (AD), a scientific field in which we have limited expertise. We thus turned to EATRIS for their support. EATRIS put us in contact with Prof. Dr. Philip Scheltens, one of the leading clinical experts in AD, who helped us to understand the clinical relevance of our project. EATRIS subsequently used its network in academic and private institutions to identify scientific experts with models relevant for our target and we are now closely collaborating with them. The benefit of EATRIS is that they provide access to a large infrastructure, and as a consequence can support the complete development track, from in vitro screening, all the way to clinical proof of concept studies. For each step, they can identify the right expert and centre. Moreover, we found the EATRIS staff to be extremely knowledgeable and professional. The speed of the matchmaking and the scientific quality of the responses we received was beyond our expectations.' Josselin Caradec Discovery Program Director Oncodesign

INFRASTRUCTURE OVERVIEW

New members and observers in 2016

In 2016, EATRIS saw a substantial extension of its European-wide and bioscience institution based infrastructure.

Luxembourg, Norway and Slovenia joined as full members, while Latvia joined EATRIS as an Observer country. This expansion provides academic researchers, industry and other client users across Europe and beyond new opportunities to utilise the infrastructure and accelerate their cross-border collaboration.

Luxembourg

The Integrated BioBank of Luxembourg (IBBL) coordinates EATRIS related activities in Luxembourg. IBBL's representative Dominic Allen was nominated as Luxembourg's member of the EATRIS Board of National Directors.

Norway

A group of five institutions will initially form the EATRIS node including the University of Oslo, the University of Bergen, the Norwegian University of Science and Technology, UiT The Arctic University of Norway, supported by the four Regional Health Authorities in Southeastern, Western, Central and Northern Norway.

National director professor Kietil Tasken oversees the Norwegian EATRIS activities.

Slovenia

The Faculty of Pharmacy, University of Ljubliana hosts and coordinates the national EATRIS-TRI.SI centre. Professor Dr. Irena Mlinaric-Rascan of the Faculty of Pharmacy represents Slovenia as National Director.

Latvia

Latvia joined EATRIS as an Observer country and EATRIS related activities are coordinated by national director Uldis Berkis, Director of the Research Department of the Riga Stradins University. Latvia will use its Observership to develop a national translational research agenda and to create the national node to coordinate these activities.



Participating countries:

Czech Republic, Estonia, Finland, France, Italy, Luxembourg, The Netherlands, Norway, Spain, Slovenia, Sweden, Denmark.

Observer country:

Latvia

EATRIS institutes

88 academic & non-profit research institutes of excellence; approximately half are university medical centers

EATRIS Coordination & Support located in Amsterdam

INSTITUTIONS OVERVIEW

- Platform participation
- Platform participation new institutions in 2016
- Institution expanded its participation to new platform

Name:	ATMP	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
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 Experimental Medicine AS CR	•				
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.					
University of Tartu	•	•			
Finnish Red Cross Blood Service	•	•			
Institute for Molecular Medicine Finland (FIMM)		•			
Regea Cell and Tissue Centre (University of Tampere)	•				
Turku Centre for Disease Modeling (TCDM)		•			
University of Eastern Finland (UEF)	•				
University of Turku and Turku University Hospital		•			
VTT Technical Research Centre of Finland (VTT)		•			
Neuratris-Albert Chevalier-Henri Mondor Hospital	•	•	•	•	
Neuratris-Biotherapies Institute for Rare Diseases (BIRD)	•	•		•	
Neuratris-Brain & Spine institute IHU-A-ICM		•		•	
Neuratris-French Alternative Energies and Atomic Energy Commission (CEA)	•	•	•	•	
Neuratris-Neurosciences Bicêtre - Paris Sud (NBPS)	•		•		

		ATMP	Biomarkers	Imaging & Trad	Small Molecule	Vaccines
	Name:					
	Centro Medicina Rigenerativa (CMR)	•			0	
	CNCCS - IRBM Science Park		0		•	
	Fondazione IRCCS CRIBT		•	0	-	
	Fondazione IRCCS Fondazione Pascale	•	•		•	
	Fondazione IRCCS Giovanni Paolo II					
	Fondazione IRCCS Istituto Nazionale dei Tumori (INT-Milan)		•			
	Fondazione IRCCS Ospedale Pediatrico Bambino Gesù					
Laly	Fondazione IRCCS SDN per la Ricerca e l'Alta Formazione in Diagnostica N.					
=	IDI-Fondazione IRCCS Luigi Maria Monti					
	IRCCS Istituto Ortopedico Galeazzi					
	ISMETT	•				
	Istituti Fisioterapici Ospitalieri - Istituto Dermatologico "San Gallicano"					
	Istituti Fisioterapici Ospitalieri - Regina Elena Tumor research					
	Istituto Superiore di Sanità (ISS)					
	Mario Negri Institute				•	
	National Institute for Infectious Diseases Lazzaro Spallanzani		•			
Ruvellibourg	Rizzoli Orthopedic Institute (IOR)	•	•			
	Scientific Institute San Raffaele (HSR)	•				
מאמ	Integrated Biobank of Luxembourg (IBBL)	•	•			
_	Academic Medical Centre (AMC)					
	Biomedical Primate Research Centre (BPRC)					•
	Wageningen Bioveterinary Research					•
	Erasmus University Medical Centre					
	Intravacc					
2	Leiden University Medical Centre (LUMC)	•			•	•
ואפרוופוופו	Maastricht University Medical Center (MUMC)			•		
ב	Netherlands Cancer Institute		•			
2	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)					

