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A JOINT WELCOME FROM OUR EXECUTIVE BOARD





ANTON USSI
Operations & Finance Director



TONI ANDREU

Dear reader,

We are proud to present the Annual Report for 2017, the fourth year of active operations for EATRIS ERIC. You will learn about the year's highlights and notable milestones, presented in a more personal format, told by the passionate advocates of Translational Medicine in EATRIS.

Thinking Big, With an Open Mind is our chosen theme. These words were the feedback from a delegate that attended the Translational Medicine 2017 conference, who had enjoyed the way the conference encouraged the community to think beyond the usual boxes in which we frame our world. Indeed, Translational Medicine not only encourages but requires a boundaryless approach to science, where the focus is on bringing all possible resources to bear to transform a scientific breakthrough into a life-altering intervention for patients, safely and quickly.

At EATRIS this is the core of our mission – bringing the right people and capacities to the table for every high potential project. By removing disciplinary and sectoral boundaries so that we can all work towards the benefit of the patient.

In practice, living up to such an ambitious mantra takes considerable effort, mostly in structuring communities and reaching out to stakeholders and building the trust and relationships that are essential for success. That is why this year's report – similar to previous years – highlights such a diverse range of activities and interlocutors for EATRIS, from the small academic groups with the next breakthrough development in cell therapies, to the European Medicines Agency acting as guardians of public safety in the drug development process.

We hope you will enjoy the report, and share our enthusiasm for thinking big with an open mind, working together so that we overcome the barriers to bringing benefit to patients and society.

Sincerely, ANTON USSI TONI ANDREU



MARIANNE GRØNSLETH Chair of the Board of Governors

Overall, the performance of EATRIS in 2017 has provided a solid foundation for further growth.

For 2018 we would like to continue our path to further establish standards of excellence and develop an effective brand strategy that will create a unique sense of organisational identity through scientific collaboration. We would like to see EATRIS as a space where scientists, funders, regulators, industry and patients can work effectively together.

We were delighted to end the year with the good news that the Scandinavian country of Sweden joined EATRIS as a Member State who, after being involved with EATRIS since 2015, decided to upgrade their status from observer to fully committed member in January 2018.

All EATRIS ERIC Members and Observers are fully committed to supporting EATRIS in reaching its important goal of accelerating and optimising the translational research to bridge the gap between medical research and clinical applications.

MARIANNE GRØNSLETH



MARIAN HAJDÚCH Chair of the Board of National Directors

The EATRIS team can look back on 2017 with great satisfaction. We have seen our infrastructure continue to advance and make a real impact on the state of translational research, not only in Europe but globally too, through continued collaboration. Last year EATRIS organised its third biennial conference, 'Translational Medicine 2017', in the beautiful city of Prague. It was an event open to a wide range of stakeholders including Industry, Academia, Policymakers. Experts from all over the world gathered together to explore and discuss the latest advancements in Translational Medicine. The conference received acclaim and appreciation from within the translational research community and cemented EATRIS as a leader, trainer and advocate of translational research in the development of novel therapies for our society.

In 2017 each of the individual EATRIS platforms continued to grow in their own unique way, developing strong and relevant initiatives to enhance the

translational pipeline of the therapies they represent. With EATRIS now firmly established as a key player in Europe's Translational Medicine sphere, we are turning our attention to the future. 2017 saw the initial development of a new EATRIS scientific strategy, to be inaugurated in 2019, which will put innovative science and patient benefit centre stage.

Although full details are to be released it is fuelled by our united mission, as well as our dedication, for better translational science for better patient health. Finally, after four great years as the Chair of the Board of National Directors, 2017 was my last year in this role. It is a time I look back on with a great sense of fulfilment and I look forward to observing the new scientific strategy propel EATRIS further down the path of success.

Sincerely, MARIAN HAJDÚCH

EATRIS HIGHLIGHTS FROM 2017



RI-TRAIN Staff Exchange hosted in Amsterdam

May

EATRIS organises CORBEL 'Industry Networking' Webinar



TRANSVAC2 EU-project kick started in Heidelberg

Signing of Memorandum of Understanding to set up ERIC forum



EATRIS joins panel at RICH symposium in Lisbon



EATRIS delegation at BIO Convention San Diego, US

August

MRCA signed for Immunoinflammation imaging Hub



Translational Medicine 2017 Conference held in Prague



Launch of Translation Together

Combined Platform Meeting held in Prague



Hosting of annual CORBEL meeting in Amsterdam



C-COMEND Translational Medicine course for PhDs held in Berlin



Toni Andreu appointed as new Scientific Director



First successful Translational Neuroscience event organised by NeurATRIS

EATRIS signs two MoU's with Japanese partners

UCB announces multi-year collaboration with two EATRIS sites



Sweden joins EATRIS as full member

TRANSLATIONAL MEDICINE '17 'ENHANCING PREDICTIVITY' BROADENS MINDS

FOUR DAYS OF KNOWLEDGE SHARING INSPIRES TRANSLATIONAL MEDICINE COMMUNITY.



What our attendees said:

'The Translational Medicine '17 conference inspired me to think big and keep an open mind.'



'The EATRIS conference 2017 is a must for any scientist in the field of translational research.'









Last September, **180 people** in the field of Translational Medicine joined us in Prague for the conference from over **20 countries**, to listen to **32 world-class speakers** on Enhancing Predictivity. With **72%** of attendees reporting they would recommend the conference to a colleague, we consider it a great success and look forward to the next edition.

139 users, asked **35 questions** and responded to **3 bespoke polls**, in direct, real-time response to conference material that was being presented, using an app on their mobile phone. The Sli.do app gave attendees the ability to ask questions, and create and participate in polls anonymously, during conference presentations, increasing interactivity and ensuring queries were not left unanswered.

The Sli.do app gave attendees the ability to ask questions.

'How do you evaluate the impact in the real world of the first wave of IMI projects?'

'Some European countries separate engineering/material science research from medical research. Is that a lost opportunity?'

'How do IMI project leaders view the role of EATRIS, e.g. in providing capabilities through one central portal?'









Sanofi speaker kicked off plenary sessions

Dr. Elias Zerhouni, President of R&D at Sanofi, was able to kick off three plenary sessions via a series of exclusive recorded interviews, touching upon current challenges and opportunities in Translational Medicine. The videos were pre-recorded and played ahead of each plenary session, offering thought-provoking insight and context.

See the trailer:

https://eatris.eu/events/translational-medicine-2017/

Educational pre-conference workshops were added to the programme

On Sunday 24 September, an entire day of six workshops, across two parallel work streams, was offered ahead of the official conference programme, covering a range of technical and non-technical themes in Translational Medicine. Topics were chosen based on their current relevance. Each workshop was designed to be intimate and highly interactive so that participants could gather insight from international key opinion leaders.

EATRIS combined platform meeting concluded events

The combined platform meeting, offered exclusively to EATRIS Product Platform members and aimed at fostering cross-platform interaction, concluded events in Prague on 26-27 September. The meeting focused on implementing the EATRIS Disease Working Groups (DWGs) identified under the EATRIS survey and allowed rich knowledge exchange on technologies and practices across specific diseases, as well as lively discussion that identified translational gaps together with potential solutions.

With services now well-defined within the platforms, EATRIS initiated a survey around specific disease areas that was tasked to triage projects and concepts to serve "users," in academia or industry, in addition to charities and national funding agencies, by disease type. The survey was a successful attempt to inventorise our expertise and technological capacity, with over **90 participants** completing the survey from over **50 institutions** across **11 countries**.

Kick-off group teleconferences were held in July and September to pilot three working groups where a framework for each, including a research agenda, was discussed and established.

Subsequently, in Prague an estimated 60+ EATRIS members and disease experts participated in three parallel Breakout Sessions; Neurodegenerative, Oncologic and Rare Diseases. An afternoon was devoted to discussing the way forward for these DWGs and in particular the need to identify project ideas in which the group could review and prioritise accordingly, with the view to developing two to three key ideas and formulating a funding plan for each.

The following themes were discussed, to brainstorm project ideas in three areas:

Neurodegenerative diseases

- Protein misfolding
- Neuroinflammation therapies
- Progressive supranuclear palsy
- Also discussed: Early diagnostics, real world biomarkers and structural and functional connectivity measures; preclinical ultra high-field MRI.

Oncology

- Early cancer detection
- Cancer drug sensitivity screening
- Drug repurposing (Read more on the topic in the publication)
- Also discussed: Tumor microenvironment, targeted immunotherapies and pediatric oncology and patient stratification.

Rare diseases

- Genomics
- PDX models for rare cancers, organoids
- Blood-brain barrier modelling
- Also discussed: Phenotypic screens, enzyme replacement therapies, gene therapies, drug repurposing, links to European Reference Networks & registries.

DRUG REPURPOSING AS A PROMISING APPROACH TO MEET THE NEED FOR IMPROVED CANCER TREATMENT.

Summary:

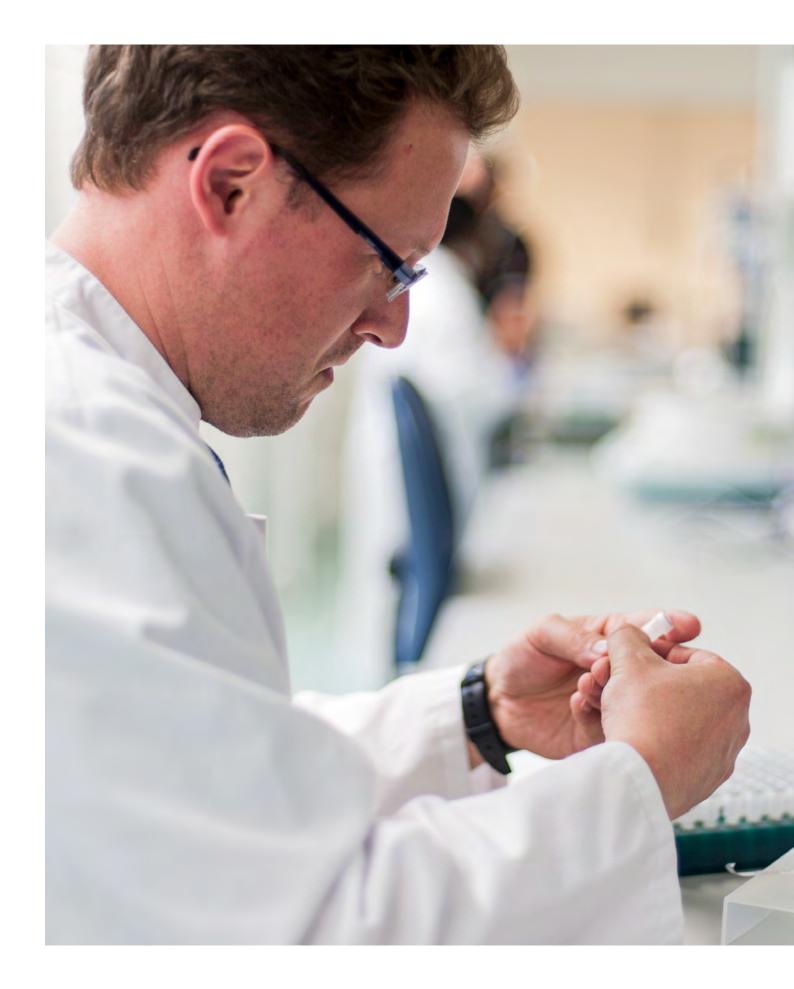
In this Nature paper, Skrott and co-authors from across the globe, highlight the potential for repurposing disulfiram, an old alcohol-aversion drug that has been shown to be effective against diverse cancer types in preclinical studies.

Synopsis:

Cancer incidence is on the rise and is a global challenge exacerbated by tumour resistance to available medicines. A promising approach to meet the need for improved cancer treatment is drug repurposing. Disulfiram (Antabuse™) which has been used over 50 years as an alcohol aversion agent, has demonstrated to have promising preclinical activity against several different types of cancers. Nationwide epidemiological studies reveal that patients who continuously used disulfiram have a lower risk of death from cancer compared to those who stopped using the drug at their diagnosis. The ditiocarb-copper complex was identified as the metabolite of disulfiram that is responsible for its anti-cancer effects. Additionally, the authors provide methods to detect preferential accumulation of the complex in tumours and candidate biomarkers to analyse its effect on cells and tissues. Functional and biophysical analyses reveal the molecular target of Disulfiram's tumour-suppressing effects as NPL4, an adaptor of p97 (also known as VCP) segregase, which is essential for the turnover of proteins involved in multiple regulatory and stress-response pathways in cells.

