ANNUAL REPORT 2015

eatris

European infrastructure
for translational medicine

NEW EATRIS LOGO IN 2016!

EATRIS

European Infrastructure for
Translational Medicine

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TABLE OF CONTENTS

ACRONYMS

ADME	Absorption, Distribution, Metabolism, and Excretion
ATMP	Advanced Therapy Medicinal Products
BBMRI-ERIC	Biobanking and BioMolecular Resources Research Infrastructure
BMS RI	Biological and Medical Research Institutes
BSL-3	Biosafety level 3
CBG-MEB	Netherlands Medicines Evaluation Board
C-COMEND	Competency-based course on Translational Research and Medicines Development for PhDs and Post-docs
CDRD	Centre for Drug Research and Development
CORBEL	Coordinated Research Infrastructures Building Enduring Life-Science Services
CRUK	Cancer Research UK
DSP	Downstream Process
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
EDRN	Early Detection Research Network
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSI	European Fund for Strategic Investments
EMA	European Medicines Agency
EPR	Enhanced Permeability and Retention
EPSRC	Engineering and Physical Sciences Research Council
ERA-NET	European Research Area Network
ERIC	European Research Infrastructure Consortium
ESFRI	The European Strategy Forum for Research Infrastructures
EUPATI	European Patients' Academy on Therapeutic Innovation
EURIPRED	European Infrastructure for Poverty-Related Diseases
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HTS	High-Throughput Screening
IMI2	Innovative Medicines Initiative 2
IPROVE	Innovation Partnership for a Roadmap on Vaccines in Europe
ISCT	International Society for Cellular Therapy
MoU	Memorandum of Understanding
NCI-US	The U.S National Cancer Institute
NIH-NCATS	US National Institutes of Health National Center for the Advancement of Translation Science
NIH NCI	National Institutes of Health - National Cancer Institute
NRDD	Nature Reviews Drug Discovery
PAC	Patient Advisory Committee
PET/CT	Positron Emission Tomography - Computed Tomography
PPP	Public Private Partnership
RI	Research Infrastructures
RI-TRAIN	Research Infrastructures Training Programme
SMEs	Small and medium-sized enterprises
SOP	Standard Operation Procedure
TB	Tuberculosis
TBVI	Tuberculosis Vaccine Initiative
TIA	Therapeutic Innovation Australia
UHF-MRI	Ultra High Field MRI
USP	Upstream Process
VC	Venture Capitalist
VE	Vaccines Europe
WP	Work Packages

1. FOREWORD

FOREWORD: OPERATIONS & FINANCE DIRECTOR

Anton Ussi, MSc

Dear reader,
We proudly present to you our annual report for 2015. Just like all preceding years in the short history of EATRIS - and no doubt many more to come - 2015 was an exciting continuation of our journey towards better output of novel medicines, diagnostics and vaccines in Europe.

In our second year of operations, we focused heavily on increasing EATRIS' profile, through active marketing of our excellent catalogue of translational research services, professionalising our communications efforts, and cultivating the varied relationships so crucial to success in this multi-disciplinary field. We are happy to report that this is yielding results; we have seen growth in all relevant metrics – more and more researchers and small companies are approaching us for services, we have ongoing projects and explorations with several medium and large pharma companies, the competitive funding proportion of our operating budget is increasing steadily, and the feedback we are receiving from all stakeholders is very positive. And we remain committed to being a learning organisation, receptive to feedback and constantly interacting with our stakeholders to learn of real needs on the work-floor of biomedical R&D.

2015 was also a year of continuing to form the long term infrastructure projects that will help us reach the main goal of a more productive innovation pipeline. Notable examples include our interactions with the regulatory agencies, our continued development of EATRIS Inside as a solution for public and non-profit funders, and our global collaborative with infrastructures on several other continents. And finally, we welcomed with open arms Sweden into the EATRIS family of member countries. In the few short months that we have been working together, we already start to bear the fruits in the form of company interactions that may lead to projects, and are integrating the world class capabilities into our infrastructure offering.

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

Sincerely,

Anton Ussi
Operations & Finance Director, EATRIS

FOREWORD: CHAIR OF THE BOARD OF NATIONAL DIRECTORS

Marian Hajduch

Dear Reader,

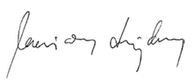
As the Chair of the Board of National Directors, it is with pleasure that I look back on the activities of EATRIS-ERIC in 2015. 2015 represented our second year of full-scale operations and with it significant progress towards realizing the EATRIS vision and mission and serving the needs of our many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

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

Some of our key accomplishments in 2015 include: a marked increase in matchmaking projects which saw EATRIS acquire and develop projects of high translational merit with big pharma, multiple SMEs and academia. 2015 also marked the beginning of positive dialogue with the EMA as we seek to bridge the gap between our drug development pipeline and the complex regulatory environment. This year saw a substantial increase in EATRIS participation in EU-funded projects including EATRIS involvement in a number of Horizon2020 projects, which will serve as key initiatives in the coming years. We continued to seek greater collaboration with the learned societies as we aim to combine resources and expertize in specific disease and treatment areas. With these initiatives and more, we also continued to develop our education and training portfolio where 2015 saw EATRIS develop and contribute to successful workshops in teaching academics and industry stakeholders alike how to overcome some of the many challenges in translational medicine development.

EATRIS remains dedicated to driving innovation and promoting the highest standards of quality and integrity in translational research and drug development. Our continued growth and success is driven by the collaborative spirit of our infrastructure of now over 70 world-class institutions and growing, with a view of developing the right drug for the right patient in the most efficient way and as a result, benefiting our society as a whole.

Sincerely,



Marian Hajduch,
Chair of the Board of National Directors

FOREWORD: CHAIR OF THE BOARD OF GOVERNORS

Maria Ferrantini, PhD

Dear Reader,

As the Chair of the Board of Governors, I am happy to share with you the achievements of EATRIS in 2015, which are highlighted in this Annual Report.

Importantly, the EATRIS ERIC family has grown with Sweden joining as an observer and already contributing to EATRIS product platforms with two institutes. In addition, five new institutions from EATRIS countries have been included in the infrastructure. In May, the second EATRIS conference “Building Bridges in Translational Medicine” offered a unique forum for examining new ways for de-risking translation and drug development through effective collaboration with industry.

The EATRIS portfolio of public-private collaborations with companies from the diagnostics, biotech and pharmaceutical sectors continued to grow and related marketing activities were established.

During the last year, the EATRIS participation in projects funded by the European Commission substantially increased. With the important contribution of EATRIS, the “Innovation Partnership for a Roadmap on Vaccines in Europe” (IPROVE) launched a strategy setting out a vision for vaccine research and innovation in Europe over the next 20 years. In the context of Horizon 2020, EATRIS is actually contributing to two highly relevant 4-year projects, CORBEL (Coordinated Research Infrastructures Building Enduring Life-Science Services) and RI-TRAIN (Research Infrastructures Training Programme, on the training of management staff of research infrastructures), which together will strengthen EATRIS’ synergies and collaborations with other Biological and Medical Sciences Research Infrastructures. Of note is also the EATRIS coordination of C-COMEND (Competency-based course on Translational Research and Medicines Development for PhDs and Post-docs), a two-year European project supported by the Erasmus plus programme for training of PhD students and Post-docs in medicines development.

Considering these developments, EATRIS is destined to a bright future. High expectations for the growth and utilisation of the EATRIS ERIC infrastructure in Europe and globally are held by the Board of Governors. The EATRIS ERIC Members and Observers will continue to work together in the future to support EATRIS meeting these expectations.

Sincerely,

Maria Ferrantini, PhD
Chair Board of Governors

2. INTRODUCTION

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.

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

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

EATRIS is a non-profit European Research Infrastructure Consortium (ERIC). Our institutions are selected on the basis of their track record in public-private collaboration in translational development and their multidisciplinary teams of leading academic experts, high-end research facilities, production laboratories and licenses.

EXECUTIVE SUMMARY

With 2015, EATRIS entered in its second year of operations and continues engaging with the scientific community for supporting the development of high-potential medicines and diagnostics that meet patients' needs and positively impact their health outcome.

EATRIS Services:
EATRIS offers a comprehensive set of translational research services via its 'one-stop shop'. It allows access to the technical expertise and resources provided by the institutions together with additional knowledge brought on board as needed, including legal, intellectual property and regulatory expertise.

In 2015, EATRIS engaged more actively in outreach and marketing of its services with approaching more than 100 companies with the support of the EATRIS Product Platform chairs and during partnering meetings. Those interactions confirmed the need for efficient public-private partnership and fast access to academia's high-end facilities.

As a result, EATRIS supported the exploration of three large translational drug development projects involving multiple EATRIS sites, along with several more one-to one projects.

The number of interactions and leads is climbing steadily as a result of the marketing and gradual increase in awareness, through EATRIS branding activities. We expect many more projects to be initiated in 2016.

Long-term EATRIS Infrastructure Development:
In 2015 we supported a considerable portfolio of long-term initiatives that ultimately are intended to ease one or more bottlenecks in medicines development, whether operational or technical. These long-term initiatives result from interactions with various stakeholders and international players in the field of translational medicine.

In 2015, several early-stage long-term infrastructure projects were advanced with the drafting of concept papers and engagement with the relevant stakeholders in the field. As an example, in 2015 a meeting with the European Medicines Agency (EMA) was organised to explore the opportunities in structural interaction with academia. Similarly, EATRIS started working as lead representative on a concept for a personalized medicine innovation pipeline, in collaboration with the BMS RIs group.

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

We also welcomed Sweden to the EATRIS family of countries. The coordination team has made a flying start to developing the Swedish node and participation, and the first industry contacts have been made.

Education and Training:
In 2015 EATRIS delivered its first in-house trainings, with two face-to-face courses in the ATMP field. In addition, since November EATRIS is coordinating the Erasmus+ project C-COMEND, which will develop and deliver face-to-face and e-learning training on translational research and medicines development for PhDs and early postdocs.

EATRIS Conference 2015:
In May 2015, EATRIS held its second conference, entitled 'Building Bridges in Translational Medicine'. This two-day conference, attended by approx. 250 stakeholders and key opinion leaders in the field of translational medicine, focused on how to access and mobilise the proper expertise in such a way that mitigates project risk and optimises translation and drug development.