Name:	ATMP Biomarkers Imaging & T Small Molec Vaccines
Bergen Institute of Medicine	• • • • •
Norwegian University of Science and Technology (NTNU)	0 0 0 0
University of Bergen (UiB)	
University of Oslo (UiO)	• • • •
University of Tromsø (UiT)	
University of Ljubljana	0 0 0 0 0
August Pi i Sunyer Biomedical Research institute (IDIBAPS)	0 0 0 0 0
Bellvitge Biomedical Research Institute (IDIBELL)	• • • • •
BioDonostia Health Research Institute	• • • • •
Fundacion Jimenez Diaz Institute for Medical Research (IIS-FJD)	0 • 0 0 0
Germans Trias i Pujol Foundation (IGTP)	0 • • 0 0
Health Research Institute of Santiago de Compostela (IDIS)	0 0 • 0 0
Hospital de la Santa Creu i San Pau (IR-HSCSP)	• • • • •
Hospital La Fe (IIS-La Fe)	• • • • •
Hospital La Paz Institute for Health Research (IdiPAZ)	• • • • •
INCLIVA	• • • • •
Insitute of Biomedicine of Seville (IBIS)	• • • • •
Instituto Ramón y Cajal (IRYCIS)	0 0 0 0
University Hospital La Princesa (IIS-IP)	• • • • •
Vall d'Hebron Research Institute (VHIR)	• • • • •
Uppsala University	
Uppsala University Hospital	

INTRODUCTION PLATFORMS



Giovanni Migliaccio

Scientific Director
Coordination & Support Office

EATRIS is organised along five product platforms:

- Advanced Therapy Medicinal Products (ATMP)
- Biomarkers
- Imaging & Tracing
- Small Molecules
- Vaccines

Each platform offers a specific set of infrastructure services targeted to the needs of specific users (industry, academia, charity funders and governments). Additionally, the institutes work together to overcome bottlenecks in translational research, for instance by undertaking standardisation and best practice exchange projects. The product platforms are composed of academic and non-profit research institutions in biomedical translational research.

All members possess well-established track records in:

- entering clinical development
- hosting unique infrastructures and licenses
- clinical expertise with access to a broad array of patient cohorts (including rare diseases).

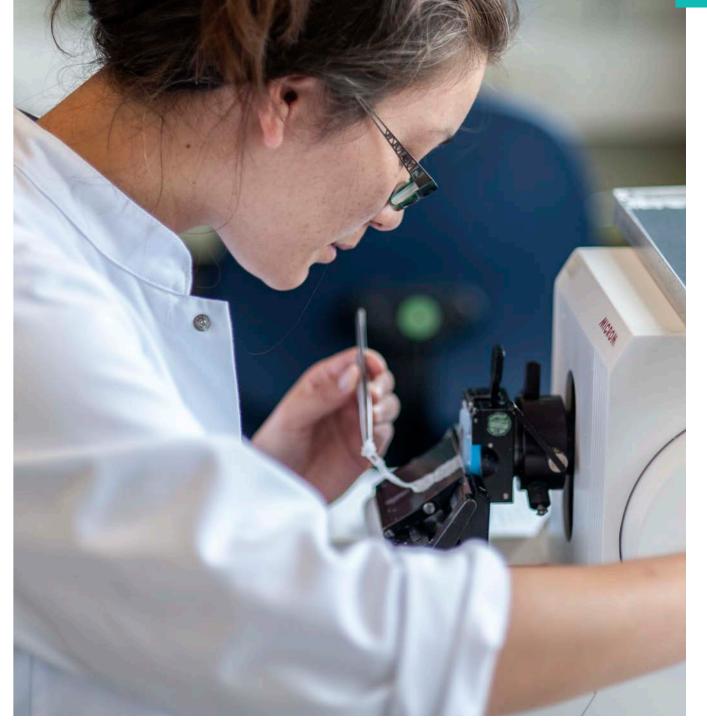
EATRIS institutions offer top quality expertise in line with the standards and certifications required for particular studies and provide a complete translational pipeline via a distributed infrastructure by using the hub-and-spoke model whereby the EATRIS Coordination & Support Office acts as the coordinating hub.