Authors:

Skrott Z, Mistrik M, Andersen KK, Friis S, Majera D, Gursky J, Ozdian T, Bartkova J, Turi Z, Moudry P, Kraus M, Michalova M, Vaclavkova J, Dzubak P, Vrobel I, Pouckova P, Sedlacek J, Miklovicova A, Kutt A, Li J, Mattova J, Driessen C, Dou QP, Olsen J, Hajduch M, Cvek B, Deshaies RJ, Bartek J. Alcohol-abuse drug disulfiram targets cancer via p97 segregase adaptor NPL4. Nature: 2017 Dec 14;552(7684):194-199. doi: 10.1038/ nature25016. [restricted access]



PRODUCT PLATFORM HIGHLIGHTS 2017

A year of achievement and growth. The EATRIS Product Platforms have been a hive of activity over 2017, initiating and contributing to several projects in various roles.

ATMP PRODUCT PLATFORM

The addition of the IMIBIC Health Research Institute in 2017, from Spain, means the ATMP platform now consists of over 38 top-tier institutions across nine countries.

The ATMP Platform has continued to focus its attention on the bottlenecks that hinder the progress of therapies to patients by authoring an EATRIS white paper, published last September, entitled 'Addressing pressing needs in the development of advanced therapies.' This paper promoted the need for an innovation group which involves the funder, industry, regulator and academic Research Institutes to address systemic challenges in ATMP development.¹ Elsewhere, the platform was represented at a host of international conferences through the calendar year, such as the ISCT in London and the PDA ATMP Conference in Valencia in June, as well as being part of a panel discussion on the topic of utilising academic infrastructure for ATMP development at the Cell Therapy Manufacturing & Gene Therapy Congress in Amsterdam, in December.

At our own EATRIS Conference in Prague in September, the ATMP Platform organised a workshop on 'Potency Assays in ATMP and Vaccine development.' The session was

facilitated by our ATMP and Vaccine Chairs, in addition to a panel of four regulators from national competent authorities across Europe. Our ATMP platform experts also began two matchmaking projects to assist SMEs in expanding their GMP facilities for their cell therapy development needs in 2017.

1 David Morrow, Anton Ussi and Giovanni Migliaccio. Addressing Pressing Needs in the Development of Advanced Therapies. Front. Bioeng. Biotechnol. 2017 Sept 25; 5: 55.doi: 10.3389/fbioe.2017.00055



David Morrow Programme Manager **EATRIS** Coordination & Support



Maria Cristina Galli Chair (ISS, Italy)



Miguel Chillon Co-Chair (VHIR, Spain)

BIOMARKERS

For the Biomarker Platform, 2017 started with the publication of a position paper in Nature Reviews Drug Discovery¹ highlighting the need for an integrated biomarker pipeline with shared best practices in Europe dedicated to biomarker validation.

2017 was also the start of the CliniMARK project. The COST Action, coordinated by Theo Luider from Erasmus Medical Centre in Rotterdam, organised its first networking meeting in October. The overall goal of the project is to enable Good Biomarker Practice to increase the number of clinically validated biomarkers. Alain van Gool and Sulev Koks, Chairs of the Biomarker Platform are part of the Management Committee whereas Andreas Scherer and Laura Bermejo, Co-Chairs of the Biomarker Platform are both Action Participants.

In 2017, the ECaDE (Early Cancer Detection Europe) initiative kept developing after the publication by the end of 2016 of a joint letter to the Editor of the International Journal of Cancer advocating for better access to the infrastructure, resources and expertise necessary for a coordinated R&D in early cancer detection and management in Europe. And during the summer of 2017 EATRIS, through the ECaDE initiative, offered its optimisation service to the applicants of the TRANSCAN-2 JTC 2016 call. See Case study p21. Finally, the Biomarker Platform organised a workshop next to the EATRIS conference on "translating biomarkers into in-vitro diagnostics (IVDs)". The workshop provided input on all the steps involved in in-vitro diagnostics development starting from biomarker discovery to product marketing and reimbursement; the main requirements needed to successfully turn a biomarker into an IVD, from product definition to product development, and the potential roadblocks researchers need to tackle in order to navigate successfully the development path.



Florence Bietrix Programme Manager **EATRIS** Coordination & Support Office



Alain van Gool Chair (Radboudumc. The Netherlands)



Andreas Scherer Co-Chair (FIMM, Finland)



Suley Koks Co-Chair (University of Tartu, Estonia)



Laura Garcia Co-Chair (IRYCIS, Spain)





IMAGING & TRACING

In 2017, the Imaging & Tracing Platform consolidated its translational molecular imaging infrastructure capacity to offer collaborative research services to global pharmaceutical clients from the UK, Belgium and Japan.

The Platform's most notable milestone was the establishment of a Master Research Collaboration Framework with GlaxoSmithKline and six EATRIS centres based in Sweden and the Netherlands. This initiative will generate a portfolio of smartly designed pre- and early clinical projects to validate imaging tools for immuno-inflammation therapeutics development.

Another industry partnering highlight for Imaging & Tracing was the successful conclusion of an advanced quantitative multimodal (PET-MRI) imaging study in non-human primates using a radiolabelled antibody, with extensive coordination from our French partner CEA/NeurATRIS.

In addition to these public-private projects, several institutions continued their efforts in public-public collaborations, including the maturation of the EANM/EARL 89Zr accreditation programme and the launch of a new H2020 project comprising validation of new magnetic nano-biomaterials for brain repair and imaging after stroke (MAGBBRIS, EuroNanoMed3). The latter project will be led by Vall d'Hebron Research Institute (Barcelona, Spain) and is a highly multidisciplinary translational partnership with Scientific Institute San Raffaele IRCCS (Milano, Italy) and four other partners. Anticipating the potential of translational imaging to accelerate the development of cellular therapies, contact was established with the Health and Environmental Sciences Institute (HESI) to join forces for the implementation of robust cell tracking methodologies in ATMPs development.



Martin de Kort Programme Manager **EATRIS** Coordination & Support Office



Bert Windhorst Co-Chair (VU Medical Centre, The Netherlands)

SMALL MOLECULES

This year the Small Molecules Platform continued to develop its translational infrastructure capabilities, to support the development of innovative novel chemical entities around emerging themes in personalised medicine.

Several requests for expertise and research capacity were handled by EATRIS to support the formation of H2020 consortia (e.g. involving small molecules for neglected disease, and nanomedicine formulations for advance drug delivery). An increased interest was observed to facilitate access to regulatory support, such as (e.g.) Orphan Drug Designation of investigational drugs, or (early, informal) scientific advice at a national competent authority. With this year marking the kick-off of the Oncology Working Group, interest was sparked to engage with (cancer) drug sensitivity screening platforms.

Finally, the Platform received various requests from SMEs to assist in mechanism of action studies of their lead candidates. The platform will continue to build its translational research activities in alignment with the recently launched global collaboration initiative Translation Together.

The primary focus of Translation Together is improving quality exchange and dissemination of knowledge addressing translational bottlenecks for (academic) drug development. See Case Study p51.



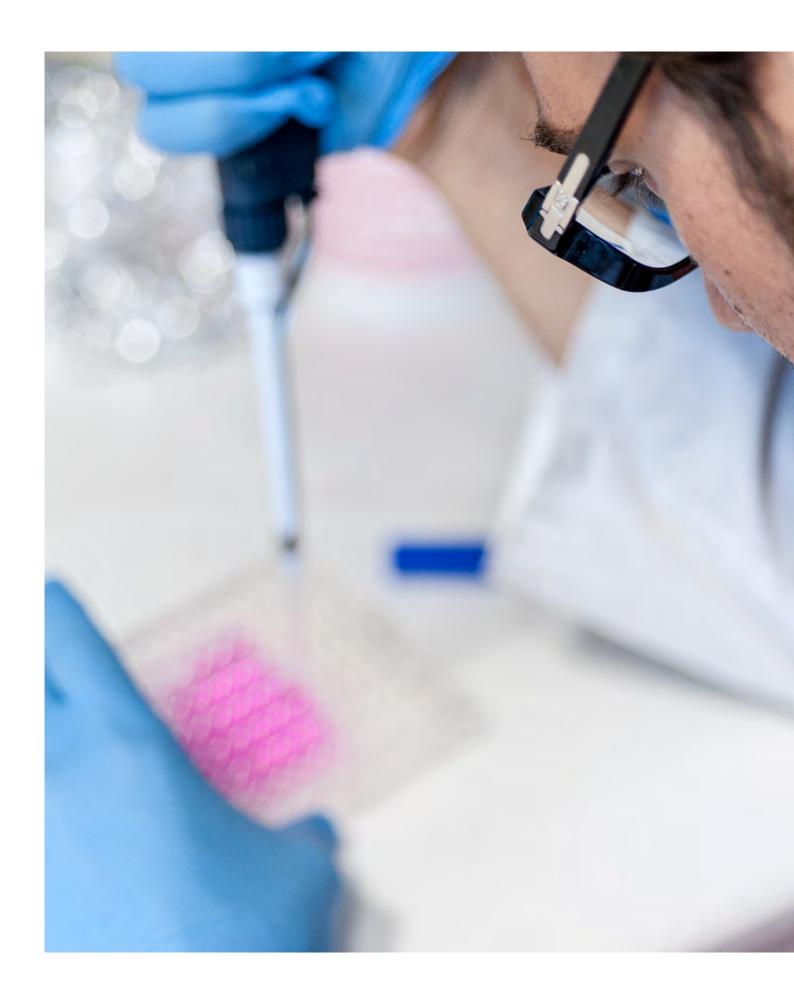
Martin de Kort Programme Manager **EATRIS** Coordination & Support Office

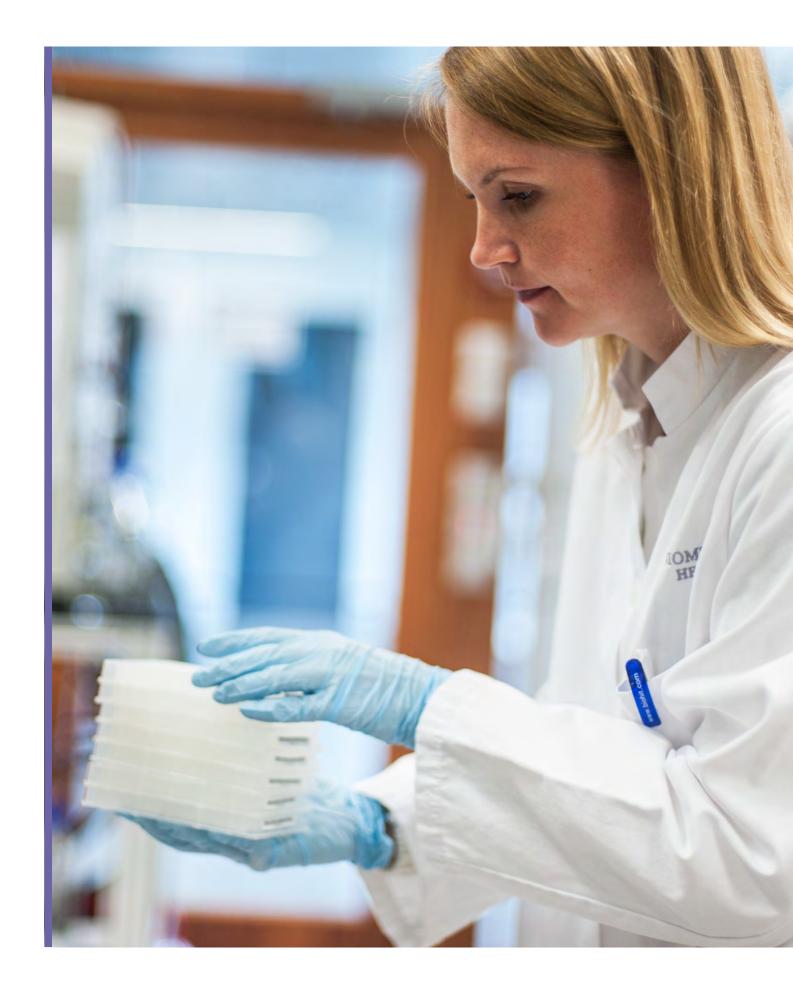


Mario Salmona Chair (Mario Negri Institution, Italy)



Alfredo Budillon Co-Chair (Fondazione IRCCS Fondazione Pascale, Italy)





VACCINES

2017 saw the Vaccine Platform boast 15 centres across six countries, as it continued its work in European-wide initiatives, focused on improving vaccine development and promoting better quality and standards within this field.

