ANNUAL REPORT 2018

EMPOWERING COMMUNITIES TO ACCELERATE TRANSLATION

eatris

European infrastructure
for translational medicine

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FOREWORD

MARIANNE GRØNSLETH

Chair of the Board of Governors

EATRIS in 2018 has unequivocally strengthened the foundations for further growth within translational medicine. The highlight of last year was the release of the Strategic Plan 2019-2022. This plan sets the priorities in empowering communities to accelerate translation and serves as a guide for the activities of the coming years. We would like to see EATRIS as a transnational ecosystem where scientists, funders, regulators, industry and patients can work together effectively to transform scientific breakthrough into life-altering interventions for patients.
Furthermore, the joint statement of EATRIS, BBMRI and ECRIN with regards to the upcoming Horizon Europe framework programme was a stepping stone towards closer collaborations between the three Research Infrastructures focusing on medical breakthroughs. This signifies a new era in the application of biomedical research.

The existence of a common line of actions can accelerate further the tackling of systemic bottlenecks in research such as undesired duplication, fragmentation and irreproducibility. I strongly believe that such a coalition will help position innovative science and patient benefit in the centre of the European Research Area.

In 2018, we were also delighted to welcome Portugal and Bulgaria as a Full Member and as an Observer respectively. All EATRIS ERIC Members and Observers are fully committed to supporting EATRIS in reaching its important goal: bridging the gap between medical research and clinical application by accelerating and optimising translational research.

Sincerely,
MARIANNE GRØNSLETH

MATS LARHED

Chair of the Board of National Directors

2018 was a truly significant year for EATRIS. The joint GSK Hub was officially announced on June 4, providing a new collaborative model for EATRIS to promote translational research and public-private collaboration in Europe.
EATRIS launched the new EATRIS Flagship project support, enabling development and management assistance to five selected funding applications identified as key initiatives with the potential to strongly improve translational R&D processes in Europe.
Another important achievement by EATRIS during 2018 was the strong increase in services offered to academia, a development I believe in and hope will continue to advance.

From a personal perspective, 2018 was my first year as the Chair of the Board of National Directors. I have enjoyed this new role and especially working with the EATRIS team together with my participation in the EATRIS Annual Meeting in Ljubljana, Slovenia.

I look forward to 2019 and to contributing to building a strong EATRIS with the support of our Strategic Plan. I am very confident that next year will also be a highly successful year for EATRIS.

Sincerely,
MATS LARHED

ANTON USSI
Operations & Finance Director

TONI ANDREU
Scientific Director

It is with great pleasure that we present to you our 2018 Annual Report. As with all previous years in our short history as the European Infrastructure for Translational Medicine, the year was an exciting blend of growth, adaptation and maturation.

Starting the year with Toni Andreu taking on the role as Scientific Director, under his guidance we finalised the Strategic Plan 2019-2022, the result of a wide consultation process with our key stakeholders. The product is a concise, robust and exciting programme designed to meet the needs of our community of users and members. A highlight of this is the special focus on supporting national community development and the initiation of the EATRIS Strategic Research & Innovation Agenda in support of that goal.

2018 also witnessed significant growth in our portfolio of services for academic users, to augment our sector-leading portfolio of industry services. As a result, we are enjoying rapid expansion of our active user base by supporting the development of ground-breaking therapies and diagnostics and translational tools. The development of imaging tools for the tracking of cell therapies in the body as seen in the EPPIC proposal is a highlight, along with the IMI selection towards second stage application of EU-PEARL, an ambitious proposal to develop a long-term framework for platform trials in a wide variety of disease areas.

These efforts directed at academia do not, however, come at the expense of industry services. 2018 marked the formal initiation of the EATRIS-GSK Immune Inflammation Imaging Hub, a long-term pre-competitive innovation hub developing new tools for drug development. Already boasting several active preclinical and clinical projects, we see it as a blueprint for many more public-private endeavours in the translational domain.