Over the course of 2016, several new countries and thereby new centres joined EATRIS. The expanded capacity of the infrastructure allows coverage of all translational needs, thus making them accessible to researchers.

Support tools in fields like legal and regulatory have been designed and are now entering the implementation phase.

Overall, these services and tools provide access to technologies and resources which are not usually available to small enterprises or academic researchers, and – with regard to certain specialized apparatus and resources – not even within large companies.

Meetings combining multiple platforms around specific technologies or disease areas allow the identification of several cross-platform projects targeted to specific gaps and bottlenecks in the translational pipeline. These services are targeted at researchers with innovative products in search of the right groups and supporting capacities to further enhance their development along the pipeline. These initiatives are important efforts to improve the overall efficiency of the translational pipeline.





(ISS, Italy)



Miguel Chillon

Co-Chair (VHIR, Spain)

ATMP

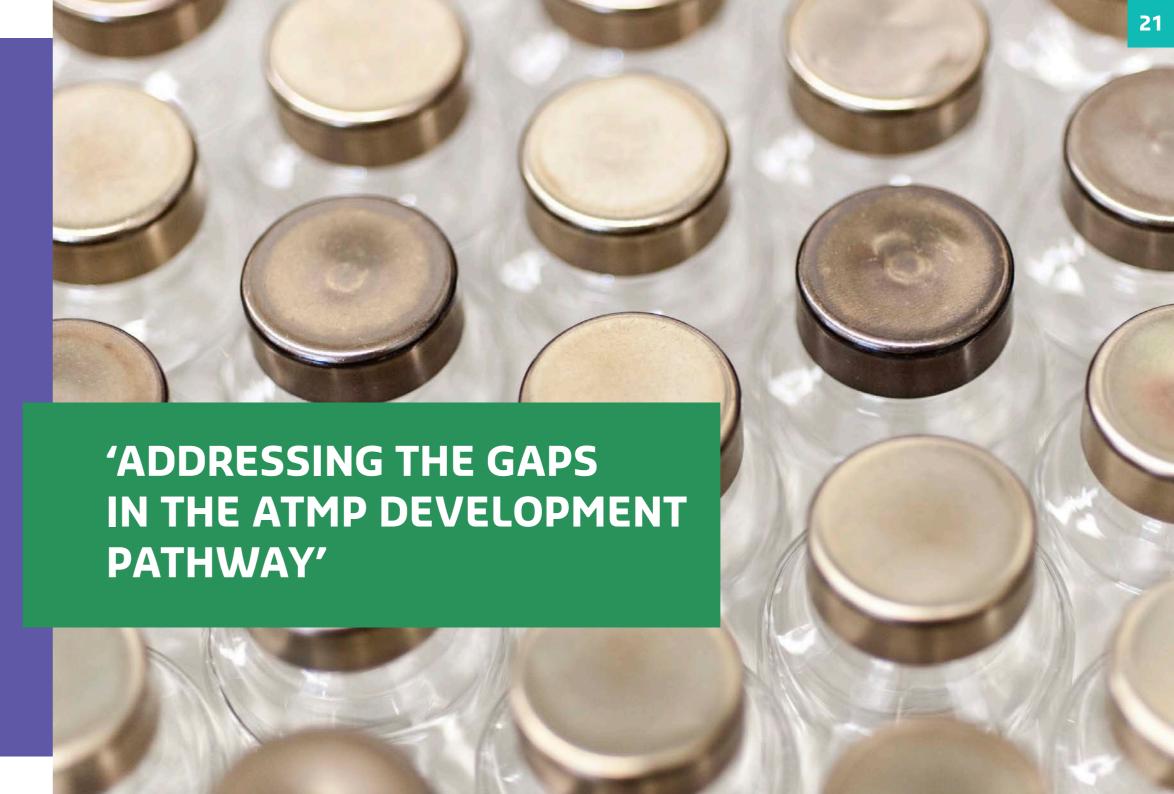
Platform

2016 saw the further expansion of the ATMP platform with the Finnish Red Cross Blood Service (Finland), Biodonostia (Spain), the Department of Dermatology of VUmc (The Netherlands), and the IBBL (Luxemburg) joining the platform, taking the total number of ATMP institutions to 35. The platform continued to participate in initiatives to address the gaps in the ATMP development pathway which continue to hinder the field's potential as an effective clinical option and which prevent the transition of ATMPs from a cottage industry to a large-scale one.