The FP7 funded EURIPRED initiative concluded at the end of 2017 as a collaborative infrastructure programme. Its objective was to reinforce knowledge sharing across diseases, to speed up the development of new tools (vaccines, drugs, microbicides) to combat tuberculosis, human immunodeficiency virus, malaria, hepatitis B virus and hepatitis C virus.

In May the TRANSVAC2 project (2017-22) was launched and we, at EATRIS, became one of 25+ partners. TRANSVAC2 is a collaborative infrastructure project funded by the European Commission (EC), under Horizon 2020.

The project is a joint effort from a series of leading European groups in the field of vaccine development, that is coordinated by the European Vaccine Initiative (EVI). TRANSVAC2 is designed to accelerate vaccine development by offering services and training to European vaccine researchers.



David Morrow Programme Manager **EATRIS** Coordination & Support Office



Jan Langermans Chair (BPRC, The Netherlands)



Lucia Gabriele Co-Chair (ISS, Italy)

1

ZonMw, with EATRIS, develops early Health Technology Assessment (HTA) framework

2

ECaDE makes a case for supporting early cancer detection

ZonMw, with EATRIS, develops early Health Technology Assessment (HTA) framework

In 2017 EATRIS was approached by ZonMw (The Netherlands Organisation for Health Research and Development) to help develop an early HTA framework to be utilised for translational research projects funded by the organisation. In a pilot study EATRIS, with the help of HTA experts from the San Raffaele Hospital in Italy, performed an HTA assessment on four projects already funded by ZonMw (Translationeel Adult Stamcelonderzoek 2016). Elements such as safety and clinical efficacy, together with cost effectiveness and the legal or ethical impact of the projects were analysed according to the HTA Core Model® produced by EUnetHTA. The use of the multidimensional analysis provided insight into the factors considered in the HTA Core Model®, based on the data available at the actual developmental stage of the technology. As expected, the relatively early stage development of the projects, manifested in a lack of data on clinical efficacy or safety, and manufacturing and application costs, did not enable a complete review of all dimensions expected under the HTA core model.

However, it allowed an understanding of the main strengths and limits of the technology and addressed potential further research activities in the topics and issues that lacked evidence. Based on these initial results, EATRIS delivered a four-stage framework based on a projects status and the results collected. It involves an early translational assessment, for early translational projects, and the implementation of HTA components while the project progressed. Such a framework will be optimised further and implemented in 2018 thanks to additional HTA experts to be identified in EATRIS Member States. The service offers an objective, realistic and consistent assessment of the expectations and promise of a biomedical product, at an early stage development, to educate on its future implementation in medical care and usefulness. Visit ZonMw: https://www.zonmw.nl/en

ECaDE makes a case for supporting early cancer detection

The challenges of biomarker development

Advancing a promising biomarker towards clinical application is a complex and highly multidisciplinary undertaking. Historically, this has led to high failure rates and very long development timescales, generally measured in decades. One of the leading reasons for this is the difficulty that researchers have in accessing the wide variety of expertise and resources needed to advance a project, in order to reduce the many sources of variability that lead to failure. Any given biomarker validation pathway will require expert opinion and guidance on, among other topics, the mechanistic understanding of the disease biology; the clinical expertise on current workflow and fit of the potential biomarker;

pre-analytical handling requirements of patient samples for validation, or regulatory requirements.

It is for this reason that EATRIS and leading oncology experts from around Europe, formed the ECaDE initiative in early 2016, with the aim of improving the development of promising biomarkers for early cancer detection and differentiation of indolent from aggressive lesions. We do this by providing access to experts, facilities and resources for high potential projects.

ECaDE and TRANSCAN-2

In 2017, ECaDE offered free of charge support to applicants of the joint transnational call of TRANSCAN-2: "Minimally and non-invasive methods for early detection and/or progression of cancer."

Applicants were offered the opportunity to benefit from the expertise of the ECaDE steering committee, to optimise the feasibility and quality of their biomarker validation projects. Expertise was provided on one pre-proposal and on four proposals shortlisted after the first-phase application. Assessment was performed based on the advanced draft provided by the principal investigator and according to the specific needs they identified.

"Free of charge support to optimise the feasibility and quality of their biomarker validation."

Overall proposals were very ambitious in nature, led by esteemed researchers in their respective fields. Each proposal aimed to address a clear medical need. However, all assessed and subsequently shortlisted proposals could be improved from a methodological perspective. This was pointed out by ECaDE experts in one or more rounds of communication with applicants. The issues identified by ECaDE experts suggested that the research teams may have included insufficient expertise in epidemiology, study design and statistics, which is an issue that was pointed out previously (see e.g. lonannadis et al. 2014).

Through ECaDE's involvement, however, potential problems were diagnosed earlier. This way, applicants had earlier access to independent advice, improving their chances of success, while the funder could avoid having to (e. g.) reject potentially strategic projects purely on the basis of insufficient description of the research plans, misunderstanding or similar issues. ECaDE will be providing free support to the new joint transnational call published by TRANSCAN-2 in December 2017. In parallel, the steering committee has been in dialogue with various European charities, including Cancer Research UK, to seek closer collaboration.

Read more: https://eatris.eu/projects/ecade

PARTICIPATING COUNTRIES:

Czech Republic, Estonia, Finland, France, Italy, Luxembourg, The Netherlands, Norway, Spain, Slovenia, Sweden, Latvia (observer).

EATRIS INSTITUTES

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

EATRIS
Coordination & Support
located in Amsterdam



INSTITUTIONS OVERVIEW

- Platform participation
- Platform participation new institutions in 2017

Name	ATMP Biomarkers Imaging 6 Tracing Small Molecules Vaccines
CZECH REPUBLIC	
Masaryk University	
Central European Institute of Technologies (CEITEC)	• • • • •
Charles University	• • • • •
Institut of microbiology of the AS CR, v.v.i	0 0 0 0
Institute of Chemical Technologies Prague	• • • • •
Institute of Experimental Medicine AS CR	• • • • •
Institute of Macromolecular Chemistry Prague (IMC ASCR)	• • • • •
Palacky University - 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.	
St. Anne's University Hospital Brno	• • • • •
ESTONIA	
University of Tartu	• • • •
FINLAND	
Finnish Red Cross Blood Service	• • • • •
University of Helsinki - Institute for Molecular Medicine Finland (FIMM)	
University of Tampere - Regea Cell and Tissue Center	• • • • •
University of Eastern Finland - National Virus Vector Laboratory (NVVL)	• • • • •
University of Turku	
VTT Technical Research Centre of Finland (VVT)	•
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)	• • • • •

- Platform participation
- Platform participation new institutions in 2017

	•				Vaccines
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			•		
IDI-Fondazione IRCCS Luigi Maria Monti	•				
IRCCS Istituto Ortopedico Galeazzi	•	•			
ISMETT	•	•			•
Istituti Fisioterapici Ospitalieri - Istituto Dermatologico "San Gallicano"					•
Istituti Fisioterapici Ospitalieri - Regina Elena Tumor research	•			•	
Istituto Superiore di Sanità (ISS)	•	•	•	•	•
Mario Negri Institute for Pharmacological Research				•	
National Institute for Infectious Diseases Lazzaro Spallanzani		•			•
Rizzoli Orthopedic Institute (IOR)	•	•	•		
Scientific Institute San Raffaele (HSR)	•		•		
NETHERLANDS					
Academic Medical Centre (AMC)					
Biomedical Primate Research Centre (BPRC)					•
Wageningen Bioveterinary Research					•
Erasmus University Medical Centre		•	•		
Intravacc					•
Leiden University Medical Centre (LUMC)	•		•	•	•
Maastricht University Medical Center (MUMC)			•		
Netherlands Cancer Institute		•			
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)	•	•	•		•

- Platform participation
- Platform participation new institutions in 2017

	ATMP Biomarkers Imaging & Tracing Small Molecules Vaccines
Name	S n S n
NORWAY	
Norwegian University of Science and Technology (NTNU)	• • • • •
University of Bergen (UiB)	• • • • •
University of Oslo (UiO)	• • • • •
University of Tromsø (UiT)	• • • •
SPAIN	
August Pi i Sunyer Biomedical Research institute (IDIBAPS)	• • • • •
Bellvitge Biomedical Research Institute (IDIBELL)	• • • • •
BioDonostia Health Research Institute	• • • • •
FIBICO, Foundation for Biomedical Research of Cordoba (IMIBIC)	• • • • •
Fundacion Jimenez Diaz Institute for Medical Research (IIS-FJD)	0 0 0 0
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)	• • • • •
INCLIVA	• • • • •
Insitute of Biomedicine of Seville (IBIS)	• • • • •
Instituto Ramón y Cajal (IRYCIS)	
University Hospital La Princesa (IIS-IP)	• • • • •
Vall d'Hebron Research Institute (VHIR)	• • • • •
SWEDEN	
Chalmers University of Technology	
Karolinska Institute	
KTH Royal Institute of Technology	
University of Gothenburg	0 0 0 0 0
Uppsala University and Uppsala University Hospital	
LUXEMBOURG	
Integrated Biobank of Luxembourg (IBBL)	• • • • •
SLOVENIA	
University of Ljubljana	• • • •

SUCCESS STORIES FROM OUR MEMBER STATES AND EATRIS INSTITUTIONS.

SWEDEN JOINED EATRIS AS FULL MEMBER

During its two years as an observer, the Swedish node stimulated great interest in becoming part of EATRIS, among Swedish Universities. So, at the end of 2017, Sweden elected to become a fully committed Member State.

The Swedish node, which consists of six centres, distributed across Sweden,

has infrastructures representing in three platforms: Biomarkers, Imaging & Tracing and Small Molecules.

A number of project inquiries have already been made and new collaboration agreements between EATRIS sites, initiated. The node, whose decision was supported by the Swedish Research Council, are said to be optimistic about their continued collaboration with EATRIS as full members.

IBBL AND THE MOVE TO NEW FACILITIES IN DUDELANGE

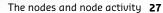
The Integrated BioBank of Luxembourg (IBBL), a member of EATRIS since 2016, concluded the year 2017 with a change of location having relocated its staff, equipment and samples from Luxembourg City to Dudelange about 15 kilometres away.

It is a highly strategic move that positively impacts IBBL's activities and services.

IBBL now has a total space of 2,000 m². 500 m² is dedicated entirely to sample storage and logistics, while a further 1,000 m² are laboratories. This increased sample storage capacity means IBBL can

now accommodate about five million biospecimens, compared to its previous capacity of 500,000.

The new building provides space and opportunity for new equipment, new facilities such as a walk-in freezer room and more automation in the laboratory. Moreover, the increased space has enabled IBBL to separate its laboratories according to different activities, such as DNA and RNA extraction, to prevent cross-contamination. The move enables IBBL to expand its operations and services to support an increasing number of partners and clients internationally, and to reinforce its service offering as an EATRIS institution.





NeurATRIS and Medicen Paris Region organised the first edition of "Translational neuroscience: challenges and opportunities" on 20 November 2017, in Paris.

Gathering together experts in neurodegenerative diseases, this event aimed to foster interactions between researchers, clinicians, biotech and pharmaceutical companies.

During the plenary session, NeurATRIS preclinical and clinical experts presented several examples of translational neuro-degenerative disease projects through their multidisciplinary expertise and platforms. The 175 participants among whom 65 company representatives also had the opportunity to hear 4 industrial companies (Novartis, J&J, Merck Serono and Nikon) presenting their views and challenges in the neuroscience field, as well as 9 biotech companies disclosing their

assets and needs during a pitch session. During the matchmaking session,

115 B2B meetings took place to create and identify collaborative R&D projects.

The powerpoint and video presentations, as well as testimonials, can be found at: https://translational-neuroscience. b2match.io

The second edition "Translational neurocience" is already in preparation for the end of 2018.