3. SERVICES AND INFRASTRUCTURE

The long-term goal of EATRIS is to improve the output of high-potential medicines and diagnostics that meet patients' needs and impact their health outcomes positively. In 2015 we focused on two main areas of activity:

- Serving as a matchmaker for academic translational research capabilities, 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.

Services

Given that translational research is a multi-disciplinary, multi-stakeholder undertaking, each project requires access not only to technical expertise and infrastructure, but also insights into legal, intellectual property, regulatory, product development, and many other areas of expertise. This has been formalised into a set of services which EATRIS offers via its 'one-stop shop' matchmaking process or directly to funders via EATRIS-Inside or EATRIS-Impact. Thus clients are served primarily through the technical services provided by the EATRIS institutions, while additional expertise is brought on board as needed, either provided centrally by C&S or from institutions, depending on the requirements and availability.

Results

Reaching project agreements takes time and is highly dependent upon projects' complexities and the number of participating institutes. As an example, throughout 2015 we continued supporting three projects under exploration for one large pharma company. Each project involves complex timelines, numerous interdependencies and - in two cases - more than one EATRIS institution. We expect project agreements to be signed in Q1-Q2 2016 for the three projects. Another project involving biomarker validation initiated at the end of 2014 will reach completion in early 2016.

In 2014, EATRIS initiated its marketing strategy and first approach to clients, especially with its first participation to Bio-Convention and Bio-Europe. In 2015 we implemented a more systematic approach and follow-up to strengthen the marketing and engagement with clients. Participation to partnering events increased together with the drafting and distribution of targeted communication materials (such as the platform technology leaflets, see pages 19, 21, 23, and 27). As a result, the number of leads doubled in 2015 and five new letters of engagement for matchmaking were signed. Among them was one project involving a staphylococcus aureus challenge study for a vaccines SME which was successfully initiated and completed (see page 24).

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

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

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

In 2015, EATRIS kept offering fast-match-making using the EATRIS database. EATRIS fast matchmaking helps to quickly and objectively identify potential partners with the skills and facilities needed for any project and to build the optimal consortium to apply to national and European calls. Under an E-Rare3 call (ERA-NET for Research Programme on Rare Diseases) applicants were encouraged to utilise the services offered by EATRIS.

The year 2014 marked the introduction and successful piloting of the EATRIS-Inside service in The Netherlands. Through EATRIS-Inside, the translational feasibility of projects on elements like the best utilisation of high-end infrastructure and expertise, medical need, intellectual property, regulatory pathway, and end-product definition is

Coordination Services	Description	Clients
Matchmaking	The process of matching client requests with EATRIS institutional capabilities. We provide support to reach efficiently a project agreement and facilitate partnerships (see platforms), while the EATRIS institutes execute the resulting study plans in direct collaboration with the client	**Industry, big pharma, biotech companies, SME**
Fast Matchmaking	Similar to matchmaking, the fast matchmaking is a quick way to identify potential partners for consortium building for funding applications	**Pre-funded academia or SME**
EATRIS-Inside	Through EATRIS-Inside, EATRIS assesses the translational feasibility of projects based on elements such as intellectual property, regulatory pathway, and end-product definition. This translational assessment helps to proactively identify potential gaps and bottlenecks that may obstruct project execution, and identify key enabling technologies to support robust data generation	**Funding agencies, charities, academia**
EATRIS-Impact	EATRIS-Impact Assessment is designed to support the evaluation of the overall societal impact of biomedical research projects, based on the results available at the end of the project period, plus preliminary plans for follow-on research	**Funding agencies**
Regulatory Support	The regulatory support offers early assessment of the requirements for successful translational projects and provides the necessary information to drive the development plan for innovative technologies and products. This is also an essential part of both EATRIS-Inside and -Impact services	**Any researcher or research-funding organisation**

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

Marketing activities

In order to increase the number of users accessing the translational research services, marketing activities were established in 2015 as a dedicated program performed at three levels:

1. Establishment of relationships with the Biotech branch of industrial associations;
2. Visiting and sponsoring scientific and partnering events;
3. Direct contact with potential prospects.

Biotech organisations

In order to increase the visibility of EATRIS in the member countries relationships were established with the following branch organisations:

- Denmark – Dansk Biotec
- Finland – Finnish Bioindustries
- Italy – Assobiotec
- Netherlands – HollandBio
- Sweden – SwedenBio
- Europe – EuropaBio

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

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

Partnering events

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

Some examples are:

- ISCT meeting (International Society for Cellular Therapy), Spain; EATRIS had a booth at this event;
- EANM'15 (European Association of Nuclear Medicine), Hamburg; EATRIS organised a session on translational molecular imaging to support drug development programme.

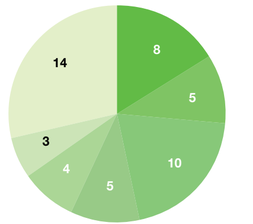
Apart from scientific meetings, we also visited various partnering and networking events:

- Innovation for Health (Feb 2015, The Netherlands – sponsored)
- Knowledge for Growth (May 2015, Belgium) Bio international Convention (June 2015, USA)
- HealthBio (Aug 2015, Finland – sponsored by the Finnish node; booth)
- Nordic Life Science Days (Sep 2015, Sweden)
- Biotechnology Partnering Conference, BIO-Europe (Oct 2015, Germany)
- BioFit academia-industry collaborations in Life Sciences (Dec 2015, France)

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

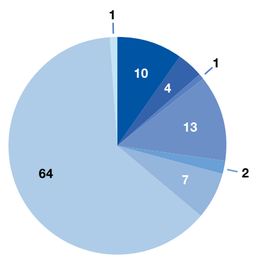
Based on the technology leaflets and backed up by platform chairs, scientific staff of over 40 companies were approached directly to seek their interest in the EATRIS services. This approach was piloted for the Imaging & Tracing and the Vaccines platforms.

Those first interactions confirmed the need for public – private efficient partnership and fast access to academia high-end facilities.



2014 - Leads

- Academia
- Charities
- Governments
- Industry
- Others
- Service Provider
- SME / Biotech Companies



2015 - Leads

- Academia
- Charities
- Governments
- Industry
- Others
- Service Provider
- SME / Biotech Companies
- VC

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		●			
	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.			●		
	Institute of Experimental Medicine AS CR	●				
Denmark	Århus University Hospital - Institut for Klinisk Medicin			●		
	Statens Serum Institute (SSI)					●
	The Hevesy Laboratory (DTU/Riso)			●		
	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		●	●		
	VTT Technical Research Centre of Finland (VTT)		●			
France	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 Biôêtre - Paris Sud (NBPS)	●		●		
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	●	●			●

	Account Name	ATMP	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
Italy	Istituti Fisioterapici Ospitalieri - Istituto Dermatologico "San Gallicano"					●
	Istituto Dermopatico 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)	●		●		
	IRCCS Instituto Ortopedico Galeazzi	●	●			
	The Italian NIH (ISS)	●	●	●	●	●
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)		●	●		
	Central Veterinary Institute (CVI)					●
	Netherlands Cancer Institute		●			
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)	●	●			
	Insitute of Biomedicine of Seville (IBIS)	●	●	●		●
	Instituto Ramón y Cajal (IRYCIS)		●			●
	University Hospital La Princesa (IIS-IP)	●	●	●		
	Vall d'Hebron Research Institute (VHIR)	●	●	●	●	
	INCLIVA	●	●	●	●	
Sweden	Sweden: Uppsala University coordinating, consortium under construction					
	Total	**30**	**37**	**33**	**17**	**13**

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.
Institute of Experimental Medicine AS CR

DK Denmark
Århus University Hospital - Institut for Klinisk Medicin
Statens Serum Institute (SSI)
The Hevesy Laboratory (DTU/Riso)
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)

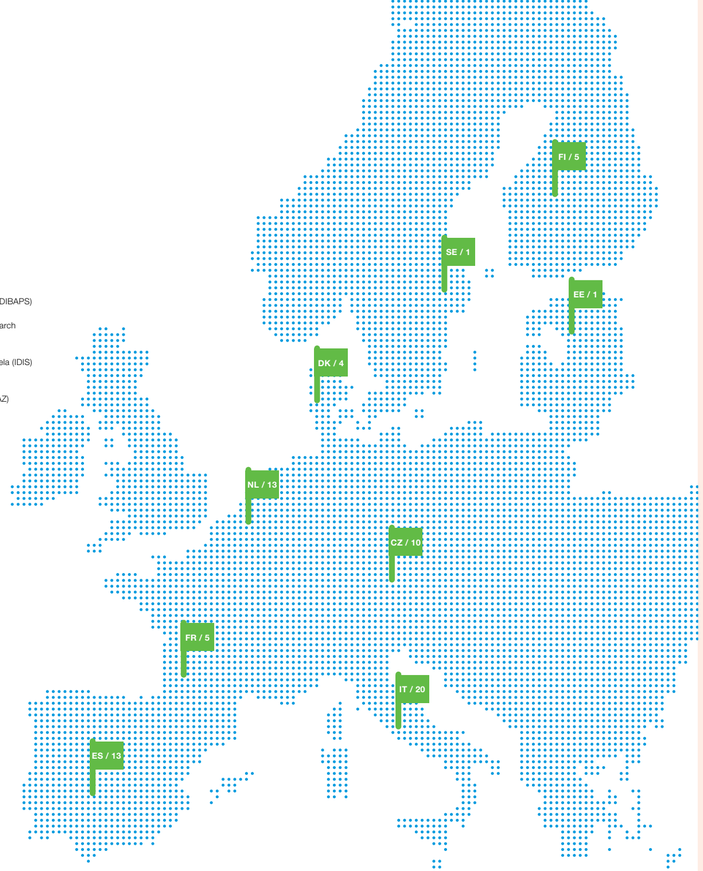
FR France
Neuratris-Albert Chevalier-Henri Mondor Hospital
Neuratris-Biotherapies Institute for Rare Diseases (BIRD)
Neuratris-Brain & Spine institute IHU-A-ICM
Neuratris-French Alternative Energies and Atomic Energy Commission (CEA)
Neuratris-Neurosciences Bicêtre - Paris Sud (NBPS)

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 Dermopatico 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)
IRCCS Instituto Ortopedio Galeazzi
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)
Central Veterinary Institute (CVI)
Netherlands Cancer Institute