Some highlights from 2016 include:

• The ATMP platform participated in an IMI consultation to identify bottlenecks in ATMP development. EATRIS formed a major part in the European Union (EU) wide consultation which resulted in the first ATMP specific calls which will be initiated in 2017/18 where EATRIS will participate in relevant consortia as they arrive.

- EATRIS was a co-organizer for the 2016 INFORMA Cell and Gene Therapy Congress in Amsterdam in November 2016.
- EATRIS was part of the European Infrastructure for Regenerative Medicine (EURO-CELL) proposal which passed the first stage to which the ATMP platform will contribute to two work packages. Submission of the second stage proposal is planned for March 2017.
- To drive potential funding calls involving the funder and the regulator, the ATMP platform developed a white paper, discussing the issues of manufacturing and reimbursement in ATMP development.
- EATRIS continued its mandate of greater alliance with scientific societies by exploring collaborations with the International Society for Cell Therapy (ISCT), the Brandenburg Center for Regenerative Therapy (BCRT) and the Parenteral Drug Association (PDA).







(Radboudumc, The Netherlands)



Andreas Schere

Co-Chair (FIMM, Finland)



Co-Chair (University of Tartu, Estonia)



Laura Garcia

Co-Chair (IRYCIS, Spain)

BIOMARKERS

Platform

continued to reinforce its long-term bjective to validate biomarker targets and expertise. In 2016, the platform reinforced consists of 45 European advanced biomarker development centers. In addition to delivering activities is to be published in Nature Reviews highlights the need for an integrated

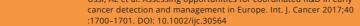
In collaboration with Cancer Research UK (CRUK) and leading experts across Europe, the

Gerrit Meijer (The Netherlands Cancer Institute (NKI), The Netherlands). In 2016, the ECaDE Steering Committee published a letter to the In this letter, the Steering Committee advocates for improved access to resources and expertise necessary for coordinated R&D Europe. In a pilot action, ECaDE offers to Research Area Network (ERA-NET) call TRANSCAN-2 by providing, free of charge, an assessment of the design of their project plan in the first phase. PIs shortlisted in the second phase (2017) will benefit from full technical

platform focused on harmonisation and (NGS) studies across genomic biomarkers. contributing to the Food and Drug Quality Control Phase 2 (SEQC2). SEQC2 is Its primary objective is to develop standard IDIBAPS (ES) and IRYCIS (ES), protocols for miRNA measurement will be exchanged and



Ussi, AE et al. Assessing opportunities for coordinated R&D in early





Martin de Kort



Prof. Otto Boerman

(Radboudumc, The Netherlands)



Prof. Bert Windhorst

Co-Chair (VU Medical Centre, The Netherlands)

IMAGING & TRACING

Platform

The Imaging & Tracing platform supports programmes to make drug development more efficient through robust and harmonised translational (PET and optical) imaging with optimised infrastructure access for industry and academic clients. In 2016, the services focused on (tracer development in) certain disease themes, such as neurodegenerative diseases, immuno-inflammation, kidney disease and muscular skeletal disorders.

Both Uppsala University and Uppsala University Hospital entered the Imaging platform with strong translational imaging capabilities in 2016. Additional institutes from Sweden and Norway (full membership established in 2016) are anticipated. In Italy, the Italian Molecular Imaging Network (IMINET) did not establish a permanent status after termination of its project, but engagement of former members of IMINET with the EATRIS Imaging & Tracing platform is ongoing.

Matchmaking and industry partnering activities resulted in the formal start and maturation of bilateral and multi-partner projects. A large pharmaceutical client explored its preclinical development project with three EATRIS partners and – after a site visit – developed an advanced molecular imaging study. A major milestone was reached after the start of a cross-site project with our partners in Turku and Amsterdam, serving a mid-cap pharmaceutical company in developing a specific tracer for its enzyme target to support transitioning of its lead compound into the clinic. Finally, the formation of a strategic hub consortium to deliver imaging tools and methodologies to support drug discovery and development in immuno-inflammatory disorders set critical steps, moving forward to a formal launch. For this key initiative, the strategy was outlined during two steering committee meetings, while five site visits (UMCG, AMC, VUmc, Uppsala and Radboudumc) enhanced the development of a portfolio of potential projects to be initiated in 2017.

EATRIS and the European Association of Nuclear Medicine (EANM) remain dedicated to promoting nuclear medicine and drug development through harmonisation and standardisation of (PET/CT) image acquisition and quantitative data analysis with their joint calibration programme, enabling multi-centre trials to utilise harmonised Zr-89 PET/CT imaging. Increasing demand in the field of complex therapeutics development including cell therapy, nanomedicines and antibody drug conjugates – will also benefit from the high-end imaging infrastructure available within EATRIS.