REFLECTIONS ON RUNNING A START-UP INFRASTRUCTURE

A RETROSPECTIVE LOOK AT EATRIS DURING ITS FIRST 5 YEARS.

ARTICLE BY FRANK DE MAN, Governance & Finance, EATRIS

Building a European Research Infrastructure, to improve human health and quality of life.

Over the last two decades European scientists, EU Member States and the European Commission (EC) have worked together to strengthen scientific research in Europe and advance their position globally.

EATRIS is part of that story.

In this article we discuss what it takes to build a brand new European Research Infrastructure from scratch and reveal how, and why, EATRIS was born.

What is a European Infrastructure?

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

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

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

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

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

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

Why translational research?

Development of new medicines is stagnating globally. Though new discoveries occur at an increasingly rapid rate, new products for patients do not.

The main reasons for this are:

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

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

EATRIS HOPED TO:

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

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

THOMAS JEFFERSON

How to build an RI

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

That RI was called EATRIS

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

Structure follows strategy follows function

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

The areas we identified were:

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

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

We hoped to breathe life into the valley of death

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

Patient driven & multidisciplinary

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

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

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

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

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

The RI as a start-up

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

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

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

Effective operations and sustainability

Being a start-up has pros and cons.

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

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

Governance

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

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

The future

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

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

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

OUR SERVICES IN 2017

DISCOVER HOW OUR SERVICES PERFORMED LAST YEAR.

Serving as a matchmaker for academics in translational research capabilities, matching supply and demand by providing access to high-end infrastructure and expertise, forms the cornerstone of EATRIS.

In 2017 we saw steady growth in the use of the services we offer accompanied by a diversification of our portfolio. EATRIS aided 14 Principal Investigators (PI) with consortium building for grant application and provided translational assessment of another 14 projects. One H2020 infrastructure project, with EATRIS as a partner, started (TRANSVAC-2, with a total project budget 10,6M Euro for 5 years) while another was granted (European Paediatric Translational Research Infrastructure (ID-EPTRI) with a total project budget 3M Euro for 2 years).

EATRIS further developed its portfolio during 2017, signing 14 Letters of Engagement (LoE) including one with a large Japanese pharmaceutical company. Plus, one SME client returned for four separate projects, showing confidence in EATRIS' services.

Finally, one small scale partnership between an SME in Sweden and a Czech Institute commenced a long-term strategic collaboration to validate a new technology.

Summary of activitiy				
Core activities	2015	2016	2017	
Consortium Building	4	18	14	
Matchmaking	5	9	14	
Translational Assessment/Expert advice	1	3 14		
Hub Partnering	1	1	1	
Income C&S Office	2015	2016	2017	
Service Fees*	€ 51,616.50	€ 100,150.00	€ 114,838	
Grants	€ 147,014.00	€ 219,035.00	€ 261,505.00	
Income Institutions (Budget negotiated)	2015	2016	2017	
Industry Projects	€ 23,474.00	€ 1,629,431.00	€ 326,571.34	
EATRIS Linked Third Party grants	€ 334,966.00	€ 430,315.00	_	
Users	NA	1400	5500	

^{*}non-grant/non-contribution income

RESEARCH SERVICES (Matchmaking)

We provide support to ensure that project agreements are reached efficiently and facilitate partnerships while the EATRIS institutes execute the resulting study plans in direct collaboration with the user. Our catalogue comprises a wide range of high value-added drug and diagnostic development studies covering most product modalities, from target validation all the way to proof of concept in humans.

Who is it for? Industry, large pharma, biotech companies, SMEs.

CONSORTIUM BUILDING

(Fast Matchmaking)

Similar to Research Services, Consortium Building is a quick way to identify potential partners for funding applications. Thanks to a comprehensive database of our infrastructure's cutting-edge technologies, EATRIS helps identify suitable partners with specific expertise and capabilities to strengthen a project proposal.

Who is it for? Academia and SMEs.

EATRIS-INSIDE

(Translational Feasibility Assessment)

With EATRIS-Inside, EATRIS assesses the translational feasibility of projects based on various elements such as intellectual property, regulatory pathway(s), and end-product definition. This translational assessment proactively aids identifying potential gaps and bottlenecks which may obstruct project execution, as well as pin-pointing key enabling technologies to support robust data generation. In addition to the translational feasibility assessment, EATRIS has developed an early HTA framework for translational projects. The framework was developed in collaboration with ZonMw (NL) for an upcoming funding programme. It is now included in EATRIS' centralised service catalogue for academic projects together with:

- regulatory work package
- innovation & impact (feasibility assessment, partnering, intellectual property)
- education (focused on translational research)

Who is it for? Funding agencies, Charities, Academia.

REGULATORY SUPPORT

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

Who is it for? Academia and SMEs.

CASE STUDY

EATRIS QUALITY INITIATIVE 2017

The EATRIS Quality Initiative (EQI) is an umbrella term for EATRIS activities addressing reproducibility, standards, and reference materials.

BY ANDREAS SCHERER, **EATRIS National Coordinator Finland**

Making use of its network, our platforms have engaged in a number of projects which address a range of biomedical needs. In 2017, strong progress was made in several of these projects.

For example, in the 89ZR PET/CT accreditation programme, developed by experts in the Imaging & Tracing Platform, four EATRIS sites have finalised the pilot phase collaboration with European Association of Nuclear Medicine (EANM) to cross-calibrate 89ZR PET/CT detectors for clinical use. First data has shown that while each site generates high-quality data, scanner calibration is pivotal in order to harmonise the measurements and enable multi-site clinical studies. The programme will open up to global sites next year onwards, through EARL/EANM.

Developing best-practice process

The Biomarker Platform is involved in the FDA-driven community effort SEQC2, with the aim to assess analytical issues and develop a best-practice process for the generation and bioinformatics analysis of massively parallel human sequencing data.

History has shown that results suffer from various sources of variability, including technology platform and bioinformatics solutions. To address these issues, hundreds of scientists worldwide are contributing to the SEQC2 project.

EATRIS contributes with four sites, that provide sequencing data, and seven bioinformatics teams. That is why they received the honour of presenting their capabilities during a SEQC2 general meeting, as well as chairing a session. EATRIS was the second organisation to provide a complete set of sequencing data back to the team for analysis.

Pioneering pilot studies

Within the Small Molecules Platform, the Translation Together consortium is performing a high-throughput screening (HTS) system ring-testing project, involving during the pilot phase NIH-NCATS and EATRIS member institute IMTM in Olomouc, Czech Republic. The goal is to identify drivers of variability in HTS, as well as to provide feedback to HTS sites on potential sources of variability in their systems. The phase 0 was successfully piloted in 2017 with the first results to be made available in Q1 2018.

Further activities in the Biomarker Platform included a pilot study to assess inter-lab reproducibility of microRNA detection. Originally, the platform had established promising contact with a Japanese consortium, exploring possibilities of benchmarking several microRNA detection methods. Unfortunately, this contact could not be maintained, due to inactivity on the Japanese side. Instead, the EATRIS groups from IRYCIS and INGEMM (both Madrid, Spain) started a pilot study to compare microRNA detection sensitivity in their own labs. Together with the EATRIS Biomarker Platform they are now looking into expanding the activities.

In other platforms, quality related studies advanced quickly as well. EATRIS was involved in the EURIPRED infrastructure project for poverty related diseases (FP7 funded project), which involved coordinating and integrating international resources into a single specialised infrastructure to support European HIV, TB, Malaria and Hepatitis B/C virus studies from early drug, vaccine and microbicide discovery to clinical trials. One of the deliverables from the project was a set of standardised SOPs for these key immunological assays. They will be made widely available to the field for preclinical and clinical vaccine development and quality control purposes.

COLLABORATION IS KEY TO BUILDING OUR COMMUNITY.

2017 demonstrated increasing collaboration with industry, as well as diverse acquisition activities to identify new industry partners. In 2017, EATRIS provided 28 instances of supporting the development of industry collaboration or providing expert advice.

In the field, Biotech and pharmaceutical SMEs are most commonly brought into contact at external conferences or via our network of National Coordinators. These SMEs often have straightforward research requests that can be handled by EATRIS Matchmaking; we identify one or more EATRIS centres that meet the brief and the sponsor chooses how and with whom they proceed.

Alternatively, research questions requiring more complex support and/or greater capacity can benefit from multiple complementary academic institutes coming together to form a central hub. Hub definition entails a longer and more complex engagement process aimed at identifying what is needed in order to determine the right organisation for the institutions, together with the sponsor and EATRIS.

Matching academic expertise to industry needs

Increasingly we, at EATRIS, observe that experimental medicine, supported with molecular imaging and other biomarkers, is a high-potential area for matching our academic expertise to industry needs.

One of the most exciting, recent examples of EATRIS providing industry with sophisticated experimental medicine and imaging-guided drug development is the GSK immune-inflammation hub, which became operational in Q3 2017 through the execution of the Master Research Collaboration Agreement (MRCA).

This MRCA tied together GSK, as the sponsor, to five leading imaging and experimental medicine Research Institutes

within EATRIS, including Academic Medical Center Amsterdam, Radboud University Medical Center Nijmegen, University Medical Center Groningen, Uppsala University and Hospital, and VU University Medical Center Amsterdam.

To ensure academic experts in the hub can fully focus on technical challenges, and that GSK receives maximum academic capacity with minimum pain, EATRIS plays the role of Portfolio Manager, and facilitates developing and administering the legal framework and operations for optimal speed and efficiency. Several projects were close to implementation at end 2017.

The hub is expected to execute at least three projects annually which closely support therapeutic development within GSK.

New projects and initiatives in 2017

The Imaging & Tracing Platform supported two other major projects in 2017, including a multi-site ImmunoPET study for antibody imaging, as well as a preclinical imaging project in non-human primates. Both these projects are a perfect fit with the EATRIS mandate of fostering collaboration, to develop or use tools and technologies to improve pipeline productivity.

In order to acquire new projects, we engaged with pharma imaging groups, listened to their needs, and made them aware of our capabilities. This was initiated in 2017 and will continue; we expect this to generate future projects but it will take time. Industry imaging experts are highly aware of individual academic centres with whom they are often already collaborating. The major lesson from the above hub example is to identify specific instances where EATRIS can provide value and where and how to structure the process beyond single-site capabilities.

EATRIS increasingly recognises the massive impact of its 90 institutions, with 45 academic medical centres among them, and is dedicated to attending research conferences focused on disease indications and therapeutic development. Two examples from 2017 include the Alzheimer's Association Annual Meeting (AAIC 2017), and the International Society for Cell Therapy Meeting (ISCT 2017). Such meetings are key in ensuring that EATRIS keeps abreast of fast developing fields, has the chance to interact both with its own academic network as well as the diverse array of industry attending such events, and directly connects disease-specific research back to the five EATRIS Platforms. 2018 will extend this activity further, using meeting attendance to support our developing Disease Working Groups as well as to provide business development and partnering supporting within subsidy proposals.

Connecting with the community

Finally, the EATRIS conference, which featured Janssen, GSK, Sanofi, UCB Pharma, Bayer Algeta, and Orion Pharma, gave us the opportunity not only to host a great event but connect with a wide range of inspiring presenters and participants via our workshops and plenary sessions. We expect that our 2019 conference will be even more heavily attended by industry as our partnerships increase and deepen.



Today, Translational Medicine is pivotal to the development of medicine in the 21st century. In the last ten years we have seen how the explosion of scientific knowledge and technological developments, triggered by the last World War, have rapidly grown.

The great paradox of medicine in this transitional period between two centuries is that, for the first time in human history, the entrepreneurial spirit of science has generated knowledge faster than society can incorporate it. We generate so much knowledge that it is difficult, not only to implement it, but replicate and valide it too.

Of course each new era faces challenges as society evolves, which must be overcome in the interest of progress. It is essential that the human community participates in these advances by identifying the barriers and designing efficient processes to navigate them.

In a society built on the fallacy that there are only two options: rapid success or failure. Translational Medicine illustrates that the age-old method of trial and error can offer a solid base upon which the great medical discoveries of the future can be made.