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)
Insitute of Biomedicine of Seville (IBIS)
Instituto Ramón y Cajal (IRYCIS)
University Hospital La Princesa (IIS-IP)
Vall d'Hebron Research Institute (VHIR)
INCLIVA

SE Sweden
Uppsala University Coordinating, Consortium
Under construction



HIGHLIGHT: SWEDEN NEW MEMBERSHIP

In 2015, Sweden joined EATRIS as a full-fee observing member, with first goals to establish a national node and to identify the most relevant Swedish infrastructure to complement the already established set of infrastructure services that exist within EATRIS. The Swedish Coordination Center is located in Uppsala and involves a National Director (Erik Ingelsson) and a National Coordinator (Ulrika Bäckman). During the past year, the Swedish node has inter alia achieved the following:

- Key persons responsible for infrastructures at all Swedish universities have been identified for presentation of EATRIS, in order to make the initiative national.
- A roadmap describing suitable infrastructures available at Swedish universities and how to approach them has been developed and managers have been contacted.
- To reach SMEs and academic researchers, innovation offices have been approached to identify the proper mechanisms for presenting EATRIS

EATRIS COORDINATION & SUPPORT TEAM OVERVIEW

Giovanni Migliaccio, PhD
Scientific Director

Anton Ussi, MSc
Operations and Finance Director

Frank de Man, LLM, PhD
Governance & Strategy

Florence Bietrix, PhD
Operations Manager, Product Platform Manager Biomarkers

Martin de Kort, PhD
Product Platform Manager Imaging and Tracing and Small Molecules

Petra van der Valk
Office Manager

Oskar Uzun, LLM
Legal Counsel

Rebecca Ludwig, PhD
Education & Training Manager

Tim Moser , MSc, MBA
Industry Partnering Specialist

Anne-Charlotte Fauvel, MA
EU Coordinator

David Morrow, PhD MBA
Product Platform Manager ATMP and Vaccines

Josephine Sanders
Team Assistant

Kees de Ruig, MSc MBA
Business Development Manager

Nigel Wagstaff, PhD CCHem MRSC
Innovation

Joost Wesseling, MSc
Marketing & Communication Manager

PRODUCT PLATFORMS OVERVIEW

Giovanni Migliaccio, PhD
EATRIS Scientific Director

Product Platform Overview

EATRIS is organised along five product platforms: Advanced Therapy Medicinal Products (ATMP); Biomarkers; Imaging & Tracing; Small Molecules; and Vaccines. Each platform offers a specific set of infrastructure services to be targeted at specific users, namely: industry; academia; charity funders and governments. These services are accompanied by infrastructure development projects designed to overcome the significant 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 infrastructures and licenses;
- Clinical expertise with access to broad array of patient cohorts (including rare diseases).

EATRIS institutions work to top quality level according to the standards and certifications required for the particular studies, offering a complete translational pipeline via distributed infrastructure (using hub-and-spoke model whereby C&S acts as the coordinating hub).

In 2015, several new centres have joined EATRIS. The expanded capacity of the infrastructure is progressively covering all the needs for translational tools and making them accessible to the researchers.

Support tools in fields like legal and regulatory have been designed and are now entering the implementation phase, with plans to open access to internal and external stakeholders. A new model of combined meeting of the platform members was developed in 2015 and implemented successfully in 2016 resulting in the identification of a number of cross-platform projects targeted to specific gaps and bottlenecks in the translational pipeline.

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

In the following product platform sections, our work in these areas will be further elaborated.

IMAGING & TRACING PLATFORM

Prof. Otto Boerman, Chair
Radboudumc, The Netherlands

Prof. Bert Windhorst, Co-chair
VU Medical Centre, The Netherlands

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

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

Institutions in Spain (INCLIVA, Madrid) and Sweden (Uppsala University) were welcomed into the imaging platform as new members, with their capabilities in high-end translational imaging technologies. With strong translational centres joining (currently 39), the arsenal of available tracers and capacity to develop novel compounds (e.g. C-11, F-18) for druggable targets in various therapeutic areas continues to expand. This will further contribute to the platform's mission to establish advanced translational imaging as an indispensable tool for the monitoring of drug exposure, drug effects and disease progression, and the selection of optimal therapeutic dose/dose range and stratification of patient population.

In October, EATRIS together with EARL/EANM organised a joint pre-congress symposium at the annual meeting, EANM'15 in Hamburg, Germany, entitled "Translational Molecular Imaging to Support Drug Development". EATRIS experts presented key aspects on the quality aspects for translation and quantitative imaging while invited speakers portrayed the current state of the art in PET applications biologicals (B.M. Zeglis, New York) and small molecules (C. Halldin, Stockholm).

Immuno PET imaging, involving Zr-89 labelling, is established as platform service allowing the detailed study of the pharmacodynamics, kinetics and targeting of antibodies, peptides and nanomedicines.
An information package with SOPs has been made available to the EATRIS network to save time and resources and make a head start for regulatory compliant production of radiolabelled (bio)pharmaceuticals, by adapting these documents to the local situation.

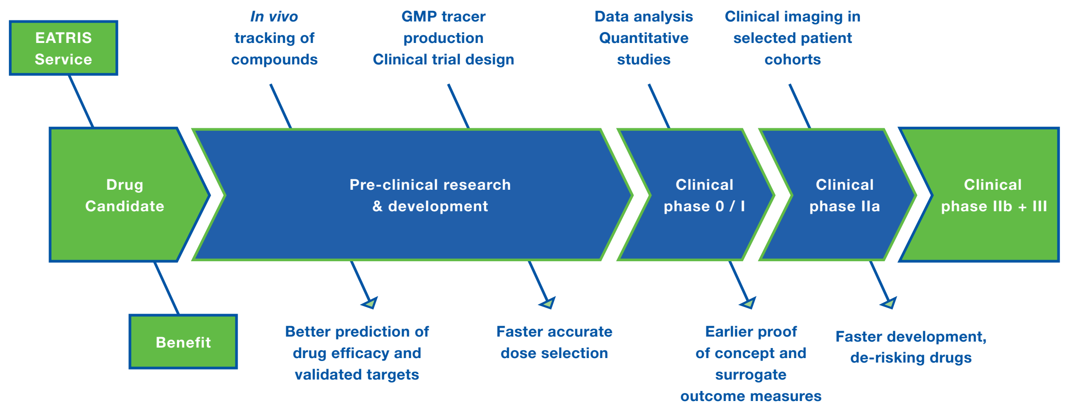
The technology leaflets describing the platform service offering (PET imaging, tracers

development and UHF/MRI) were utilised at various conferences and partnering meetings including Bio-Convention and Bio-Europe and the targeting of industry contacts will continue to be actively pursued via EATRIS Key Opinion Leaders.

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

EARL is the EANM Research Ltd initiative (earl.eanm.org) to promote multicentre nuclear medicine and research through harmonisation and standardisation of (PET) image acquisition and quantitative data analysis. EATRIS and EARL are jointly developing a novel pilot calibration programme for harmonisation of clinical PET/CT imaging involving Zirconium-89 (Zr-89). The goal of the program is to enable multi-centre trials utilising harmonised Zr-89 PET/CT imaging to support drug development. The testing phase involving 3 institutions was successfully concluded in 2015 and the pilot phase is underway with 7 sites within the EATRIS network. In the future more than 120 FDG-accredited sites will be eligible for the program. Prof. Ronald Boellaard (UMCG, Groningen, The Netherlands), chair of EARL FDG PET/CT accreditation programme, presented an update of the accreditation programme development at the EANM'15 meeting.

EATRIS Imaging & Tracing Platform provides in the following translational domains:



EATRIS

TRACERS: IN VIVO IMAGING OF DISEASE SPECIFIC MARKERS IN DRUG & DIAGNOSTICS DEVELOPMENT

DECREASE RISK, IMPROVE INSIGHTS, AND INCREASE VALUE

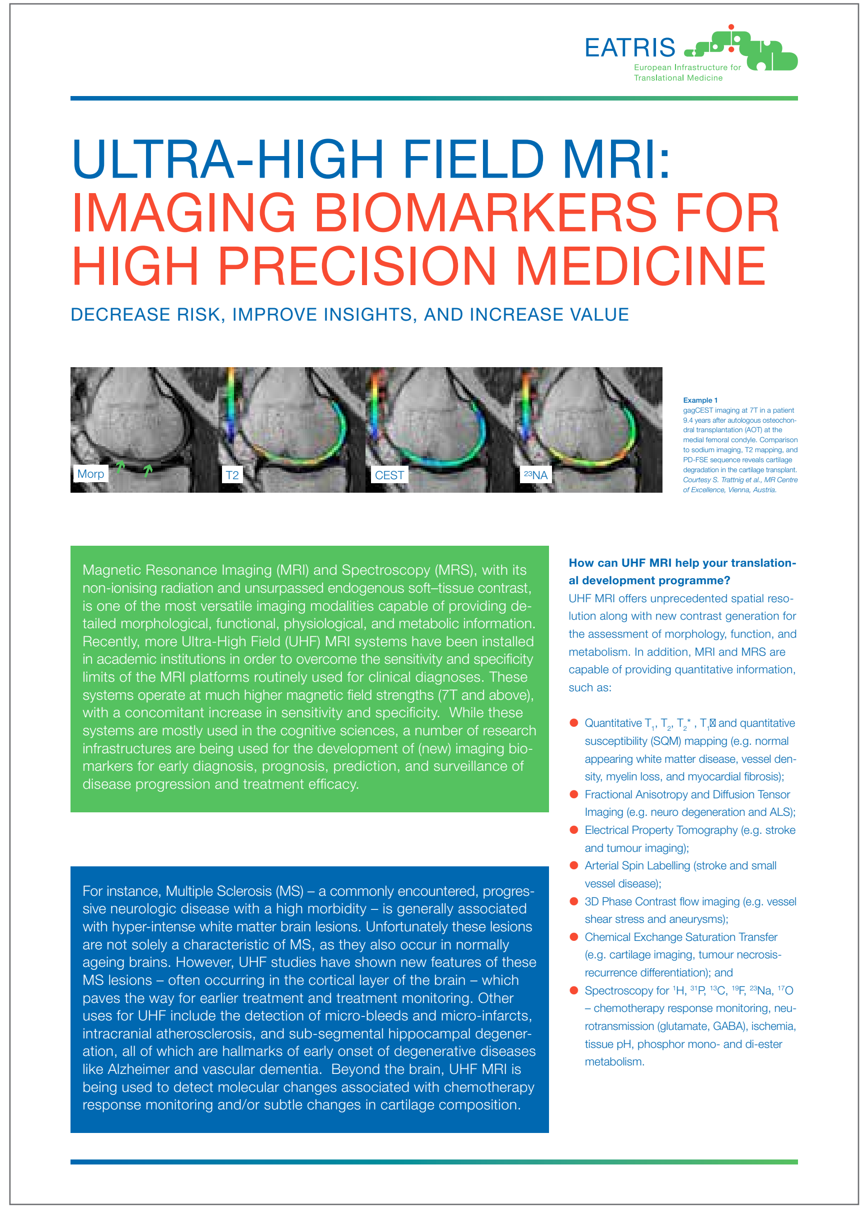
A key challenge in drug development is the adequate and expedite selection of the most promising candidates, while excluding compounds with unfavourable properties to prevent late-stage failures. Tracer compounds used in PET or optical molecular imaging are capable of visualising and quantifying of *in vivo* biomarkers at high specificity and sensitivity.