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Martin de Kori

Programme Manager
EATRIS Coordination & Support Office



Dr. Mario Salmon

Chair (Mario Negri Institution, Italy)



Dr. Alfredo Budillon

Co-Chair Fondazione IRCCS Fondazione Pascale, Italy

SMALL MOLECULES

Platform

The Small Molecules platform aims to enhance the efficiency of clinical translation of novel chemical entities using cutting-edge technologies combined with unique access to patient materials and clinical expertise. This includes advanced drug screening in 3D cultures and primary cells, novel peptide drugs, absorption, distribution, metabolism, and excretion (ADME) profiling as well as pre-clinical and clinical validation of nanomedicines and formulations.

The Faculty of Pharmacy of the University of Ljubljana in Slovenia was added as a new member to the platform in 2016. The Faculty is a leading regional research and higher educational institution in the field of pharmacy, clinical biochemistry, toxicology and cosmetology. It provides complementary expertise to the platform, including drug design and synthesis, FDA compliant development and validation of (bio)analytical methods, biodistribution and high-end formulation studies.

Additional institutes from Sweden and Norway (full membership established in 2016) are anticipated.

Matchmaking and industry partnering activities intensified and saw an increase in interest from SMEs to support their portfolio development in a targeted manner, benefiting from single point of access to high-end infrastructure and expertise available within EATRIS. Notable examples of successful project explorations encompass the integration of hydrogen-deuterium exchange mass spectrometry (HDX-MS) as an emerging technique into a client's fragment-based drug discovery platform (ACSR, Prague), and the preclinical profiling of lead candidates of a client in a translational cellular screening model for neurodegenerative diseases. In addition, an increasing number of academic partners submitted requests to enrich their public drug candidate research and development programmes with academic expertise and capacity in ADME profiling and academic medicinal chemistry capacity.

EATRIS engaged with NANBIOSIS, a service-oriented nanomedicine network in Spain as a lead partner in the design and production of biomaterials, nanomaterials and devices to their preclinical validation.

EATRIS Global Collaboration Initiative considers the reproducibility and inter-site variability High Throughput Screening (HTS) assays in small molecules drug research a high priority. This has resulted in the development of an initiative where multiple sites can participate (in an anonymous fashion) in a ring test screening campaign, using a centrally distributed and commercial compound library, and a robust and standardised biochemical assay. This allows comparison of (the deviation of) their individual data sets to those of the larger group. Five EATRIS screening centres have signed up for this initiative.





(BPRC, The Netherlands)



Lucia Gabriele

Co-Chair (ISS, Italy)

VACCINES

Platform

With now 16 high end facilities following the addition of the Department of Dermatology of VUmc (The Netherlands) and IBBL (Luxembourg) to the platform, EATRIS initiatives in 2016 such as the publication of (EURIPRED) initiative. The platform voted for a (BPRC) being confirmed for a second term and

IPROVE

on Vaccines in Europe", financed under the

EURIPRED

EATRIS continued its functional role in the is a collaborative infrastructure program, its hepatitis C virus (HCV). One of the key Vaccine platform formed the Vaccine Working Group to engage industry in exploring the assess where academic institutions could add value to the process. The first meeting was SmithKline (GSK). The platform continued its



IMPACT

Overview of collaborations and publications

In 2016, EATRIS continued to support a portfolio of long-term initiatives ultimately intended to improve the effectiveness of the translational pipeline. These long-term initiatives result from the interaction with various stakeholders and international players in the field of translational medicine. Below is an overview of the ongoing infrastructure development initiatives.



European Medicines Agency

Description: Facilitate EMA-academic dialogue, develop a regulatory research agenda.

Status: The EMA framework for reinforced collaboration with academia was adopted early 2017¹. This development will hopefully lead to opportunities for the European Research Infrastructures to contribute to the advancement of Regulatory Sciences.

Platform:

All (ATMP most benefit).

National Competent Authorities

Description: Collaborate with NCAs to provide access to early, informal scientific advice for EATRIS users.

Status: Memorandum of Understanding (MoU) (NL, Fl, CZ)

Platform:

All (ATMP most benefit).

Virtual development team

Description: Provide access to cross-disciplinary teams supporting the design of translational development plans for leading projects.

Status: Concept developed and under implementation.