In fact, the history of medicine is full of examples of great advances that required long periods of maturation and a trial and error approach. Penicillin took more ten years to reach clinical use after it initial discovery. Shortly after his discovery Fleming thought that the lifetime of the drug in the body would be too short to produce a therapeutic effect and the first clinical trials failed because the doses used were subtherapeutic. It took almost five years to correct these first erroneous conclusions and finally Merk started its industrial development a further five years after that.

Translational Medicine generates a model of continuous evolution

The generation of scientific knowledge, focused on innovation in health intervention, results in a system that ensures knowledge is not diluted.

Translational Medicine creates a developmental playground where scientists can design experimental approaches, while maintaining a view of the implications their work may have

in the discovery of new therapies. This fact alone initiates a positive dynamic with transformational potential that mobilises basic scientists, technologists, researchers and clinicians along the same axis of inquiry, creating a space for cooperation and collaboration. It is a disruptive idea indeed, because traditionally scientists and doctors have developed their work in disconnected departments as a result of differences in language and culture, priorities and perspectives, preventing them from occupying a common space.

Thankfully Translational Medicine creates a defined path that allows researchers from different disciplines to walk together in harmony, transcending the barriers left behind by medicine's historical legacy.

Translational Medicine is, ultimately, a process. And, like so many innovative processes its course is non-linear. It is a perilous trail full of pitfalls, roadblocks and barriers, since each individual route must evolve across the mysterious landscape of human biology. Obviously, the goal is to advance the process and develop new interventions beneficial to the patient. Yet to this end a new generation of pioneer is

needed; those who have the capability, knowledge, mindset and adaptability to meet the challenges that emerge from the process and thus create a new paradigm in the history of science – transdisciplinarity.

Translational Medicine transforms science by pushing scientists to create a new language in which molecular biology, statistics, chemistry, clinical medicine, ethics and other disciplines meet and interact, generating new questions and new ways of addressing scientific problems. Today, more than ever, it is essential that translational medicine be reinforced within the research community and the medical community, as well as the pharmaceutical and medical technology industries.

The search for new drugs is at a historic moment of crisis. The process is becoming unsustainable, in spite of enormous technological advances, since the technological explosion has not been accompanied by a reinforcement of quality in experimental designs, especially in the discovery phases. The high level of failure at clinical trial in Phase II swallows up economic resources, generates exhaustion among researchers and clinicians and, more seriously, induces frustration

'There is a nasty puzzle at the heart of modern biomedical research. On the one hand, the technologies that people think are important have become hundreds, thousands, or even billions of times cheaper. On the other hand, it costs nearly 100 times more to bring a drug to market today than it did in 1950. New drugs can be very expensive, yet the industry is closing labs and firing scientists. Our work goes some way towards explaining the puzzle. Governments, companies, and charities should focus on identifying and funding predictive methods, even if they don't match current scientific fashion.'

(Jack W. Scannell, Jim Bosley. When Quality Beats Quantity: Decision Theory, Drug Discovery, and the Reproducibility Crisis. PLOS ONE, 2016).

The completion of the human genome in the year 2000

represented the moment when Translational Medicine

Information is the key

began to be understood as a discipline, since it allowed us to dive into the biology of cellular processes in an exceptional way. We discovered new perspectives, approaches and targets and, as a result, started to address the challenges posed by complex diseases such as cancer, neurodegenerative diseases or rare diseases, among others. Biomedical science produces enormous amounts of biological information, providing an excess of information which researchers must navigate. This is a process fraught with difficulties, in which the information technologies are the protagonists. The production of biological data, as well as how that data is sorted, stored and used is, without a doubt, the aim of the future development of Translational Medicine, as well as one of the greatest issues to be overcome by science and technology in the 21st century. The reclassification of pathological processes through the identification of molecular signatures creates a new classification of the human diseasome that is breaking down conceptual barriers and redefining how we understand disease. The repositioning of hierarchical classifications of diseases to molecular profiles, and not phenotypic manifestations, can only be strengthened if the biological information management systems are robust and efficient. With this in mind, the concept of FAIR data (Findable, Accessible, Interoperable, Reusable) has been developed, which should be a catalyst in the acceleration of outcome applicability. Future developments in Translational Medicine should be built on this strategy, where biological data is managed in a meaningful way to support a fast-track development process. This is particularly important in the pre-implementation phase where technological outcomes from different experimental models will determine the successful implementation of health care interventions.

Putting the patient at the centre of the process

Yet the key to the future of Translational Medicine is not centred exclusively on scientific or technological considerations. Rational analysis of the ethico-social landscape provides us with a guidance on how to advance forward, well into the next decade. The truth is societies are not transformed by technology alone, but by the way in which societal relations evolve in the wake of technological developments. If we were to consider a conceptual (not technological) revolution in the field of medicine in the 21st century, imagine a world where patients are empowered to take control of their health and how their health care system provides its services, on a preventative, diagnostic and therapeutic level.

Placing patients at the centre of the process transforms them into agents of change. They are the co-decision makers, helping to safeguard and foster constructive interaction between themselves and the healthcare system. Assuming responsibility for their own health will lead to medical innovation and, ultimately, create an open dialogue and mutual understanding between patients and the medical community. In fact, for some, patients are indispensable.

The debate around the price of medicines has to be conducted with patients to guarantee access to innovation at an affordable price. In this context, HTA strategies for implementing innovative therapies will be carried out with patients side-by-side. They are the ultimate users of health technologies and they can advocate and promote models for patient involvement among other stakeholders. Nothing will facilitate the dialogue among scientists, clinicians and society more effectively than the creation of a pathway, constructed together, and bound by a common objective.

In this way Translational Medicine can create a great testing ground, with the goal of developing an interactive space where scientists and citizens can commune, with mutual understanding, and become a pillar of social education.

The role of the RI in Translational Medicine: EATRIS as a driving force

Translational Medicine is a new discipline which needs an operational framework in order to progress. So, it is important to recognise the role of Research Infrastructure (RIs) as the threads of cohesion and dynamisation in the fabric of European science.

This organisational model creates a web of scientific capacities, characterised by transnationality and complementarity, and will play a key role in the development of medical innovation in Europe and knowledge excellence.

European infrastructures are a great strategic move by the European Commision. Through this model, Member States can be directly involved in the governance of the system and the design of a holistic strategy.

It is anticipated that RIs will continue to play a fundamental role in the development of Translational Medicine, given that four of them (BBMRI, ELIXIR, ECRIN and EATRIS) have a direct impact on scientific activities within the medical arena.

The RIs guarantee a solid foundation for scientific development by creating a critical mass of complementary capacities to tackle ambitious challenges. They guarantee the incorporation of innovation and knowledge by bringing together the parties needed to push forward novel therapies in the European sphere.

The medicine of the 21st century need RIs as providers of excellent scientific services that are integral to the process of therapeutic innovation and gatekeepers of quality. RIs do not necessarily create structure themselves but synergise existing structures, and produce, through the creation of common projects, bottom-up alignment of the scientific strategies of EU Member States instead. Therefore, it is fundamental that the Member States perceive the RIs as allies to their own agenda, committed to their governance. It is in this space that EATRIS will shine. EATRIS' goal is to create harmony and synchronisation between the scientific and technological activities, as well as other stakeholders, that the medical RIs have been working on since their inception. It is important, that in the coming years, an environment is created where RIs can complement one another and provide mutual support to each other, in order to ensure scientific advances are translated into the development of new interventions to improve the health of citizens.

One of EATRIS' most valuable assets is its capacity to foster collaboration with industry partners and bring them together with academic groups in order to accelerate therapeutic innovations. This mean high quality technical services are available to industry at the critical moments in the life-cycle of medicine development.

In addition, EATRIS participates actively in raising awareness of regulatory frameworks in academic and industry sectors, identifying barriers and solutions to accelerate regulatory processes in the development of new therapies.

Whilst other RIs focus their efforts on specific bottlenecks in the process EATRIS is dedicated to developing a holistic perspective of the process. This widening of the strategic spectrum focuses attention on the pipeline rather than on specific technologies. It is this focus that defines EATRIS as a driving force behind the concept of Translational Medicine, ensuring that Europe possesses an active framework in which science can respond to the greatest challenges posed by society. When we speak of the future of Translational Medicine, we must embrace the idea that it is a dynamic, living, evolving concept which, in the coming decades, will be the foundation of technological development and complicity for scientists, industry, citizens, policy-makers and health authorities.

The resources which society assigns to its citizens' health are not infinite and in a Europe which believes in equality of all men and women, equal access to health care must be guaranteed for all citizens regardless of their country, gender, or social class. It is an ethical imperative, therefore, that all those in the Translational Medicine community forge forward with conviction, rigour, generosity and transparency. The health of the next generations depend on the decisions we take today.

THE CONCEPT OF TRANSLATIONAL MEDICINE AND WHERE IT CAME FROM

DID YOU KNOW THE CONCEPT OF TRANSLATIONAL MEDICINE EMERGED ALMOST TWENTY YEARS AGO AT THE NATIONAL INSTITUTES OF HEALTH, USA, **UNDER ELIAS ZERHOUNI?**

> The purpose for its development was to ensure that the explosion of scientific knowledge in life sciences and, more specifically, advances in human biology generated by technological developments in the late 90s, could be utilised with maximum efficiency and turned into medical innovations for patients.

Translational Medicine focuses on the development of a drug towards the clinic, covering any type of therapeutic innovation including care processes, medical imaging, robotics or new materials. In parallel, "bench to bedside and back" emerged as a new paradigm creating new space in which basic researchers and clinical researchers work together harmoniously, building on each other's work. At its core, Translational Medicine attempts to bring cutting edge analytical technologies to bear to gain a deep understanding of the biological process underlying a disease, and the mechanism by which a new therapeutic may have an effect. Effectively bringing technology, biology and clinical expertise to the table is a hallmark of good translation.

Multidisciplinary collaboration is the signature of Translational Medicine. It adds value by creating multilinear, multidisciplinary relationships, among other generators of knowledge and processes in engineering, computer science, mathematics, and all those disciplines that add value to the process of developing new ideas focused on creating products that can be used to improve the health of the individual.

A SELECTION OF OUR PUBLICATIONS FROM 2017

LEARN ABOUT THE PAPERS PUBLISHED IN 2017.

Addressing pressing needs in the development of Advanced Therapies

David Morrow, Anton Ussi and Giovanni Migliaccio. Addressing Pressing Needs in the Development of Advanced Therapies. Front. Bioeng. Biotechnol. 2017 Sept 25; 5: 55.doi: 10.3389/fbioe.2017.00055 [OPEN ACCESS]

Summary: This article focuses on two of the most urgent areas in ATMP development, namely manufacturing and reimbursement. It promotes the concept of innovation-dedicated research infrastructures to support a multi-sector approach for ensuring the successful development, entry, and survival of ATMPs in the healthcare market.

Synopsis: The commercial development of Advanced Therapy Medicinal Products represents great opportunity for therapeutic innovation but is beset by many challenges for its developers. Although the field continues to progress at a rapid pace, evidenced by the increasing number of clinical trials conducted over the past few years, several factors continue to complicate the introduction of ATMPs as a curative treatment for multiple disease types, by blocking their translational pathway from research to the patient. While several recent publications, as well as an Innovative Medicines Initiative (IMI) consultation in 2016, highlighted the major gaps in ATMP development, with manufacturing, regulatory, and reimbursement issues at the forefront, there remains to be a coherent strategy formulated to address these by bringing the relevant stakeholders to a single forum, whose task it would be to design and execute a delta plan to alleviate the most pressing bottlenecks.

Bridging the translational innovation gap through good biomarker practice

van Gool AJ; Bietrix F; Caldenhoven E; Zatloukal K; Scherer A; Litton JE; Meijer G; Blomberg N; Smith A; Mons B; Heringa J; Koot WJ; Smit MJ; Hajduch M; Rijnders T; Ussi A. Bridging the translational innovation gap through good biomarker practice. Nat Rev Drug Discov. 2017; 16(9):587-588 doi:10.1038/nrd.2017.72

Summary: In collaboration with three European biomedical Research Infrastructures, Prof. van Gool and other scientists from the Biomarker Development Center (BDC), published a comment in Nature Reviews Drug Discovery to help define good biomarker principle guidelines, that will support successful biomarker discovery and development activities.