Tracers have become indispensable tools as 'disease-specific contrast agents' in providing a wealth of information when it comes to novel drug-target interactions and clarifying molecular pathophysiology. Upon labelling of these compounds/cells, molecular imaging can serve to: track targeted drugs—like monoclonal antibodies, peptides, small molecules etc.—carrier systems like liposomes, or cells *in vivo*. Additionally, by using the appropriate tracers, molecular imaging can be used to assess the effect of unlabelled pharmaceuticals on critical disease processes. Tracers can be used for initial diagnosis and prognosis, for treatment selection, and for outcome monitoring with the same techniques applicable *in vivo* in animals and in humans. The EATRIS consortium offers clients validated methods, high-end infrastructure, the skill sets to visualise and quantify tracers, and the expertise to process and interpret images.

How can tracers guide your (pre)clinical drug development programme?

- Accurate delineation and identification of disease to be targeted by the drug;
- Target validation in translational animal models;
- Picomolar level detection of disease-specific contrast agent, substrate, or receptor ligand;
- Detailed study of pharmacokinetics/pharmacodynamics with non-invasive quantification;
- In vivo assessment of dose-dependent receptor occupancy in target tissue;
- Target engagement in competitive binding studies with unlabelled pharmaceuticals;
- Tissue distribution, tissue blood flow;
- Response measurements of target tissue: metabolic, gene expression, enzyme activity, etc.;
- Correlation of receptor occupancy with drug plasma kinetics and efficacy;
- Accurate detection of drug threshold levels (efficacy versus side effects), optimising dose regimen; and
- Correlation of non-responders with drug receptor occupancy and tissue distribution.

"The development of pharmaceuticals for CNS disorders is challenging due to inherent difficulties in providing evidence of pharmacodynamics CNS effects in early human trials. For this reason PET data on target engagement has proven to be one of the most useful tools in guiding dose selection for further phase 2 trials in patients."
- Juha Rouru, Head of Therapy Area, CNS, at Orion Pharma



EATRIS

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

DECREASE RISK, IMPROVE INSIGHTS, AND INCREASE VALUE

Morp | T2 | CEST | ^{23}NA

Example 1
gagCEST imaging at 7T in a patient 9.4 years after autologous osteochondral transplantation (AOT) at the medial femoral condyle. Comparison to sodium imaging, T2 mapping, and PD-FSE sequence reveals cartilage degradation in the cartilage transplant. *Courtesy S. Trattnig et al., MR Centre of Excellence, Vienna, Austria.*

Magnetic Resonance Imaging (MRI) and Spectroscopy (MRS), with its non-ionising radiation and unsurpassed endogenous soft–tissue contrast, is one of the most versatile imaging modalities capable of providing detailed morphological, functional, physiological, and metabolic information. Recently, more Ultra-High Field (UHF) MRI systems have been installed in academic institutions in order to overcome the sensitivity and specificity limits of the MRI platforms routinely used for clinical diagnoses. These systems operate at much higher magnetic field strengths (7T and above), with a concomitant increase in sensitivity and specificity. While these systems are mostly used in the cognitive sciences, a number of research infrastructures are being used for the development of (new) imaging biomarkers for early diagnosis, prognosis, prediction, and surveillance of disease progression and treatment efficacy.

For instance, Multiple Sclerosis (MS) – a commonly encountered, progressive neurologic disease with a high morbidity – is generally associated with hyper-intense white matter brain lesions. Unfortunately these lesions are not solely a characteristic of MS, as they also occur in normally ageing brains. However, UHF studies have shown new features of these MS lesions – often occurring in the cortical layer of the brain – which paves the way for earlier treatment and treatment monitoring. Other uses for UHF include the detection of micro-bleeds and micro-infarcts, intracranial atherosclerosis, and sub-segmental hippocampal degeneration, all of which are hallmarks of early onset of degenerative diseases like Alzheimer and vascular dementia. Beyond the brain, UHF MRI is being used to detect molecular changes associated with chemotherapy response monitoring and/or subtle changes in cartilage composition.

How can UHF MRI help your translational development programme?
UHF MRI offers unprecedented spatial resolution along with new contrast generation for the assessment of morphology, function, and metabolism. In addition, MRI and MRS are capable of providing quantitative information, such as:

- Quantitative T_1, T_2, T_2^*, $T_{1\rho}$ and quantitative susceptibility (SQM) mapping (e.g. normal appearing white matter disease, vessel density, myelin loss, and myocardial fibrosis);
- Fractional Anisotropy and Diffusion Tensor Imaging (e.g. neuro degeneration and ALS);
- Electrical Property Tomography (e.g. stroke and tumour imaging);
- Arterial Spin Labelling (stroke and small vessel disease);
- 3D Phase Contrast flow imaging (e.g. vessel shear stress and aneurysms);
- Chemical Exchange Saturation Transfer (e.g. cartilage imaging, tumour necrosis-recurrence differentiation); and
- Spectroscopy for ^{1}H, ^{31}P, ^{13}C, ^{19}F, ^{23}Na, ^{17}O – chemotherapy response monitoring, neurotransmission (glutamate, GABA), ischemia, tissue pH, phosphor mono- and di-ester metabolism.

ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP) PLATFORM

Dr. Maria Cristina Galli, Chair
Istituto Superiore di Sanità, Italy

Dr. Miguel Chillon, Co-Chair
VHIR, Spain

David Morrow
Product Platform Manager
EATRIS C&S, The Netherlands

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

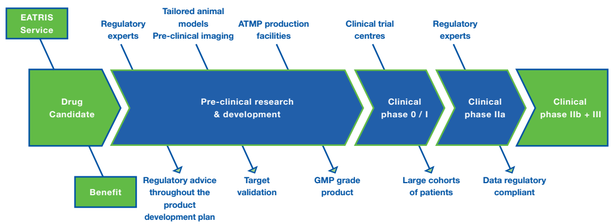
The ATMP platform organized two educational workshops in 2015, the first being the "Introductory ATMP Development Regulatory Course" in Rome in September, which consisted of 9 speakers and 29 registrants from academia, SMEs and pharma. This was followed by an additional course in "Development of Advanced Therapy Medicinal Products" in collaboration with Ri.MED in Palermo in November. This international workshop consisted of 9 speakers with 79 registrants again from academia, SMEs and pharma. Both courses offered intense programs with key opinion leaders providing lectures and panel discussions on the ATMP development pipeline and the gaps that presently exist.

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

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

In 2016, this partnership will be developed to promote mutual marketing, the establishment of Cell Therapy educational courses in Europe and the possible joint development of research agendas.

EATRIS ATMP Platform provides support in the following translational domains:



EATRIS
European Infrastructure for Translational Medicine

ACADEMIC GMP MANUFACTURING: ADVANCED THERAPY MEDICINAL PRODUCTS

ACCESS EXPERTISE, IMPROVE QUALITY, DECREASE RISK

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

Complete workflow from manufacturing with documentation QA/QC, Drug Master File filing, distribution under GDP traceability to therapy or disease-specific regulatory assistance and clinical trials in joint academic medical centres.

Technical and scientific **expertise**, in addition to product development and RA, presenting an effective option for development and early-stage clinical trial manufacturing. EATRIS offers therapy-specific knowledge and **flexibility** in production.

Assay validation along with personnel to operate and perform QA/QC. Customised training courses, GMP training for the client's personnel, and an option for clients to work on-site.

BIOMARKER PLATFORM

Prof. Alain van Gool, Chair
Radboudumc, The Netherlands

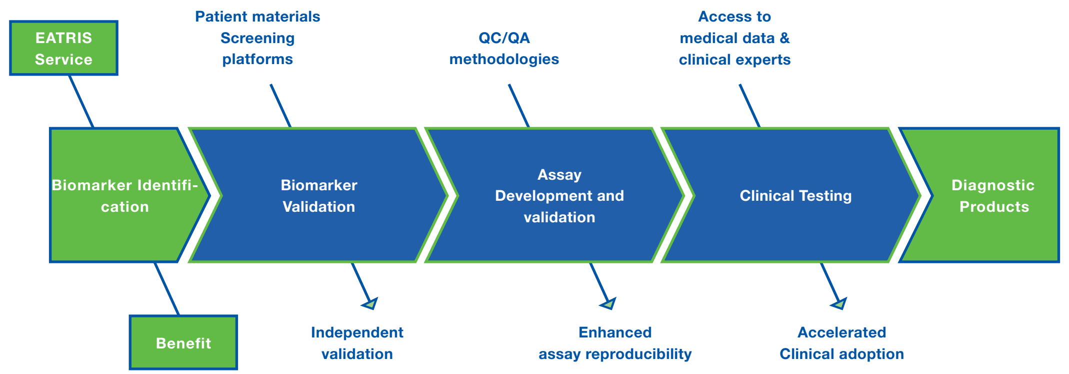
Dr. Maria Laura Garcia Bermejo, Co-Chair
IRYCIS, Spain