Platform:

ΔΠ

Assessing opportunities for coordinated R&D in early cancer detection and management in Europe

Anton E. Ussi¹, Matejka Rebolj², Mangesh A. Thorat², Florence Bietrix¹, Anne-Charlotte Fauvel¹, Marian Hajdúch³, Catherine Hill⁴, Ian Walker⁵, Manon van Engeland⁶, Jack Cuzick² and Gerrit Meijer⁷

Global Collaboration

Description: Maintaining an exchange of initiatives and best practices with global members of initiatives in translational medicine. An alliance with NIH NCATS (USA), TIA (Australia), CDRD (Canada), and MRC T echnology (UK).

Status: Position paper published in NRDD². Organisation of a session at Bio-International convention, San Francisco, June 7, 2016.

Platform:

ΑII

Putting translational science on to a global stage

C. Taylor Gilliland, Dorit Zuk, Petr Kocis, Mike Johnson, Stewart Hay, Marian Hajduch, Florence Bietrix, Gregorio Aversa, Christopher P. Austin and Anton E. Ussi

Global collaboration in translational science promises to accelerate the discovery, development and dissemination of new medical interventions. Here, we introduce a new international collaboration of translational science organizations and highlight our initial strategy to reduce or remove bottlenecks in translation.

Personalised medicine innovation fund

Description: Investigating mechanisms to utilise EFSI funds for long term financing of innovation infrastructure in personalised medicines; collaboration with other biomedical ESFRIs.

Status: Explorations underway with EC, EIB, member states; Support from MRC Technology.

Platform:

Learned societies and other initiatives MoU signed with Center for Clinical and Translational Research, Kyushu University

Description: Collaborations to allow joint education, marketing, access to expertise. Ongoing with EANM, ISCT, TBVI.

Status: Various MoU and collaboration agreements signed.

Platform:

Reproducibility in Biomedical Sciences

Description: Tackling the reproducibility issue to ensure responsible research.

Status: Initiation and implementation of the EATRIS quality initiative (see platform pages).

Organisation of a high-level session at ESOF 2016 (Manchester).

Platform:

All.

BUSINESS DEVELOPMENT

& Marketing

Business development focused on expanding and elaborating the activities set in motion in 2015 as well as sharpening the business proposition of EATRIS and increasing user recognition. On both ends, major achievements were made in 2016.

Due to the broad scope of EATRIS, the services proposition will always be challenging. We offer "the right expert at the right time" and feedback from the market indicates that this appeals to clients in general. In order to provide more specific support, we initiated a dedicated services concept targeted at specific types of company: Academic Network Solutions (ANSwer). A first example of this approach is the Trial Readiness Network (TREND) which focusses on PET imaging in tauopathy.

In order to increase market recognition, EATRIS focused on networking and partnering events. Networking events are highly instrumental to showcase EATRIS' capabilities towards a large audience in a relatively short timeframe.

Highlights in 2016 were the BIO International Convention, during which we hosted a session on Models for De-Risking Early Translational Projects and at which our new brand identity was launched, BioJapan and BioFit, where EATRIS participated in a panel discussion. Furthermore, the National Coordinators in Finland and Sweden have been very helpful in supporting EATRIS' business development. Close proximity remains important to EATRIS' clients as was demonstrated by the participation to the NLSDays at which Ulrika Båckman joined us to specifically engage with Swedisch SMEs. This resulted in various company explorations and at least two Letters of Engagement. Naturally, visibility during scientific conferences is important to gain credibility. During the summer of 2016, EATRIS organised and chaired a session at the EuroScience Open Forum (ESOF). ESOF is the largest interdisciplinary science meeting in Europe.

The session entitled "Reproducibility in the Biomedical Sciences" brought together editors of scientific journals, funders of academic research and leading scientists to discuss the alarming irreproducibility rate in biomedical research as well as common solutions. Furthermore, EATRIS is always grateful for platform chairs and KOLs who broadcast their EATRIS membership when attending conferences.

MARKETING ACTIVITIES

Over the course of 2016, EATRIS took its brand identity to the next level by presenting its new logo, a full rebranding of all communication materials and the launch of a completely new website.

The new website is a powerful tool to attract clients and to fuel collaboration by comprehensively presenting the EATRIS institutions as well as publishing compelling content on translational medicine, biomedical innovation and the added value of EATRIS.

EATRIS also started working on a brochure to support the promotion of services, which is expected to be available in print at the end of Q2 2017.



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EDUCATION & TRAINING

Education and training activities are strongly aligned with other EATRIS activities, and specifically focus on providing training opportunities about translational medicine which have high impact on researchers' daily practice; Developing curricula that support the education of the next generation of translational scientist.

Projects

Since November 2015, EATRIS has been coordinating the C-COMEND project, for which it has co-designed a competency profile, an e-learning and a face-to-face course intended for PhD students and early post-docs. The first cycle of the course has successfully been held in the autumn of 2016. The e-learning entitled "The Landscape of Translational Medicine" covers biomarker development, target validation, regulatory environment (freely available at http://elevatehealth.eu/ course/landscape-translational-medicine).