Synopsis: The value of biomarkers has increased tremendously in the last decade. Not only are they used to predict and detect a disease, they are playing a more crucial role in predicting therapeutic outcomes. This means robust, well-validated biomarkers are crucial to enable effective treatment. Unfortunately, few biomarkers are validated and standardised ensuring FAIR data. This means that although the potential of biomarkers is great, it is not used effectively. To bridge this gap, three European biomedical RIs - EATRIS-ERIC (Translational Medicine), BBMRI-ERIC (Biobanking) and ELIXIR (Data sharing) are paving the way to develop and share best practices for biomarker validation, stimulating research innovation. These guidelines will be defined in the COST action CliniMARK, initiated and coordinated by Dr Luider of the BDC.

The role of global collaborations in preclinical translation

Ussi AE, de Kort M, Coussens NP, Aittokallio T and Hajduch M. In Search of System-Wide Productivity Gains – The Role of Global Collaborations in Preclinical Translation. Clin Transl Sci. 2017 Nov;10(6):423-425. doi: 10.1111/cts.12498. [OPEN ACCESS]

<u>Summary:</u> In this article, authors showcase some initiatives to tackle systemic bottlenecks in the increasingly complex biomedical innovation pipeline.

Synopsis: Identifying and validating tools to better predict the likelihood of proof of concept, reduction of variability through harmonisation and standardisation exercises, and validation of biology to support precision medicine, are some of the systemic bottlenecks that need to be jointly tackled. Using examples from EATRIS authors advocate for actors in all domains related to preclinical translational research, to expand their collaborative horizons to leverage resources and mitigate risks to reduce the costs and duration of drug development.

A key initiative involves collaborators from around the globe, including Therapeutic Innovation Australia, the Center for Drug Research and Development (CDRD) in Canada, LifeArc (formerly MRC Technology) in the UK, and NIH's National Center for Advancing Translational Sciences (NIH-NCATS). The logistical challenges of such a geographically spread initiative, including holding monthly teleconferences spanning 14 time-zones, have been far outweighed by the advantages of bringing together like minded experts in the field. Structured as a modular, light collaboration, the group identifies joint advocacy, educational, technical and harmonisation projects in a bottom-up manner, with operational teams formed on a voluntary basis.

EMA framework for reinforced collaboration with academia adopted

Ussi AE and Migliaccio G. The EMA Framework of Collaboration With Academic Stakeholders. Mol. Ther. 2016 Nov; 24 (11):1883–1884. doi: 10.1038/mt.2016.187 [OPEN ACCESS]

Summary: In March, the EMA Management Board adopted a framework for collaboration between EMA and academia. The framework aims to reinforce and further develop the interactions with the academic community.

Synopsis: The EMA is committed to maintaining a strong working relationship with European academics and researchers. Collaboration between the Agency and academia is necessary for the Agency to be prepared for future challenges and opportunities offered by advances in science and technology. In order to contribute to the implementation of the EMA Network Strategy to 2020, and to respond to challenges posed by emerging technologies, personalised medicines, and advanced therapies among others, this framework aims to achieve the following long-term objectives:

- Raise awareness of EMA's role within the European medicines regulatory network.
- Promote and further develop regulatory support for translating academic research into novel methodologies and medicines.
- Ensure that the best scientific expertise and academic research is available to inform regulatory decision-making.
- Collaborate on areas of research on regulatory science, such as novel approaches, endpoints and methodologies.

Additionally, EMA has developed a supporting action plan which includes initiatives for mutual education and training, staff exchange programmes to promote mutual learning, a strategic research agenda for regulatory science and the creation of an EMA entry point for academia, to receive information on available support within the EU Regulatory Network. In this context, the EMA recently launched a dedicated webpage for academics providing regulatory advice and support to medicine developers applying for H2020 funding.

Scherer A. Reproducibility in biomarker research and clinical development: a global challenge. Biomark Med. 2017 Apr;11(4):309-312. doi: 10.2217/bmm-2017-0024

Summary: In April of 2017, EATRIS Biomarker Platform Co-chair Andreas Scherer commented in the journal of Biomarkers in Medicine on the reproducibility crisis of biomarkers, highlighting some solutions and promoting global collaboration to tackle this challenge.

Synopsis: In recent years, the robustness and reproducibility of data, including those of promising biomarkers, have been a topic for discussion. The validity of data is threatened by many issues, such as poor protocols and design, as well as lack of experiment standardisation and publication bias. EATRIS addresses this reproducibility crisis by supporting Translational Medical research towards clinical applications. EATRIS provides assessment of the clinical need addressed in project proposals, identifies the relevant translational tools and facilities for optimal data generation and provides regulatory and IP support. Furthermore, EATRIS currently establishes collaborations on a global scale to develop strategic plans to reveal sources of irreproducibility in the pre-clinical space, including the biomarker field. One of these initiatives is Translation Together, in which the US, Canada, Australia and UK join forces with EATRIS to utilise complementary expertise from all areas in translational research, with the goal of expediting the development of quality therapeutic interventions and explore the criteria for reproducibility of key technologies in biomedical research.

Open letter to journal editors on: International Consensus Radiochemistry Nomenclature Guidelines

Coenen HH, Gee AD; Adam M; Antoni G; Cutler CS; Fujibayashi Y; Jeong JM; Mach RH; Mindt TL, Pike VW, Windhorst AD. Open letter to journal editors on: International Consensus Radiochemistry Nomenclature Guidelines, featured in the following three journals:

- 1) Ann Nucl Med. 2018 Feb 8
- 2) Nucl Med Commun. 2018 Mar
- 3) J Labelled Comp Radiopharm. 2018 Jan 13

Summary: Last year a group of imaging experts, including key opinion leaders from VU Medical Center (the Netherlands), Uppsala University (Sweden) and King's College (UK) wrote open letters to editors of the major nuclear medicine journals to reach consensus on radiochemistry nomenclature guidelines.

Synopsis: After observing an increased incidence of imprecise and sometimes erroneous use of nuclear chemistry, radiochemistry and radiopharmacy related terms and nomenclature in scientific reports, an international working group of experts was assembled to address the issue. Upon extensive consultation over a three-year period, with peers within the field of radiochemistry and radiopharmaceutical science, and open discussion, consensus was achieved during the International Symposium on Radiopharmaceutical Sciences earlier this year in an open forum. The resulting, harmonised, nomenclature recommendations have now been published with following objectives:

- Provide a reference source for nomenclature good practice in the radiopharmaceutical sciences.
- Clarify the use of terms and rules concerning exclusively radiopharmaceutical terminology, i.e. nuclear- and radiochemical terms, symbols, and expressions.
- Address gaps and inconsistencies in existing radiochemistry nomenclature rules.
- Provide source literature for further harmonisation beyond our immediate peer group (publishers, editors, IUPAC, pharmacopoeias, etc.).

PROJECT CONTENT AND COLLABORATIONS

ID-FPTRI

Funding programme: H2020 (Research Infrastructures)

Total budget: € 3 M **Budget EATRIS:** ~200 K

Coordinator: Consorzio per Valutazioni Biologiche e

Farmacologiche (CVBF)

Website: https://www.cvbf.net/eptri

Starting - end date: January 2018 - December 2019 **EATRIS role:** WP2 Leader- Governance and sustainability;

responsible for drafting the business plan.

Project description: The main objective of this project is to design a framework for the European Paediatric Translational Research Infrastructure (EPTRI), a new RI aimed to enhance technology-driven paediatric research in discovery and early development phases to be translated into clinical research and paediatric use of medicines. The starting point of the proposal is the serious lack of medicines for children in EU and worldwide as well as the lack of a development model for paediatric medicines that integrates technology-driven aspects with clinical trials. The design for this infrastructure will be based on the following main pillars:

1) to harness efficiency and delivery of paediatric research activities and services strengthening collaboration within the scientific paediatric community;

2) to be complementary to the existing RIs covering the current gaps, while avoiding any duplication;

3) to represent a one-stop-shop and common services for advice in paediatric drug development matters. The project was recently kick-started in Rome.

TRANSVAC2

Funding programme: H2020 (Research Infrastructures)

Total budget: € 10.6 M Budget EATRIS: € 211.831

Coordinator: European Vaccine Initiative (EVI) Website: http://www.euvaccine.eu/portfolio/

project-index/transvac2

Starting - end date: May 2017 - April 2022

EATRIS participating institutions: Masaryk University

(CZ), ISS (IT)

EATRIS role: WP16 Leader - Regulatory support; responsible for the development of two regulatory workshops.

Project description: TRANSVAC2 supports innovation for both prophylactic and therapeutic vaccine development. By applying cutting-edge technologies to address critical issues in modern vaccine development, the project will increase the quality of services provided. EATRIS' involvement in this infrastructure project will include primarily the development of a regulatory platform for preclinical, marketing authorisation and pharmacovigilance. In addition, EATRIS will seek to identify inconsistencies in the national regulatory framework while offering consultation for preclinical vaccine development. EATRIS institutions will also organise workshops around these key areas during the project's lifetime.

RITRAIN

Funding programme: H2020 (Research Infrastructures)

Total budget: € 1.9 M **Budget EATRIS:** € 35.000 **Coordinator: BBMRI-ERIC** Website: http://ritrain.eu/

Starting - end date: September 2015 - August 2019 EATRIS role: participation in WP2 (Definition of competencies) and WP5 (Continued professional

development)

Project description: RItrain (Research Infrastructures Training Programme) builds on the results of the RAMIRI2 project to provide high quality training directed at the management of RIs, with a particular emphasis on distributed research infrastructures. RItrain is developing a flagship training programme enabling RIs across all domains to gain expertise on governance, organisation, financial and staff management, funding, IP, service provision and outreach in an international context. It is designed and delivered by experts who have set up and managed RIs from concept to maturity. The project is defining competencies required by RI through consultation with their senior managers. The resulting competency framework is underpinning a Bolognacompliant degree, the Master in Research Infrastructure Management, meant for professionals working in RIs, management teams, recent graduates or others wishing to enhance their employability. Europe's research community and global collaborators will gain from world-class facilities to support excellent, high-impact research.

C-COMEND

Funding programme: Erasmus+

Total budget: € 294.174 **Budget EATRIS:** € 69.122 **Coordinator: EATRIS**

Website: www.eatris.eu/c-comend.html

Starting - end date: November 2015 - October 2017

EATRIS role: Project coordinator

Project description: C-COMEND was a two-year European training project supported by the Erasmus Plus programme, which started on November 1st 2015. The overall objective of the project was to develop 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. A competency profile, developed with input from many stakeholders, served as a basis for the development of the course curriculum: a free online course and a five-day workshop for PhDs and postdocs. The workshop ran twice during the project's life and welcomed 57 participants from many different European countries. A business plan was developed to ensure sustainability of the project's outputs.

EURIPRED

Funding programme: FP7 **Total budget:** € 8.484.910 **Budget EATRIS:** € 89.273 **Coordinator:** NIBSC (UK)

Website: http://www.euripred.eu

Starting - end date: November 2013 - October 2017

EATRIS participating institutions: ISS (IT);

BPRC (NL); HZI (DE)

EATRIS role: Leader WP2 Networking

Project description: The EURIPRED (European Research Infrastructures for Poverty Related Diseases) was a collaborative programme with the objective to reinforce the knowledge infrastructure across diseases. The aim was to speed the development of new tools (vaccines, drugs, microbicides) to combat Tuberculosis, HIV, Malaria, Hepatitis B and Hepatitis C. One of the key activities was providing reference reagents, services and trainings for free.