Dr. Andreas Scherer, Co-Chair
FIMM, Finland

Prof. Sulev Koks, Co-Chair
University of Tartu, Estonia

Florence Bietrix
Product Platform Manager
EATRIS C&S, The Netherlands

EATRIS Biomarker Platform provides support in the following translational domains:



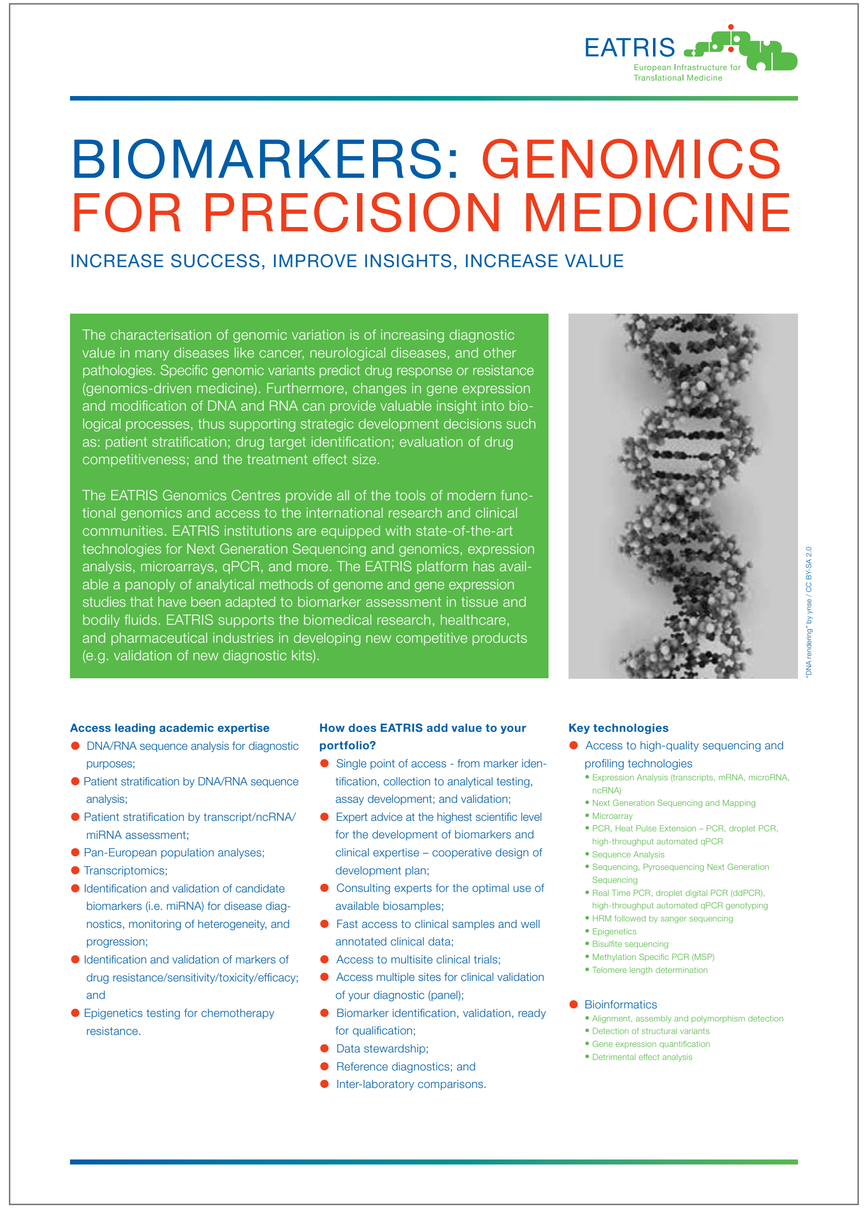
In 2015, the EATRIS Biomarker platform continued to reinforce its long-term mission to validate biomarker targets and assays for the clinic by providing access to European biobanks, assay development knowhow, and clinical expertise. In 2015, the platform reinforced its positioning for a biomarker validation platform in Europe that will support drug and diagnostics development, with the participation of three new institutions - the National Cancer Institute (NKI) in the Netherlands, the IRCCS Istituto Ortopedico Galeazzi, Italy and INCLIVA in Spain - bringing the number of European advanced biomarker development centres in the platform to 37.

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

In addition, the platform kept increasing cohesion on the international scene by organising a series of meetings with international players (i.e. ELIXIR, BBMRI (Biobanking and BioMolecular resources Research Infrasructure), NCI-US (National Cancer Institute).

In October 2015, EATRIS organised together with Cancer Research UK (CRUK) and Dr. Sudhir Srivastava, Chief Cancer Biomarkers Research Group, Early Detection Research Networks (NIH NCI - EDRN) organised a workshop in Brussels. The workshop consisted of an introduction of the NIH NCI – EDRN initiative to a group of European cancer funders and distinguished scientists to discuss the merits and challenges of a European alliance for early cancer detection and management. The workshop participants identified a list of challenges and priorities to be discussed in Europe. The findings will be made available in a position paper. Future collaboration and funding opportunities will be explored in 2016, driven by the steering committee, which is chaired by Prof. Gerrit Meijer, co-national director of EATRIS Netherlands.

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


EATRIS European Infrastructure for Translational Medicine

BIOMARKERS: GENOMICS FOR PRECISION MEDICINE

INCREASE SUCCESS, IMPROVE INSIGHTS, INCREASE VALUE

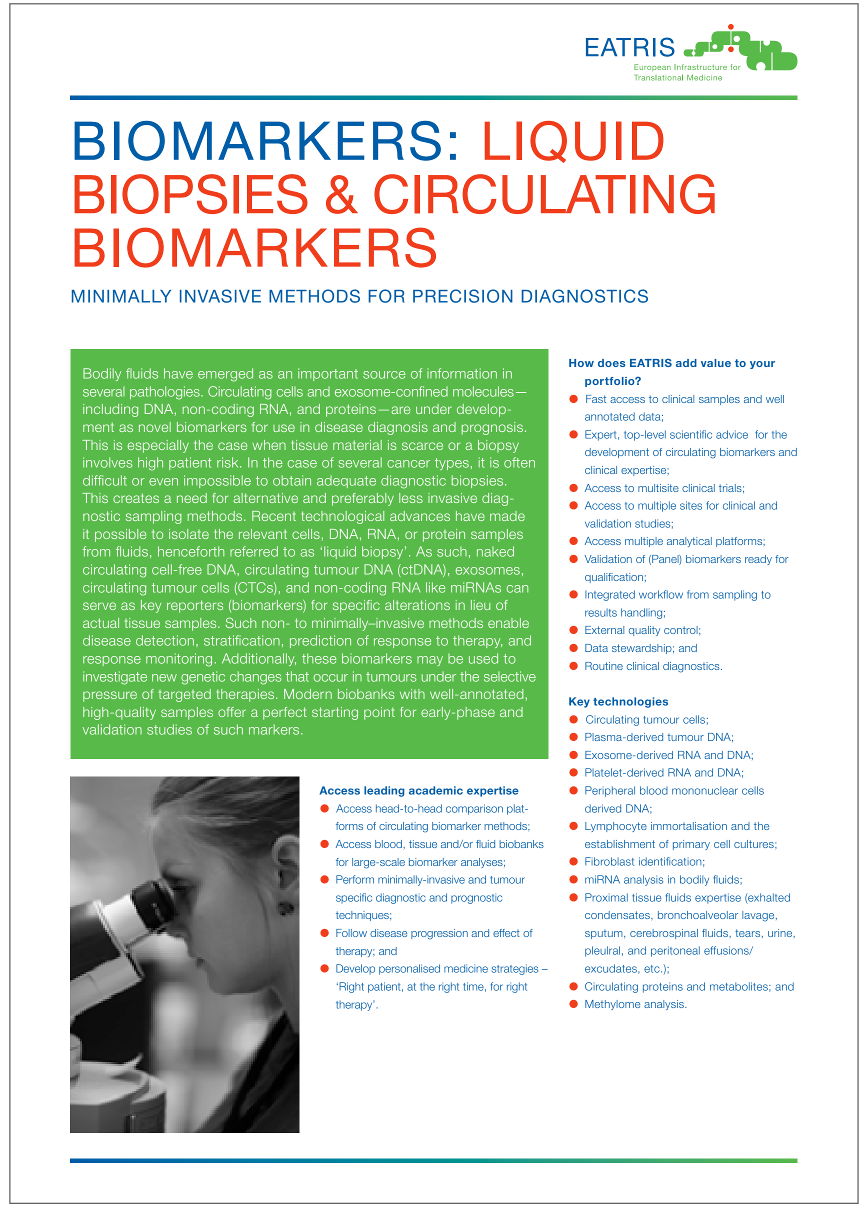
The characterisation of genomic variation is of increasing diagnostic value in many diseases like cancer, neurological diseases, and other pathologies. Specific genomic variants predict drug response or resistance (genomics-driven medicine). Furthermore, changes in gene expression and modification of DNA and RNA can provide valuable insight into biological processes, thus supporting strategic development decisions such as: patient stratification; drug target identification; evaluation of drug competitiveness; and the treatment effect size.

The EATRIS Genomics Centres provide all of the tools of modern functional genomics and access to the international research and clinical communities. EATRIS institutions are equipped with state-of-the-art technologies for Next Generation Sequencing and genomics, expression analysis, microarrays, qPCR, and more. The EATRIS platform has available a panoply of analytical methods of genome and gene expression studies that have been adapted to biomarker assessment in tissue and bodily fluids. EATRIS supports the biomedical research, healthcare, and pharmaceutical industries in developing new competitive products (e.g. validation of new diagnostic kits).

Access leading academic expertise
- DNA/RNA sequence analysis for diagnostic purposes;
- Patient stratification by DNA/RNA sequence analysis;
- Patient stratification by transcript/ncRNA/miRNA assessment;
- Pan-European population analyses;
- Transcriptomics;
- Identification and validation of candidate biomarkers (i.e. miRNA) for disease diagnostics, monitoring of heterogeneity, and progression;
- Identification and validation of markers of drug resistance/sensitivity/toxicity/efficacy; and
- Epigenetics testing for chemotherapy resistance.