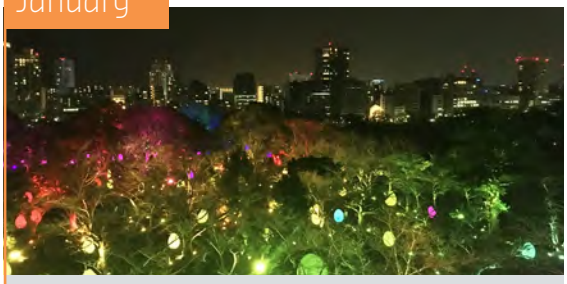
Beyond Europe, the filaments of interconnectedness extended our reach across oceans; AMED as the main funder and proponent of translational medicine in Japan joined the Translation Together family, while we joined the US-based and globally active Personalized Medicine Coalition, creating an opportunity for building collaborations in the field of Personalised Medicine across the Atlantic.
At the centre of all our endeavours, everything we do is directed towards the goal of maximising patient and societal benefit.

In 2018, EATRIS grew closer to the patient and engaged with the European Patients' Forum, with 72-member organisations, each representing patients nationally or across the EU. By aiming at having the patient's voice at the centre of our activities, we fully embrace the European Responsible Research and Innovation principles, proving that Research Infrastructures are tools to foster the design of inclusive and sustainable research and innovation.

Sincerely,
ANTON USSI
TONI ANDREU

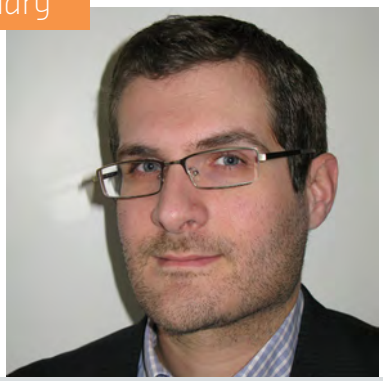
EATRIS HIGHLIGHTS FROM 2018

January



Florence Bietrix, Operations and Biomarker Platform Manager, gave lectures on Translational Research at Kyushu University, Japan

February



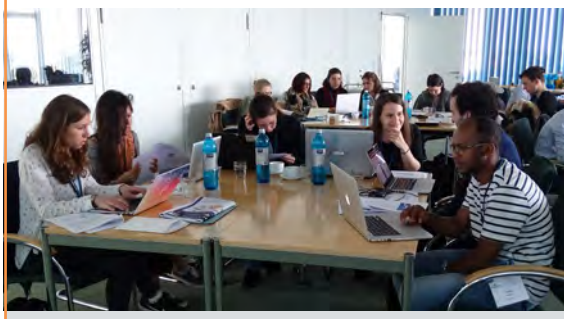
Election of Cyril Poupon (NeuroSpin, Paris, France) as new chair for the Imaging and Tracing Platform

March

Alfredo Budillon (IRCCS Fondazione Pascale Naples, Italy) and co-chair of the Small Molecules Platform hosted a seminar between EATRIS and the European Society for Medical Oncology (ESMO)

April

Portugal joined EATRIS as Full Member



5-day course on Translational Medicine held in Berlin, Germany

June

EATRIS attended the BIO International Convention in Boston, USA with EATRIS booth

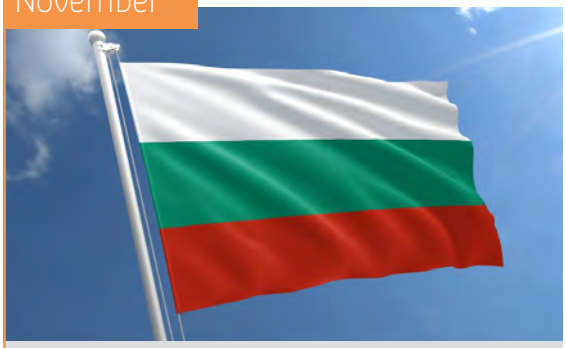
June

AMED welcomed as a new member of Translation Together at the annual face-to-face meeting of the initiative