CORBEL

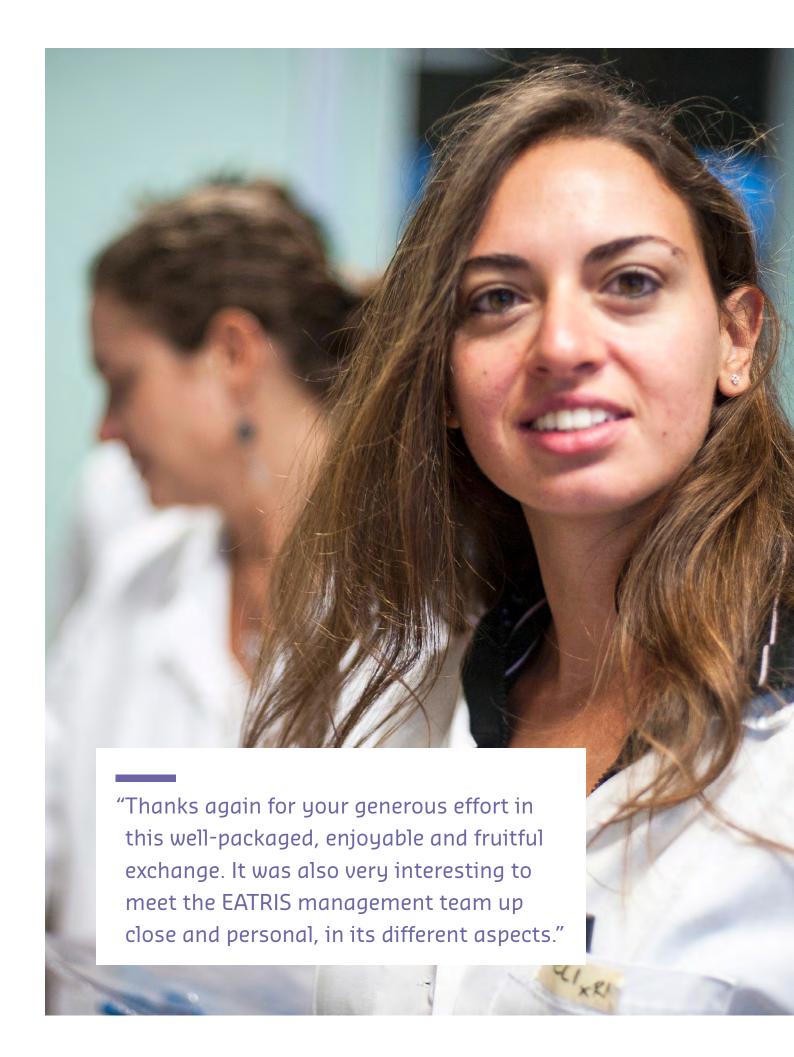
Funding programme: H2020 (Research Infrastructures)

Total budget: € 14.837.800 **Budget EATRIS:** € 745.900 Coordinator: EMBL/ ELIXIR (UK) Website: www.corbel-project.eu

Starting - end date: September 2015 - August 2019 **EATRIS participating institutions:** Stichting Lygature

(NL), IOR (IT), Netherlands Cancer Institute (NL) **EATRIS role:** Leader WP8 - Accelerating Innovation

Project description: CORBEL is an initiative of thirteen new Biological and Medical Research infrastructures (BMS RIs), which together will create a platform for harmonised user access to boost the efficiency, productivity and impact of European biomedical research. Through a user-led approach CORBEL is developing the tools, services and data management required by cutting-edge European research projects. Collectively the BMS RIs are establishing a sustained foundation of collaborative scientific services and are embedding the combined infrastructure capabilities into the scientific workflow of advanced users. Furthermore CORBEL is enabling the BMS RIs to support users throughout the execution of a scientific project: from planning and grant applications through to the long-term sustainable management and exploitation of research data. By harmonising user access, unifying data management, creating common ethical and legal services, and offering joint innovation support CORBEL is establishing and supporting a new model for biological and medical research in Europe. The BMS RI joint platform will visibly reduce redundancy and simplify project management and transform the ability of users to deliver advanced, cross-disciplinary research.



INSPIRING THE NEXT GENERATION OF TRANSLATIONAL SCIENTISTS

Education and training activities focus on providing opportunities in Translational Medicine, which have high impact on researchers' daily practice; developing curricula that support the education of the next generation of translational scientist.

Conference workshops

Memorable activities in Education and Training during 2017 were the workshops preceding the main conference in Prague.

Divided into two parallel streams, EATRIS hosted an educational afternoon comprising of six workshops, which blended technical and non-technical themes. Each session was chosen for its relevancy, and designed to be small and highly interactive, allowing for the sharing of insights from international key opinion leaders. All sessions were developed in partnership with leading organisations in their field, such as Hologic, IgenBiotech, the European Society for Molecular Imaging and our Translation Together partners.

- Using real life case studies, participants had the opportunity to learn about the common pitfalls, as well as the recipes for success in the following topics:
- Translating biomarkers into In-Vitro Diagnostics
- Challenges and best practices in academic drug development
- Building a data package fit for investment
- Potency assays in ATMPs and vaccines
- Molecular imaging supporting CNS drug development
- How to assess and maximise the potential impact of your translational research plan.

The workshops were well received, with **102 attendees** and excellent participant feedback.

C-COMEND - Successful Erasmus+ project ended

C-COMEND was a two-year European training project supported by the Erasmus + programme, which started on 1 November 2015. It began with the overall objective of bringing together stakeholders from different sectors and disciplines in order to develop a course aimed at PhD students and early Post-Docs, teaching the skills and competencies required to successfully contribute to translational research and medicine development.

In October 2017, the project ended after a second successful five-day workshop on Translational Medicine. The workshop, hosted by the Berlin Brandenburg Centre for Regenerative Therapies (BCRT), welcomed 30 PhD and early Postdoc students, as well as experts in the field of Translational Medicine, including industry representatives.

The course featured a host of learning activities, including a drug development board game, elevator pitches and patient stories. The overall course programme was evaluated with a 9.5/10 grading and the course content received a 100% recommendation rate.

A preparatory e-learning course entitled the Landscape of Translational Medicine, which was developed with experts in the field from Radboud UMC (NL), NIH-NCATS (US), University of Birmingham (UK), I3H (BE), ECRIN (FR) and industry, welcomed over 200 participants from across the globe. The course is open to anyone interested in exploring themes within the Translational Medicine field (e.g. biomarker development, target validation, predictive models, regulatory environment) and will remain available free of charge.

Find it online: http://elevatehealth.eu/online-medical-courses/the-landscape-of-translational-medicine

"I still profit from the staff exchange."

BIO International Convention, San Diego - engaging panel presentation

The BIO International Convention, held in San Diego in 2017, saw EATRIS organise a well-attended and engaging panel presentation entitled 'Getting the Human into the Dish: The Road Towards More Predictive Pre-Clinical Models.'

The session focused on providing knowledge on technology to humanise and improve models related to drug discovery and screening. The panel featured speakers from Merck, NIH-NCATS, Cellular Dynamics, Institute of Molecular and Translational Medicine (IMTM) and the Foundation Hubrecht Organoids Technology.

CORBEL Webinar

The CORBEL project brings together thirteen BMS RIs to boost the efficiency, productivity and impact of European biomedical research.

In 2017 EATRIS hosted a CORBEL webinar on identifying potential industry partners and networking. The webinar series aimed to address challenges and share best practice between BMS RIs.

The networking webinar highlighted proven strategies to present research outcomes to an industrial audience. During the one-hour session, including a Q&A session, participants had the opportunity to recognise effective venues for networking with industry, a sharp approach to summarising their proposition, and what to expect from the process of interacting with industry.

Rltrain - First successful Rltrain Staff Exchange hosted by EATRIS

In March 2017 EATRIS hosted the first Ritrain Staff Exchange in its headquarters in Amsterdam.

Eleven participants from ten different RIs came together with EATRIS staff to share best practices on strategy, governance and business development of RIs.

Infrastructure Directors, Project Managers, Finance and Policy Officers, had the opportunity to discuss the challenges of running an RI and learn from the experience of more mature RIs. This diverse mix of participants promoted exchange across diverse infrastructures and meant those involved were able to analyse challenges from a multitude of perspectives.

All participants agreed that it was a valuable experience and many of them developed new ideas on how to tackle their challenges. For EATRIS staff, the exchange was a valuable experience, as it gave the opportunity to reflect on achievements and remaining challenges with fresh perspective.

EATRIS is delighted to host a staff exchange on governance, business context and operational planning for hubs and nodes 12 – 13 June 2018.

TRANSLATION TOGETHER, A NEW GLOBAL TRANSLATIONAL SCIENCE INITIATIVE

Top global translational science organisations to catalyse biomedical innovation through new initiative.

On 25 September 2017, during EATRIS' Translational Medicine 2017 Conference, and at the height of Global Biotech Week, five of the world's top translational science organisations representing the European Union, the United Kingdom, the United States, Canada, and Australia announced they had joined forces under the new banner of Translation Together.

The collaboration, intended to leverage the complementary scientific and operational strengths of member organisations, provides a platform for shared insight into the challenges in Translational Medicine and gives the community a collective voice.

Who are the participating organisations?

Participating organisations are: LifeArc in the UK, EATRIS in the European Union, The Centre for Drug Research and Development (CDRD) in Canada, Therapeutic Innovation Australia (TIA), and the National Institutes of Health's National Center for Advancing Translational Sciences (NIH-NCATS) in the United States.

'It is very exciting for EATRIS to work with these leading organisations to jointly tackle pressing issues in drug development and advance translational medicine as a discipline.' Anton Ussi, EATRIS Operations and Finance Director.

Providing solutions to bridge the gap

There is broad consensus that the development of new medical interventions takes too long, costs too much and too often ends in failure. Furthermore, the 'innovation gap,' between fundamental discoveries related to human disease and the delivery of new therapeutic options to patients, has remained stubbornly persistent. The field of translational science is poised to provide solutions to bridge this gap, and thereby help to bring more medicines to more patients faster. In this context, Translation Together envisions a global translational research community of diverse stakeholders, empowered to effectively and efficiently translate discoveries into treatments and cures for the benefit of patients and society.





'Each of our organisations is dedicated to the common goal of accelerating the translation of scientific discovery into new therapeutic products. By tackling that challenge together we will be able to maximise the respective impact we have on the lives of patients."

Dr. Christopher P. Austin, NIH-NCATS Director.

Translation Together's Objectives

Objectives and activities to be undertaken through Translation Together will centre around education and training, facilitating and conducting research and development, and fostering greater awareness of Translational Medicine. More specifically, Translation Together aims to coordinate and develop programmes and resources to equip the next generation of translational scientists. The collaboration also intends to assist investigators in the conduct of translation and translational science by connecting them to resources, tools, technologies, and expertise.

Translation Together's mission is to conduct collaborative research projects to systematically remove barriers, catalyse translation and foster a broad understanding and appreciation for translational science among diverse stakeholders.

Visit the website: translationtogether.org

FINANCIAL SUMMARY

Development in income and expenses result:

Compared to the previous year, the contributions income changed with € 54 K due to a decrease in members (-100 K, Denmark) and an increase in other income (+46 K). EATRIS covered the gap by a better project income than budgeted. The subsidy income decreased by € 83 K, mainly due to a lack of NWO stimulus subsidy (2016:125 K).

Personnel expenses (salaries and wages and sub total staff) have decreased due to an increase in staff costs charged to projects and an increase in received illness payments.

	Annual report 2017	approved budget 2017	Annual report 2016
	€	€	€
Contributions income	1,369,937	1,435,000	1,423,677
Catch up budget		180,000	
Subsidy income	261,505	-	344,367
Total income	1,631,442	1,615,000	1,768,044
Salaries and wages	835,482	806,339	844,849
Sub total staff	187,488	267,274	196,852
Personnel expenses	1,022,971	1,073,613	1,041,701
Depreciation	8,552	5,000	8,404
Other expenses	810,242	536,338	733,744
Total expenses	1,841,764	1,614,951	1,783,849
Total operating result	-210,322	49	-15,805

	2017	2016	Analysis
Activa	x € 1,000	x € 1,000	
Tangible fixed assets	18	20	The book value of the tangible fixed assets decreased as a result of a higher amount of deprecation than investments.
Current receivables	605	391	The increase is due to more outstanding contributions at year-end 2017 compared to last year. Therefore more contribution income is still a receivable at year end rather than received as a cash position.
Cash at banks	303	788	Cash at banks decreased due to an increase in current receivables and a decrease in accrued liabilities.
	926	1,199	
	2017	2016	Analysis
Equity & Liabilities	x € 1,000	x € 1,000	
Reserves	469	679	The reserve was adjusted with a net of € 210 K, equal to the negative result of the financial year.
Current liabilities	457	520	The decrease is caused by the other liabilities and accrued expenses. Primarily due to a lower amount in advance receipts of subsidy money in 2017 compared to 2016.
	926	1,199	

A FINAL WORD FROM GIOVANNI MIGLIACCIO ON HIS RETIREMENT AS SCIENTIFIC DIRECTOR.