How does EATRIS add value to your portfolio?
- Single point of access - from marker identification, collection to analytical testing, assay development; and validation;
- Expert advice at the highest scientific level for the development of biomarkers and clinical expertise – cooperative design of development plan;
- Consulting experts for the optimal use of available biosamples;
- Fast access to clinical samples and well annotated clinical data;
- Access to multisite clinical trials;
- Access multiple sites for clinical validation of your diagnostic (panel);
- Biomarker identification, validation, ready for qualification;
- Data stewardship;
- Reference diagnostics; and
- Inter-laboratory comparisons.

Key technologies
- Access to high-quality sequencing and profiling technologies
  - Expression Analysis (transcripts, mRNA, microRNA, ncRNA)
  - Next Generation Sequencing and Mapping
  - Microarray
  - PCR, Heat Pulse Extension – PCR, droplet PCR, high-throughput automated qPCR
  - Sequence Analysis
  - Sequencing, Pyrosequencing Next Generation Sequencing
  - Real Time PCR, droplet digital PCR (ddPCR), high-throughput automated qPCR genotyping
  - HRM followed by sanger sequencing
  - Epigenetics
  - Bisulfite sequencing
  - Methylation Specific PCR (MSP)
  - Telomere length determination
- Bioinformatics
  - Alignment, assembly and polymorphism detection
  - Detection of structural variants
  - Gene expression quantification
  - Detrimental effect analysis


EATRIS European Infrastructure for Translational Medicine

BIOMARKERS: LIQUID BIOPSIES & CIRCULATING BIOMARKERS

MINIMALLY INVASIVE METHODS FOR PRECISION DIAGNOSTICS

Bodily fluids have emerged as an important source of information in several pathologies. Circulating cells and exosome-confined molecules—including DNA, non-coding RNA, and proteins—are under development as novel biomarkers for use in disease diagnosis and prognosis. This is especially the case when tissue material is scarce or a biopsy involves high patient risk. In the case of several cancer types, it is often difficult or even impossible to obtain adequate diagnostic biopsies. This creates a need for alternative and preferably less invasive diagnostic sampling methods. Recent technological advances have made it possible to isolate the relevant cells, DNA, RNA, or protein samples from fluids, henceforth referred to as 'liquid biopsy'. As such, naked circulating cell-free DNA, circulating tumour DNA (ctDNA), exosomes, circulating tumour cells (CTCs), and non-coding RNA like miRNAs can serve as key reporters (biomarkers) for specific alterations in lieu of actual tissue samples. Such non- to minimally–invasive methods enable disease detection, stratification, prediction of response to therapy, and response monitoring. Additionally, these biomarkers may be used to investigate new genetic changes that occur in tumours under the selective pressure of targeted therapies. Modern biobanks with well-annotated, high-quality samples offer a perfect starting point for early-phase and validation studies of such markers.

How does EATRIS add value to your portfolio?
- Fast access to clinical samples and well annotated data;
- Expert, top-level scientific advice for the development of circulating biomarkers and clinical expertise;
- Access to multisite clinical trials;
- Access to multiple sites for clinical and validation studies;
- Access multiple analytical platforms;
- Validation of (Panel) biomarkers ready for qualification;
- Integrated workflow from sampling to results handling;
- External quality control;
- Data stewardship; and
- Routine clinical diagnostics.

Key technologies
- Circulating tumour cells;
- Plasma-derived tumour DNA;
- Exosome-derived RNA and DNA;
- Platelet-derived RNA and DNA;
- Peripheral blood mononuclear cells derived DNA;
- Lymphocyte immortalisation and the establishment of primary cell cultures;
- Fibroblast identification;
- miRNA analysis in bodily fluids;
- Proximal tissue fluids expertise (exhalted condensates, bronchoalveolar lavage, sputum, cerebrospinal fluids, tears, urine, pleulral, and peritoneal effusions/excudates, etc.);
- Circulating proteins and metabolites; and
- Methylome analysis.

Access leading academic expertise
- Access head-to-head comparison platforms of circulating biomarker methods;
- Access blood, tissue and/or fluid biobanks for large-scale biomarker analyses;
- Perform minimally-invasive and tumour specific diagnostic and prognostic techniques;
- Follow disease progression and effect of therapy; and
- Develop personalised medicine strategies – 'Right patient, at the right time, for right therapy'.

VACCINES PLATFORM

Dr. Jan Langermans, Chair
Biomedical Primate Research Centre
The Netherlands

David Morrow,
Product Platform Manager
EATRIS C&S, The Netherlands

In 2015 the Vaccine platform continued to move forward in providing cutting edge services for the next generation of vaccines by adopting a multidisciplinary approach. The platform, which now comprises 13 advanced vaccine development centers, provides state-of-the-art technologies and expertise including: antigen characterisation; specialised GMP manufacturing facilities covering USP and DSP; formulation & adjuvantation; animal facilities up to BSL3; animal models including non-human primates and GLP-toxicology; and immunomonitoring and clinical capacity. The vaccine platform welcomed two additional institutions in 2015, the Statens Serum Institute (SSI) in Denmark and the Central Veterinary Institute (CVI) from the Netherlands. There were 3 matchmaking projects in 2015 comprising a challenge study, a request for regulatory support and an on-going project in protein configuration analysis. Key Vaccine platform infrastructure development achievements centered on identifying and affiliating with new institutes, fostering collaborations, and implementing EU-funded projects. The latter included:

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

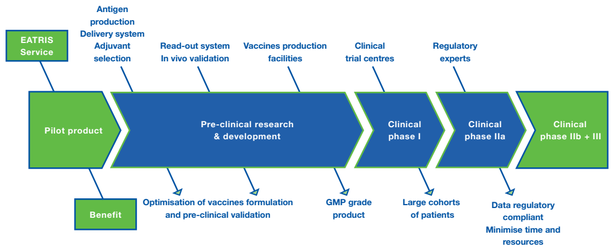
At the end of 2015 the final version of the roadmap was produced with the final summit planned for March 16th 2016 at the European Parliament in Brussels.

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

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

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

EATRIS Vaccines Platform provides support in the following translational domains:



HIGHLIGHT: IBIS-IMAXIO PARTNERSHIP

EATRIS facilitated a new partnership between IMAXIO, an integrated vaccines-focused biotech company based in France, and the Infectious Disease group of the Institute of Biomedicine of Seville (IBiS), Spain.

The initial contact with the company was initiated at the BIO USA 2014 convention in San Diego, California. The final objective of this study was to determine the efficacy of different S. aureus vaccines in a sepsis peritoneal model of infection due to *S. aureus*.

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

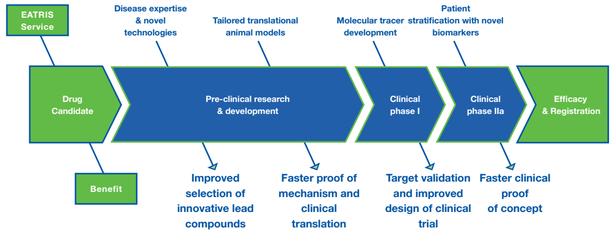
ABOUT IBiS:
The Institute of Biomedicine of Seville (Instituto de Biomedicina de Sevilla - IBiS) is a multidisciplinary biomedical research centre to undertake competitive research at an international level on the causes of the most prevalent pathologies in the population, and to develop new methods for their diagnosis and treatment. IBiS contributes to four out of five EATRIS Product Platforms, namely ATMP, Biomarkers, Imaging and Tracing and Small Molecules. (www.ibis-sevilla.es).

SMALL MOLECULES PLATFORM

Dr. Mario Salmona, Chair
Mario Negri Institution, Italy

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

EATRIS Small Molecules Platform provides support in the following translational domains:

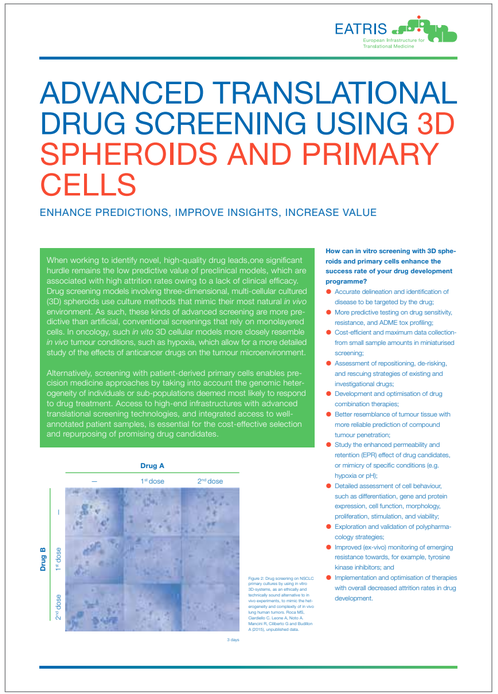


In 2015, the small molecules platform continued to work on its long-term mission to enhance the efficiency of clinical translation of novel chemical entities using cutting-edge technologies with access to patient materials and pre-clinical and clinical expertise. The strategic focus areas of the 24 European translational centres involved are advanced drug screening in 3D cultures and primary cells, peptide drugs and the pre-clinical and clinical validation of nanomedicines and -formulations. Several (fast) matchmaking requests have been handled to date which have resulted in the identification of suitable collaborators with a wide range of expertise, including rare diseases (e.g. Wolfram Syndrome), drug repositioning (orphan drug filing support), GLP-tox studies, re-formulation for topical administration, new therapeutic approaches to treat fibromyalgia and translational animal models for, amongst others, eye disease and vascular thrombosis. For the E-Rare 3 call, focused on drug repurposing, applicants were encouraged to utilise biomedical research infrastructures, like EATRIS.

Collaboration and interaction between several platform members such as the Vall dHebron (Barcelona, ES), IMTM (Olomouc, CZ), the Mario Negri Institution (Milan, IT) and IRCCS (Naples, IT) has resulted in the exchange of personnel, with the intention to expand these activities with cross-synergy to other EATRIS platforms, leveraging with education and training activities. Further integration of platform activities is anticipated with the support of target identification and validation activities for the development of novel imaging probes for immuno-inflammatory diseases, requiring medicinal chemistry expertise for the development of small molecule tracers (F-18, C-11).

The platform welcomed institution INCLIVA (Prof. María Jesús Sanz, ES), to complement EATRIS expertise available, such as chemical analytical capabilities available at the Institute of Macromolecular Medicine (Prague, CZ) or GLP-certified safety and efficacy testing at Tartu University (Tartu, EE).