September

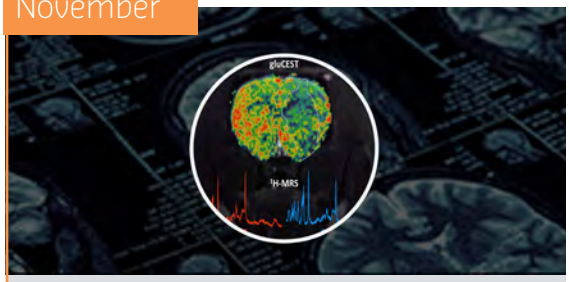
EATRIS organised a workshop on non-invasive cell tracking at the Phacilitate Leaders Europe Conference

November



Bulgaria joined EATRIS as an Observer

November



EATRIS together with NeurATRIS organised a series of Webinars on Imaging

December

EATRIS Annual Meeting in Ljubljana, Slovenia and launch of the Strategic Plan 2019 – 2022

Workshop on Best Practices in Public-Private Collaborations organised through the CORBEL project

RELEASE OF OUR STRATEGIC PLAN 2019-2022

EMPOWERING COMMUNITIES TO ACCELERATE TRANSLATION

The development of our Strategic Plan started in the summer 2017, driven by the Executive Board and the Coordination and Support Office (C&S), in close collaboration with the Board of National Directors (BoND) and the Platform Chairs (PCs). The final proposition received the approval of the Board of Governors (BoG) in November 2018. The official public release took place during our EATRIS Annual Meeting in Ljubljana, Slovenia on December 12, 2018.

The rationale for this strategy derives from a comprehensive analysis of our past actions and activities. We identified the challenges in the translational medicine landscape and presented a coherent package of actions empowering EATRIS as one of the main actors supporting the development of novel medicines in the 21st century.

This strategy reflects our vision for the future of the Infrastructure to empower national communities and our ambition to raise awareness about EATRIS and ultimately to advance the field of translational medicine. Our Mission and Vision define EATRIS as a translational organisation where members contribute with all relevant resources to transform scientific breakthroughs into life-altering interventions for patients, and effective preventive measures for better health.

VISION:
Making translation of scientific discoveries into medical products more effective to improve human health and quality of life.

MISSION:
To support researchers in developing their biomedical discoveries into novel translational tools and interventions for better health outcomes for society.

The Strategic Plan is built on five pillars (goals) that have the ambition of maximising the impact of EATRIS on the translational medicine landscape.

GOALS:
- Build on our academic credentials: reinforcing EATRIS community;
- Create an effective translational medicine ecosystem;
- Synchronise the capacities of the medical RIs;
- Raise EATRIS awareness;
- Education and training as a driving force for the translational medicine community.

IMPACT:
Engender a vibrant and committed multidisciplinary scientific community utilising cutting-edge academic expertise and technology services to improve the flow of academic and SME knowledge towards the patient, while reducing barriers to public-private and public-public collaboration.

Develop tools and models to reduce the cost and time associated with early medicines development, thereby enhancing biomedical innovation at European and global levels.

Widen the circle of EATRIS' close partners and collaborators, resulting in increased visibility for potential users of the infrastructure, the patient community and society as a whole.

Address the systemic obstacles hindering biomedical innovation in Europe with coherent messaging and input that will assist the policy-making process.

OUR SERVICES IN 2018

CONSOLIDATING OUR PORTFOLIO AND DEVELOPING OUR ACADEMIC SERVICES

Since the start of its operations in 2014, EATRIS ERIC has enriched its set of academic services both for public and private users in Translational Medicine.

The broad nature of the EATRIS research infrastructure has proven to serve needs and requests from diverse user groups. We do it through creating the right multi-disciplinary teams according to project requirements and through accessing the latest translational tools for effective transition to the clinic.