"EATRIS has been always a very innovative dream in the European research framework. It began as a small group of excellent research centres strongly involved in Translational Medicine and was reborn as a larger collection of institutions." Giovanni Migliaccio

After eight years of involvement in various capacities at EATRIS, I stepped down from my position as Scientific Director in December 2017 and embraced retirement. It is an obvious occasion to reflect upon all the achievements and missed opportunities over these years.

EATRIS has been always a very innovative dream in the European research framework. It began as a small group of excellent research centres strongly involved in Translational Medicine and was reborn as a larger collection of institutions. Those that were selected were chosen not only for their Translational Medicine experience but their willingness to build a larger infrastructure and solve the dawning issues in the drug development pipeline.

It was a change dictated by necessity as well as ingenuity, making do with available resources in order to respond to the need for an alternative non-profit pathway drug development. We also understood that academic researchers needed access to facilities, high end apparatus and specialised expertise locally.

Looking back, I am sure we could have done a better and faster job, but we faced a huge challenge. Presenting a group of public institutions, willing to enter a field completely dominated by the bio-pharmaceutical industries for the last 50 years, to external stakeholders, was not easy.

It took time. Yet, slowly, the industry started to recognise the value of a single point of entry to 70+ top tier institutions.

Trust was built slowly but solidly and now it is a growing process which sees market awareness as the most limiting factor. Internal organisation and fostering a client focused, service oriented culture was a key challenge met in the first three years after EATRIS was awarded ERIC status. This would not have been possible without the dedication of a small group of devoted scientists who had to master how to integrate expertise from various scientific fields and develop practical processes to help manage requests from a diverse pool of stakeholders from within EATRIS Member Institutes.

Mixing scientific knowledge with managerial skills, while maintaining a vision of the translational pathway, is a skill that we had to learn, if not invent. No academic institution offers a dedicated training for this job.

That is why I am proud of the dedication and personal sacrifices made by the Coordination & Support team over the years. I will miss them. But, not too much as I am delighted to still contribute to EATRIS as Senior Advisor and help the new Scientific Director, Toni Andreu, as much as I can. Toni is as dedicated as any of us and full of energy which will propel EATRIS in the next cycle of its life.

EATRIS, under Toni's direction, will be a leader in a process that will carry the single biomedical researcher from the domestic laboratory to the use of delocalised, high-end, specialised services.

Creativity has been always part of the academic requirement and EATRIS will help to sustain the process of channelling that creativity, in an efficient way, to new personalised therapies for an increasingly wider population.

MEET THE C&S TEAM



Anton Ussi Operations & Finance Director



Martin de Kort Programme Manager Imaging & Tracing and Small Molecules platform



Giovanni Migliaccio Senior Advisor



David MorrowProgramme Manager
ATMP & Vaccines platform



Frank de ManGovernance & Finance



Anne-Charlotte Fauvel Project Manager



Florence BietrixOperations & Programme
Manager Biomarker platform



Kees de Ruig Business Development Manager



Tim Moser Industry Partnering Specialist



Tamara Carapina Legal Counsel



Lisa Marie Williams Office Manager



Katherine Blom Communications Manager



Rosan Vegter Training Project Manager



Laure BoudaudIT & Platforms Coordinator



Rebecca Ludwig Training Manager



Ben LydallFinance & Sustainability
Consultant



Nigel Wagstaff Advisor Innovation Support



Erika Groenink Finance Officer



Toni Andreu Scientific Director

ISCT

IVD

LIST OF ABBREVIATIONS

Α	AAIC	Alzheimer's Association Annual Meeting
	ATMP	Advanced Therapy Medicinal Products
	BBMRI-ERIC	Biobanking and BioMolecular Resources Research Infrastructure
В	BCRT	Berlin Brandenburg Center for Regenerative Therapy
_	BDC	Biomarker Development Centre
	BMS RI	Biological and Medical Research Infrastructures
	BPRC	Biomedical Primate Research Centre
	B2B	Business to business
c —	CASMI	Center for the Advancement of Sustainable Medical Innovation
	C-COMEND	Competency-based course on Translational Research and
		Medicines Development
	CDRD	Centre for Drug Research and Development
	CERN	European Organisation for Nuclear Research
	CORBEL	Coordinated Research Infrastructures Building Enduring Life-Science Services
D	DWG	Disease Working Group
E	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
	ECaDE	Early Cancer Detection Europe
	ECRIN	European Clinical Research Infrastructure Network
	EMA	European Medicines Agency
	EMBL	European Molecular Biology Laboratory
	EPF	European Patients Forum
	EPTRI	European Paediatric Translational Research Infrastructure
	EQI	EATRIS Quality Initiative
	ERA	European Research Area
	ERIC	European Research Infrastructure Consortium
	ESFRI	The European Strategic Forum for Research Infrastructures
	EU	European Union
	EUnetHTA	European Network for Health Technology Assessment
	EURIPRED	European Infrastructure for Poverty-Related Diseases
	EVI	European Vaccine Initiative
F	FAIR Data	Findable Accessible Interoperable Reusable Data
	FDA	Food and Drug Administration
G	GMP	Good Manufacturing Practice
н —	HESI	Health and Environment Sciences Institute
	HTA	Health Technology Assessment
	HTS	High Throughput Screening
ı —	IBBL	Integrated BioBank of Luxembourg
	IMI	Innovative Medicines Initiative

International Society for Cellular Therapy

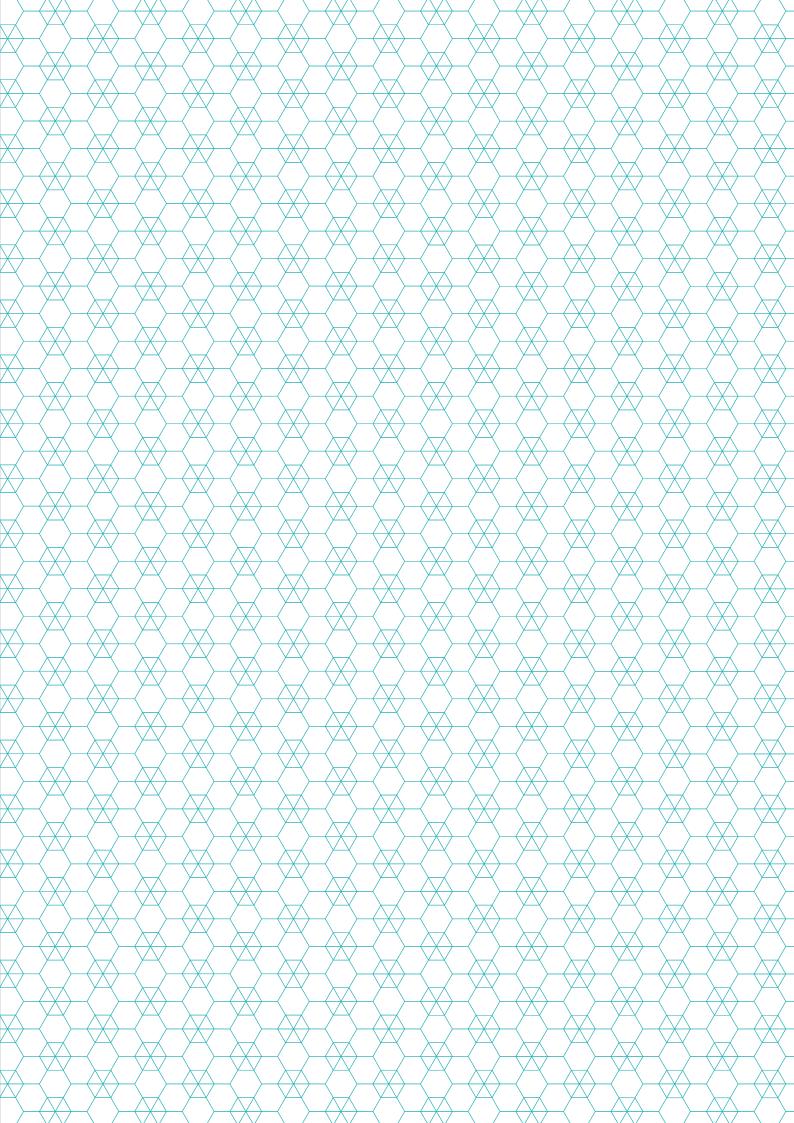
In vitro diagnostics

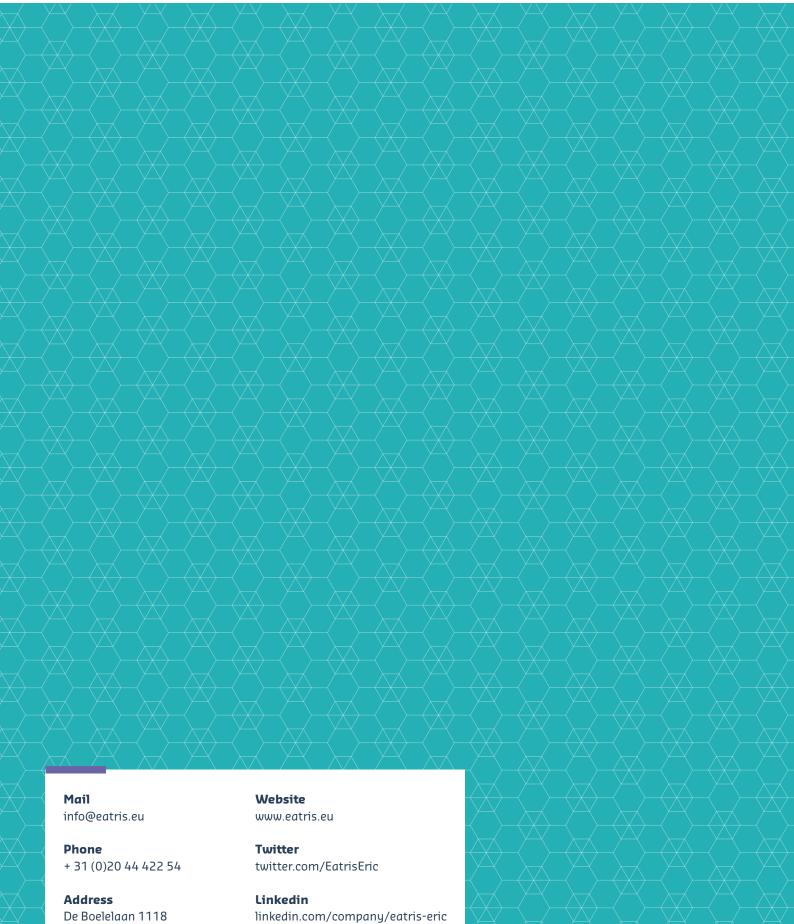
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J —	JTC	Joint Transnational Call
L	LoE	Letter of Engagement
	LTP	Linked Third Party
M	MAGBBRIS	New MAGnetic Biomaterials for Brain Repair and Imaging after Stroke
	MoU	Memorandum of Understanding
	MRCA	Master Research Collaboration Agreement
N	NIBSC	National Institute for Biological Standards and Control
	NIH-NCATS	US National Institutes of Health - National Center for the Advancement of
		Translational Science
Р ——	PDA	Parenteral Drug Association
	PET/CT	Positron Emission Tomography - Computed Tomography
	PET/MRI	Positron Emission Tomography - magnetic resonance imaging
	PI	Principal Investigator
R	R&D	Research and Development
	RI	Research Infrastructures
	RICH	Network of National Contact Points for Research Infrastructures
	RITRAIN	Research Infrastructures Training Programme
s	SMEs	Small and medium-sized enterprises
	SOP	Standard Operating Procedure
Т	TIA	Therapeutic Innovation Australia
	TRANSCAN-2	ERA-NET: aligning national/regional translational cancer research programmes
		and activities
	TRANSVAC2	European Network of Vaccine Research and Development
W	WP	Work Packages
z	ZonMw	The Dutch Organisation for Health Research and Development

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