The further development of the institutions' joint translational research to serve academic institutions and biotech companies seeking infrastructure for their projects is expanding in the following focused areas: 1) Translational animal models involving patient-derived xenografts (PDX models) for the development of personalized treatment strategies; 2) Advanced screening using 3D cultures and primary cells, for drug sensitivity and resistance testing in a HTS setting, including organoid production, for tumour type selection, target validation and study of EPR effect and hypoxia; 3) ADME profiling of innovative drugs including nanomedicines; 4) Production, characterisation and pre-clinical validation of (biopolymer) nanoparticles for delivery of cytostatic agents, including advanced biodistribution assays.



EATRIS
European Infrastructure for Translational Medicine

ADVANCED TRANSLATIONAL DRUG SCREENING USING 3D SPHEROIDS AND PRIMARY CELLS

ENHANCE PREDICTIONS, IMPROVE INSIGHTS, INCREASE VALUE

When working to identify novel, high-quality drug leads,one significant hurdle remains the low predictive value of preclinical models, which are associated with high attrition rates owing to a lack of clinical efficacy. Drug screening models involving three-dimensional, multi-cellular cultured (3D) spheroids use culture methods that mimic their most natural *in vivo* environment. As such, these kinds of advanced screening are more predictive than artificial, conventional screenings that rely on monolayered cells. In oncology, such *in vitro* 3D cellular models more closely resemble *in vivo* tumour conditions, such as hypoxia, which allow for a more detailed study of the effects of anticancer drugs on the tumour microenvironment.

Alternatively, screening with patient-derived primary cells enables precision medicine approaches by taking into account the genomic heterogeneity of individuals or sub-populations deemed most likely to respond to drug treatment. Access to high-end infrastructures with advanced translational screening technologies, and integrated access to well-annotated patient samples, is essential for the cost-effective selection and repurposing of promising drug candidates.

Figure 2: Drug screening on NSCLC primary cultures by using in vitro 3D-systems, as an ethically and technically sound alternative to in vivo models, to study the drug sensitivity and complexity of in vivo lung human tumors. Rocca MS, Ciardiello D, Leone A, Noto A, Marcelli R, Cibelli G and Budillon A (2015), unpublished data.

How can in vitro screening with 3D spheroids and primary cells enhance the success rate of your drug development programme?

- Accurate delineation and identification of disease to be targeted by the drug;
- More predictive testing on drug sensitivity, resistance, and ADME tox profiling;
- Cost-efficient and maximum data collection from small sample amounts in miniaturised screening;
- Assessment of repositioning, de-risking, and rescuing strategies of existing and investigational drugs;
- Development and optimisation of drug combination therapies;
- Better resemblance of tumour tissue with more reliable prediction of compound tumour penetration;
- Study the enhanced permeability and retention (EPR) effect of drug candidates, or mimicry of specific conditions (e.g. hypoxia or pH);
- Detailed assessment of cell behaviour, such as differentiation, gene and protein expression, cell function, morphology, proliferation, stimulation, and viability;
- Exploration and validation of polypharmacology strategies;
- Improved (ex-vivo) monitoring of emerging resistance towards, for example, tyrosine kinase inhibitors; and
- Implementation and optimisation of therapies with overall decreased attrition rates in drug development.

INFRASTRUCTURE DEVELOPMENT

Along with providing clients with cutting edge services for the biomedical innovation pipeline, EATRIS also focuses a great deal of energy on improving the effectiveness of the translational pipeline itself. Translational research is challenging, costly, and time-consuming. The development pathway is beset with structural technical and operational bottlenecks, which are particularly acute challenges for academic researchers and their funders.

In 2015, EATRIS welcomed Sweden as full observer. Sweden is represented at the Board of National Director by Erik Ingelsson, Professor of molecular epidemiology at Upssala University and Ulrika Backman as national coordinator. Sweden will contribute to the EATRIS effort and product platforms offering with the participation of top internationally ranked institutions in biomedical and translational research. The first contacts with industry have already been made.

In 2015 we supported a considerable portfolio of long-term initiatives that ultimately are intended to ease one or more bottlenecks. These long-term initiatives result from the interaction with various stakeholders and international players in the field of translational medicine. Optimally these initiatives will result in specific projects or research activities. To best maximise use of EATRIS C&S resources, a triaging process is in place to associate expected result with a specific timeframe, with low potential projects either abandoned or revised according to need.

In the table is an overview of the ongoing infrastructure development initiatives.

Initiative	Description	Status	Platforms
Operational Development Projects			
European Medicines Agency	Facilitate EMA-academic dialogue, develop a regulatory research agenda.	Exploratory meeting with EMA organised	All (ATMP most benefit)
National Competent Authorities	Collaborate with NCAs to provide access to early, informal scientific advice for EATRIS users.	MoU (NL, FI, CZ)	All (ATMP most benefit)
Virtual development team	Provide access to cross-disciplinary teams supporting the design of translational development plans for leading projects.	Concept developed	All
Global Collaboration	Maintain 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 Technology (UK).	MoU signed 2014, Position paper (NRDD accepted)	All
Personalised medicine innovation fund	Investigating mechanisms to utilise EFSI funds for long term financing of innovation infrastructure in personalised medicines; collaboration with other biomedical ESFRIs.	Explorations underway with EC, EIB, member states; Support from MRC Technology	All
EATRIS - PAC	EATRIS Patient Advisory Committee to advise on patients' involvement into projects	Strategic meeting hosted	All
Technical Infrastructure Projects			
European alliance for early cancer detection & management*	Create and fund pan-European R&D structure to support development of biomarkers for early cancer detection and management. Collaboration with CRUK, NCI EDRN (USA)	Exploration meeting by European charities organised. Drafting of a position paper	Biomarker
Good Biomarker Practice Initiative	Create comprehensive biomarker validation pipeline, collate best practices; collaboration with BBMRI, ELIXIR, industry.	Concept finalised	Biomarker
Zr-89 accreditation	Collaboration with EARL-EANM to enable harmonised multi-site imaging trials using immuno-PET/CT with Zr-89 tracers.	Testing phase completed with 3 institutions	Imaging and Tracing
ATMP reference standards	Create a community of practice to tackle lack of standards for manufacturing of advanced therapies medicinal products (ATMP).	Concept under exploration	ATMP
Learned societies and other initiatives	Collaborations to allow joint education, marketing, access to expertise. Ongoing with EANM, ISCT, TBVI.	Various MoU and collaboration agreements signed	ATMP, Biomarker, Imaging and Tracing, Small Molecules, Vaccines

RESULTS

In 2014, EATRIS began collaborating with CBG-MEB – The Netherlands drug evaluation agency – which granted EATRIS clients access to early-stage, informal advice from the agency. In the course of 2015, EATRIS continued to expand this initiative to other countries' agencies. Meetings were organized with the Finnish and the Czech Republic Competent Authorities. Both agencies expressed positive interest towards joining such collaboration. Agreements are under completion.

In addition, to facilitate the exchange of regulatory information and to help the development of innovative technologies through the translational research pipeline, EATRIS engaged in the development of a regulatory database. At the end of 2015, the database was populated with the regulatory requirements from the 10 EATRIS Member States. Quality and functionalities of the database are currently under testing before an official launch in Q3-Q4 2016.

In an effort to improve the dialogue between academic institutions and EMA (European Medicines Agency), EATRIS in 2015 initiated a dialogue with the agency. A first meeting was organised in December 2015. In 2016 EATRIS will continue dialogue with the EMA, which is currently seeking to introduce a framework for interaction with academia.

Under EATRIS-Inside, EATRIS offers the assessment of the translational feasibility of projects. While EATRIS-Inside has shown to be of tremendous utility and value to our clients, the impact on project development plan and EATRIS infrastructure utilisation are limited. In 2015, EATRIS developed the concept of a Virtual Development Team to offer the cross-disciplinary input necessary to support the design of translational plans for leading projects. In 2016 EATRIS will seek for funding opportunity to further develop and implement the initiative.

Identifying solutions to major bottlenecks in translational research is at the heart of EATRIS activities. It is also the main focus of the global collaboration initiated in 2014 with US National Institutes of Health, National Centre for the Advancement of Translational Sciences (NIH- NCATS), Therapeutic Innovation Australia (TIA) and the Centre for Drug & Research Development (CDRD) in Canada. In 2015, the collaboration worked on giving global recognition to major bottlenecks in translational research, a first itemisation of which will be published in Nature Review Drug Discovery in April 2016 (Gilliland et al., Nat. Rev. Drug Discov, in press) In addition to the four initial partners, MRC technology (UK) joined the collaboration. With more than 15 years' experience in helping to bridge the gap between basic research and commercial application, MRC Technology is a valuable addition to the collaboration. MRC Technology joined the annual face-to-face meeting organized in May 2015 in Amsterdam.

In Q4 of 2015, EATRIS started working as lead representative on a concept for a personalized medicine innovation pipeline, in collaboration with the BMS RIs group. The concept seeks to leverage opportunities to develop a large scale funding mechanism for personalized medicine development utilizing EFSI funds (European Fund for Strategic Investment). Exploration has been ongoing, including discussions with the BMS RIs, member states and the European Investment Bank (EIB). Initiatives of this scale are a long undertaking requiring EATRIS C&S to keep further identifying opportunities for a personalised medicine innovation fund in 2016.

EATRIS C&S and EATRIS Patient Advisory Committee (PAC) met in July 2015 for a kick-off meeting. The EATRIS PAC is organized under the patronage of EGAN, the Patients Network for Medical Research and Health, to advise EATRIS how patients' involvement can improve and accelerate outcomes of its operations and strategic projects. During the meeting the collaborative framework was defined together with the scope of activities and strategic projects the EATRIS PAC will undertake.

In addition to developing long-term operational solutions to pressing bottlenecks in the translational research process, EATRIS seeks research-based solutions for technical bottlenecks. Such initiatives are an integral part of the product platforms' activities. Further descriptions of the various technical initiatives undertaken by EATRIS are described within the platforms section.