Our technical services available at EATRIS member institutions combine three disciplinary pillars for early decision making:

- Accessing validated analytical tools in the context of use;
- Contributing clinical observation through our clinical capacity;
- Deep biological expertise for a mechanistic understanding.

By creating cross-disciplinary teams of leading experts, each project enjoys a more rational, mechanistically focused approach for higher chances of success.

Our services can be offered through partnerships with industrial partners, within academic funding proposals and to funders for strengthening their project portfolio.

In 2018, five requests for paid research services from industry were handled. One request signed in 2017 continued with the generation of a study plan with the aim to progress towards a collaboration in the clinic in 2019. An additional two requests came through the CORBEL Open call – Track 5 for Complex Multimodal Biomarker Profiling and, in addition, two translational assessments were performed for a charity in the Netherlands, Foundation National Reumafonds, with whom we have a long term collaboration.

2017 marked the gestation of the GSK Immune Inflammation Imaging Hub for imaging method development in inflammatory diseases. However, it was in 2018 that the long-term collaboration was officially announced through a publication released on June 4, 2018 (page 16). One year after initiation, this public-private collaboration involving eight legal entities shows significant growth and maturation not only by generating the project's initial results but also by enhancing its scientific portfolio with three preclinical projects started, two clinical projects in preparation and several concepts waiting for green light.

Regarding academia, 2018 is marked by an increase to the number of services offered to this user group (more details on those services are given on page 14). We provided our consortium building service to 15 investigators and 17 proposals included our centralised services within one or more work packages:

- Innovation Management & industry partnering
- Translational optimisation
- Regulatory support
- Training

In addition, in 2018, we launched EATRIS support for flagship projects. Flagship projects are identified as key potential contributions to the EATRIS Strategic Research and Innovation Agenda, as technical or operational initiatives with the potential to systemically improve the R&D process. For those projects we take a leading role in supporting the development and management of the proposals. In 2018, we supported 6 flagship projects, namely:

- EATRIS-Plus (H2020-INFRADEV-3) to support EATRIS capacities for personalised medicine;
- EPPIC (SC1-BHC-09) for tracking of CAR T-cell therapies;
- EJP-RD (SC1-BHC-04), a €108M initiative with EATRIS taking a leading role in translational and clinical innovation, as well as sharing responsibility for the sustainability of the project that will incubate through;
- EU-PEARL, a €24M (€12M grant) IMI project proposal coordinated by VHIR (Spain) for the establishment of a platform enabling patient-centric drug development and accepted to second stage and;
- ADVANCE, an Erasmus Plus funding application focusing on e-learning and workshops in the field of Advanced Therapy Medicinal Products (ATMPs).
- EOSC-Life (INFRAEOSC-04-2018), the cluster project coordinated by ELIXIR with the participation of 5 EATRIS Linked Third Parties (University of Helsinki (FI), IMTM (CZ), Lygature (NL), VHIR (ES), Mario Negri Institute (IT))

The experience gained in 2018 with participating in grant applications allowed us to formalise our services around four levels of support. Clear criteria for eligibility for each level were also identified.

- **Level 1:** Consortium Building
- **Level 2:** Providing Letter of Support
- **Level 3:** Joining as Partner
- **Level 4:** Supporting EATRIS Flagship projects

Summary of activitiy

Core activities	**2015**	**2016**	**2017**	**2018**
Consortium Building	4	18	14	15
Matchmaking	5	9	14	6
Translational Assessment/Expert advice	1	3	14	2
Hub Partnering	1	1	1	1
Income C&S Office	**2015**	**2016**	**2017**	**2018**
Service Fees*	€ 51,616	€ 100,150	€ 114,838	€ 32,417
Grants	€ 147,014	€ 219,035	€ 261,505	€ 309,768
Income Institutions (Budget negotiated)	**2015**	**2016**	**2017**	**2018**
Industry Projects	€ 23,474	€ 1,629,431	€ 326,571	€ 5,000
EATRIS Linked Third Party grants	€ 203,966	€ 388,859	-	€1,615,049
Users	NA	1,400	5,500	3,000