EATRIS has been involved in developing training activities in two European Community (EC) Horizon 2020 projects, RItrain (Training of management staff of Research Infrastructures) and CORBEL (Coordinated Research Infrastructures Building Enduring Life-science services). For RItrain, EATRIS has successfully submitted an invitation to host a staff exchange on Strategic Vision, Governance and Business Development.

The exchange will take place at EATRIS headquarters in April 2017. For CORBEL, EATRIS is leading the work package "Accelerating Innovation" for which a webinar on innovation has been developed.

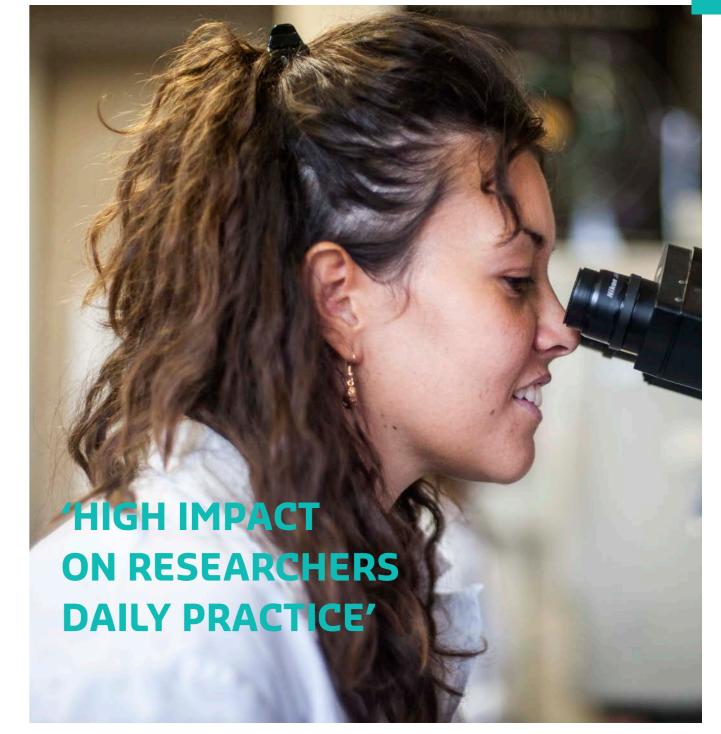
Workshop: Developing curricula for the next generation of translational scientists EATRIS hosted a workshop in October 2016 on developing curricula in translational medicine for translational scientists. Using the existing C-COMEND competency profile and e-learning, the main subject areas to be developed were identified and discussed. One of the outcomes was the need for a workshop in translational medicine targeted to senior scientists which will be developed soon.

Conference educational workshops

EATRIS is developing a series of educational workshops for the EATRIS Conference 2017 (September 24-26, Prague). The workshops will be dedicated to key topics in the field such as molecular imaging, biomarker validation or potency assays for ATMPs and vaccines.

Website

In 2016, the EATRIS Education & Training website offered 5 new courses provided by EATRIS institutes and external training partners. We encourage our partners to continue sending in additional courses which we can advertise on the website.



CASE C-COMEND

■ C-COMEND is a two-year European training project supported by the Erasmus+ program, which started on November 1, 2015. Part of this project is a free course intended for nearly finished PhD students and early postdocs who are involved in translational research. The course consists of an introductory elearning followed by a 5 day face-to-face workshop, teaching those skills and competencies required to successfully contribute to translational research and medicines development. The first face-to-face course was hosted by AstraZeneca (Alderley Park, UK) at the end of November 2016 which was very successful. A total of 28 participants from various European countries, ranging from Northern Europe, to Portugal, Hungary and Bosnia and Herzegovina attended. The 5 day program featured industry speakers and provided interactive sessions such as a real-life FDA case, a board game, elevator pitches, poster presentations and workshops on skills and competencies needed in the field of translational medicine.

Highlight of the course was the insight provided by Chloe Joyner, mother of a 7-year old with Usher Syndrome. Her emotional story about their day-to-day life and struggles as well as the power of patients to make a difference in medicine development touched the students deeply and made them understand the importance of their work. The overall course program and the special setting were evaluated with 8.5/10.

A second cycle of the face-to-face course will run in October 2017 and a third cycle has been made possible by Bayer (Berlin, Germany) in the first half of 2018.

The C-COMEND consortium led by EATRIS includes four additional partners:

- Karolinska Institutet, Sweden
- Medical University of Vienna, Austria
- Helmholtz Centre for Infection Research, Germany

Elevate Health, The Netherlands

This project receives funding from the European Union's Erasmus+ program under grant agreement 2015-1-NL01-KA203008986.