4. EU PROJECTS

EU PROJECTS

2015 has seen a substantial increase in EATRIS participation in EU-funded projects. Already involved in two FP7 projects in the vaccines field since 2013 (EURIPRED and IPROVE), EATRIS participated in the kick-off of two promising Horizon 2020-funded projects in autumn: CORBEL (Coordinated Research Infrastructures Building Enduring Life-Science Services), and RI-TRAIN (Research Infrastructures Training Programme). Those two 4-year projects supported by the H2020-Research Infrastructures Work Programme will strengthen EATRIS' synergies and collaborations with other Biological and Medical Sciences Research Infrastructures (BMS RIs), as well as with other disciplinary RIs, towards, for instance, increased harmonisation of users' access or the development of training programmes tailored to RIs' needs.

2015 saw the successful close of the BioMedBridges project (FP7), in which EATRIS and 11 other partners participated. The project partners worked together to develop the shared e-infrastructure—the technical bridges—to allow data integration in the biological, medical, translational and clinical domains and thus strengthen biomedical resources in Europe. The project is the spiritual predecessor to CORBEL.

2015 was also the start of an ambitious European training project coordinated by EATRIS and supported by the Erasmus plus funding programme: C-COMEND (Competency-based course on Translational Research and Medicines Development for PhDs and Post-docs). The project aims to develop an e-learning module and a face-to-face course in medicines development for PhD students and Post-docs, with the help of four other partners.

For more information on this particular project, please read page 31.

Projects	Funding Programme	Start/End Year	Coordinator	Main topic of activities	EATRIS main role	EATRIS institutions
EURIPRED	FP7	2013-2017	NIBSC (UK)	EURIPRED aims to develop a single specialised infrastructure to support European research in HIV, TB, Malaria and Hepatitis B virus and Hepatitis C virus.	Leader of WP2: "Networking with other groups and projects"	• Istituto Superiore di Sanita (Italy) • Biomedical Primate Research Centre (Netherlands) • Helmholtz Centre for Infection Research (Germany)*
IPROVE	FP7	2013-2016	Vaccines Europe – EFPIA (Belgium)	IPROVE established priority innovations and technologies needed to boost research in the field of European vaccines.	Leader of WP5: "Communication and Dissemination"	
CORBEL	H2020/RI	2015-2019	ELIXIR (UK)	CORBEL will establish a collaborative and sustained framework of shared services between the BMS RIs. This aims to transform biomedical research in Europe - from the discovery of basic biological mechanisms to applied medical translation – through the provisioning of harmonised services.	Leader of WP8: "Accelerating Innovation"	• Rizzoli Orthopedic Institute (Italy) • Lygature (the Netherlands)*
RI-TRAIN	H2020/RI	2015-2019	BBMRI-ERIC (Austria)	RI-TRAIN will identify the competencies required for the professional management of European RIs and design a training programme (training modules, staff visits, etc.) to fulfil these requirements.	EATRIS participates in WP2 (competency definition) and WP5 (continuing professional development).	
C-COMEND	Erasmus +	2015-2017	EATRIS	C-COMEND aims at designing and delivering a e-learning module and face-to-face training on translational medicine.	Coordinator	

* HZI and Lygature are collaborating with EATRIS under a Strategic Partnership Agreement

HIGHLIGHT: C-COMEND

C-COMEND is a two-year European training project supported by the Erasmus plus programme, and coordinated by EATRIS, which started on November 1st 2015.

The overall objective of C-COMEND is to bring together cross-disciplinary stakeholders in order to develop joint curricula and provide a course aimed at PhD students and early Post-Docs, teaching the skills and competencies required to successfully contribute to translational research and medicines development.

C-COMEND will deliver the following outputs:

- A competency profile serving as a basis for the development of the course curriculum;
- An e-learning module available on Elevate's website;
- An additional five-day long face-to-face course, hosted by pharmaceutical industry partners;
- A business plan ensuring the sustainability of the course offering.

All outputs will be made available publicly via the Erasmus plus projects' platform. The project aims at delivering the courses to a broad target group. The face-to-face course will therefore be offered twice during the project lifetime with 15 participants for each course from project partners and 15 from participants outside the consortium. The e-learning module will be made accessible to all biomedical students and professionals in Europe and worldwide.

The 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

C-COMEND will also largely benefit from close links established by the consortium with existing training networks and European projects, such as the Organisation for PhD Education in Biomedicine and Health Sciences in the European System (ORPHEUS); the European Medicines Research Training Network (EMTRAIN), supported by the Innovative Medicines Initiative Joint Undertaking (IMI) and the EUREKA Institute for Translational Medicine.

For more information, please visit C-COMEND's webpage: http://www.eatris.eu/c-comend.html

This project receives funding from the European Union's Erasmus Plus programme under grant agreement 2015-1-NL01-KA203008986

Erasmus+

COMEND

HIGHLIGHT: CORBEL - ACCELERATING INNOVATION WORK PACKAGE

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

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

EATRIS is the leader of the WP8 “Accelerating Innovation”. The aim of this WP is to support effective innovation from the BMS RIs by facilitating and simplifying interaction and collaboration between RIs and industry. To achieve this goal, the WP will provide easy access to a shared and semi-centralised “Innovation Support Office”, managed by the EATRIS team, which will offer real-time legal support and partnering advice to RIs, as well as an online expertise centre providing access to essential tools and resources for collaboration, such as guidelines on Intellectual Property Rights, Open innovation and legal templates.
EATRIS and the other WP partners will be responsible for creating and disseminating legal templates, which are key in the collaboration process (for instance material transfer agreements, collaboration agreements and confidential disclosure agreements). Additional WP tasks include the organisation of three workshops dedicated to industry-academia collaboration and the dissemination of an operational concept for joint BMS RIs Expert Centres.

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

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

5. EDUCATION & TRAINING

EDUCATION & TRAINING

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

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

Activities & Results

Projects:

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

Service activities:

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

Platform activities

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

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

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

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

The EATRIS Translational Thinking Quiz

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

6. FINANCIAL SUMMARY

FINANCIAL SUMMARY

Result financial year and analysis of balance sheet

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

Development in income and expenses result

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

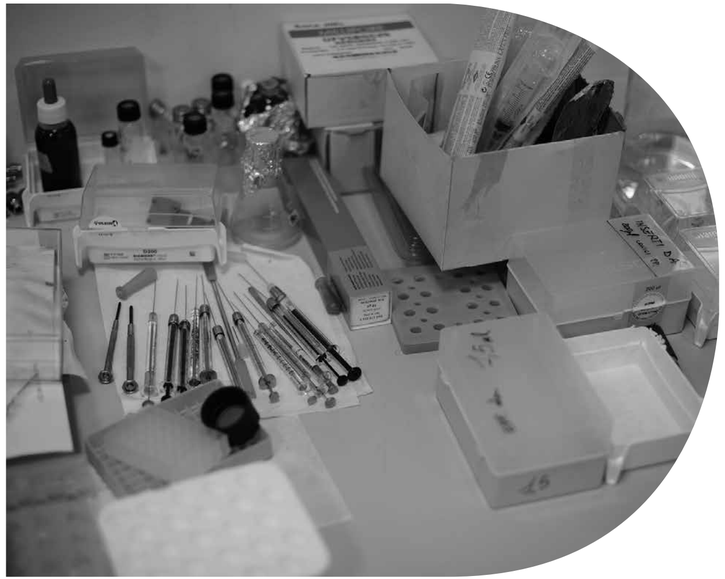
Developments in Income and Expenses

Amounts in EURO's	2015	Budget 2015	2014
Contributions income	1,578,052	1,839,741	1,300,000
Subsidy income IPROVE and EURIPRED	147,014	50,000	30,628
Total income	**1,725,066**	**1,889,741**	**1,330,628**
Salaries and wages	808,155	765,300	698,639
Sub-total staff	239,374	474,660	257,612
Depreciation	7,112	-	7,391
Other expenses	769,586	649,781	672,261
Total expenses	**1,824,227**	**1,889,741**	**1,635,903**
Total operating result	**- 99,161**	**-**	**305,275**

Financial Year & Analysis of the Balance Sheet

	2015	2014	Analysis
Activa	*€'000*	*€'000*	
Tangible fixed assets	16	23	The book value of the tangible fixed assets decreased as a result of the depreciation of prior years acquired assets.
Current receivables	192	462	The decrease is due to receipt in 2015 of two outstanding contributions at year-end 2014. This year only one contribution receivable was outstanding at year end.
Cash at banks	1,231	614	The increase is caused by the decrease in current receivables, increase in contribution and subsidy income.
	1,440	**1,100**	

	2015	2014	Analysis
Equity & Liabilities	*€'000*	*€'000*	
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**	

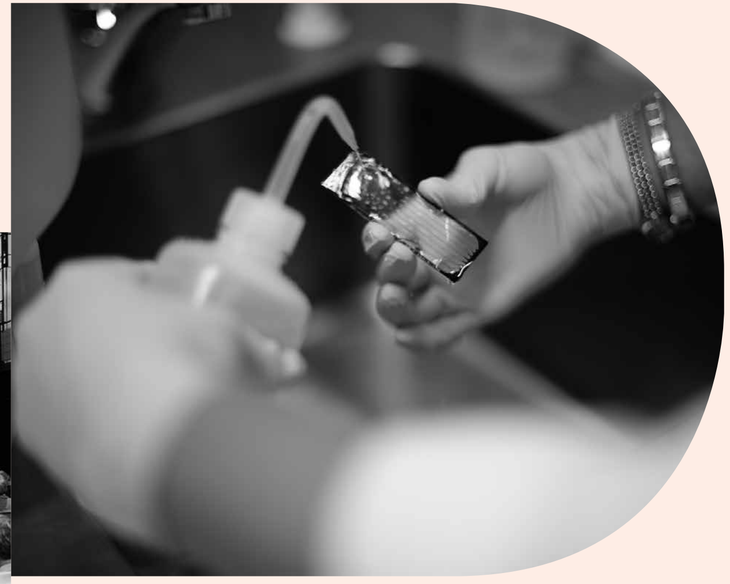


HIGHLIGHT: EATRIS CONFERENCE - BUILDING BRIDGES IN TRANSLATIONAL MEDICINE

In May 2015, EATRIS held its second conference, entitled ‘Building Bridges in Translational Medicine’. This two-day conference, attended by approx. 250 stakeholders and key opinion leaders in the field of translational medicine, focused on how to access and mobilise the proper expertise in such a way that mitigates project risk and optimises translation and drug development.

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

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



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