See http://www.eatris.eu/c-comend.html for more information on C-COMEND.





Frank de ManGovernance & Finance

FINANCIAL SUMMARY

Development in income and expenses result

Compared to the previous year, contribution and projects income increased and total operating expenses decreased. EATRIS operating cost remained within agreed budget limits. Resource allocation was in line with the budget approved by the Board of Governors. In accordance with the Board's decision, the negative operating result of -15k, which is considerably lower than the foreseen -258k in the approved budget, is covered by the reserves of EATRIS.

	Annual report 2016	Approved budget 2016	Annual report 2015
	€	€	€
Member countries	1,423,677	1,175,000	1,578,052
Project/subsidy income	344,367	289,500	147,014
Catch up budget		258,113	
Total income	1,768,044	1,722,613	1,725,066
Salaries and wages	844,849	775,341	808,155
Sub total staff	196,852	421,772	239,374
Personnel expenses	1,041,701	1,197,113	1,047,529
Depreciation	8,404	5,000	7,112
Other expenses	733,744	520,500	769,586
Total expenses	1,783,849	1,722,613	1,824,227
Total operating result	-15,805	0	-99,161

Analysis of the balance sheet

The figures in this chapter are derived from the audited financial statements 2016 of EATRIS ERIC accompanied by the auditor's report dated April 12, 2017.

	2016	2015	Analysis
Activa	€′000	€′000	
Tangible fixed assets	20	16	The book value of the tangible fixed assets
			increased as a result of acquired assets.
Current receivables	391	200	The increase is due to two outstanding
			contributions at the year end of 2016, whereas last year only one contribution
			receivable was outstanding at year end.
Cash at banks	788	1,231	Cash at banks decreased due to an
	1,199	1,447	increase in current receivables and a decrease in accured liabilities.
	2016	2015	Analysis
Equity & liabilities	€′000	€′000	
Reserves	679	695	The reserve was adjusted with a net of
			€16K, equal to the negative operating result of the financial year.
Current liabilities	520	753	The decrease is caused by the other
	1,199	1,447	liabilities and accrued expenses. Primarity due to the advance receipt of subsidy money in 2015, which was still applicable during 2016.

TEAM



Frank de Man

Governance & Finance



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Tim Moser

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Scientific Director



Martin de Kort

Programme Manager Imaging & Tracing and Small Molecules platform



Kees de Ruig

Business Development Manager



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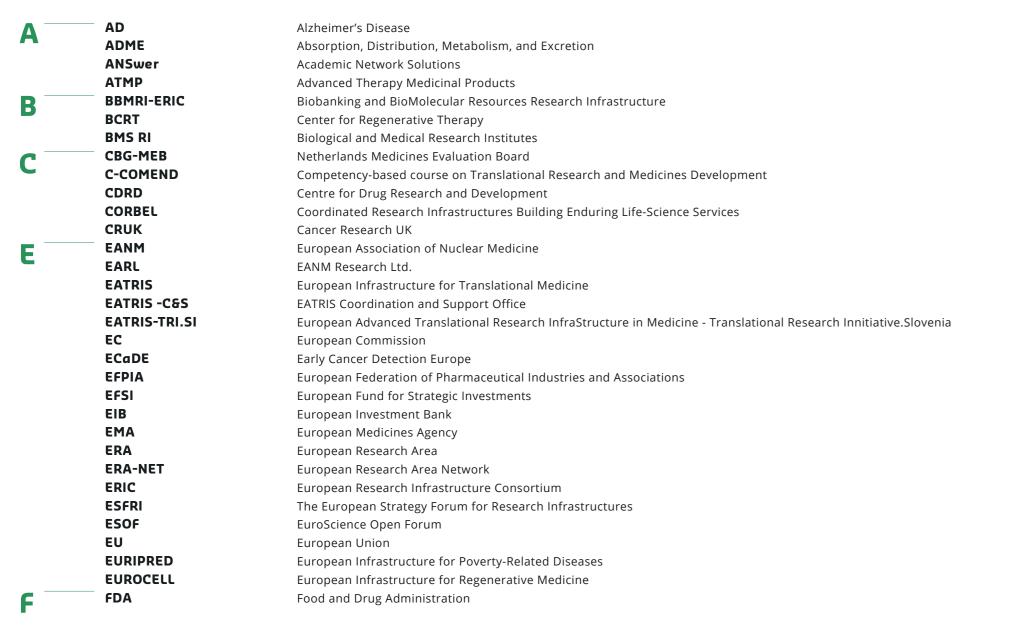
Legal Counsel

Petra Grunhagen



Office Manager

GLOSSARY





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