*non-grant/non-contribution income

OUR SERVICES

Research Sevices (Matchmaking)

EATRIS C&S Office provides 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 users. 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? For Industry, big pharma, biotech companies and SMEs

Consortium Building (Fast Matchmaking)

Like 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

With EATRIS-Inside, a unique service model in Europe, we assess 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 in 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, we have developed a catalogue of centralised services for academic users developing proposals for funding applications (see page 14 for more details):

- Regulatory work package
- Translational feasibility and early Health Technology Assessment (HTA)
- Innovation & impact (feasibility and HTA, partnering, intellectual property)
- Training (focused on translational research)
- Letter of Support
- Hands-on development and management of proposals

Who is it for? Funding agencies, Charities and 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

Set-up and management of public-private innovation Hubs

Following the successful experience of the unique alliance put in place for GSK with six EATRIS partner institutions, see page 16 for press release, EATRIS is ready to offer this service to additional industry clients. This service is typically tailored to the needs of a pharma company looking to form a long-term collaboration with multiple academic partners. It offers a novel collaboration format to enable experts in the agreement to fully focus on the scientific and technical challenges to be tackled. EATRIS acts as a portfolio manager, playing a key role in developing and administering the legal framework and management of the collaboration, for optimal speed and efficiency.

Who is it for? Industry

CASE STUDY

EATRIS FLAGSHIP PROJECT - EPPIC

Interview with Dr. Mangala Srinivas,
Assistant Professor at Radboudumc, Nijmegen, The Netherlands
and Manager of Search, Strategy and Evaluation at GE Healthcare

In 2018, EATRIS co-developed a flagship project which involved 7 EATRIS institutions amongst 19 consortium partners and which was coordinated by Dr. Mangala Srinivas from Radboudumc. This flagship project was developed over several months for submission to the H2020-SCI-BHC-15 call for up to 15 million euros in funding. Unfortunately not funded, the project titled EPPIC (Early Prognostic Platform for Imaging Cells), was built on several EATRIS ATMP initiatives which aimed at addressing major bottlenecks currently preventing cell therapies from successful application. This includes a lack of understanding of in vivo cell fate, poor regulatory clarity and poor transfer of knowledge between major stakeholders.

Interview from Dr. Mangala Srinivas

We had the exciting opportunity to talk with Dr. Srinivas about the EPPIC Project and her recent collaboration with EATRIS. She started her career in research at the National University of Singapore, before completing her Ph.D. at Carnegie Mellon University (USA). Her work focuses on contrast agents for in vivo imaging. Dr. Srinivas' early work helped establish the field of ^{19}F MRI for quantitative in vivo cell tracking, including the publication of the first article on the topic[1]. More recently, her group started working on customisable nanoparticles for imaging and advanced personalised medicine applications. Some of these nanoparticles will be tested in a clinical cell tracking study using multimodal imaging in melanoma patients.

What is/are the goal(s) of the EPPIC project? Which technology innovation does EPPIC aim to fill?

EPPIC aims to develop a broad platform for cell therapies, covering everything from manufacturing and transport, to in vivo monitoring through imaging.

What is in it for the patients?

Cell therapy can have enormous benefits, given we can improve efficacy and reduce costs. Thus, this project would have broad and significant implications.

Looking forward: How will you bring EPPIC to the patient? How are you going to turn this into a reality?

At the moment, we are working on finding funding for this idea. Another way forward is through working on building a public-private innovation Hub around cell tracking in collaboration with industry partners.

Where was the idea for the EPPIC project born and how did you first get involved with this call?

EATRIS and I were involved in a HESI group (Health and Environmental Sciences Institute), called CT-TRACS, also on cell tracking. The idea was kind of born here.

What was the involvement of EATRIS?

EATRIS was involved right from the beginning, in helping develop the idea and putting together the consortium.

How did you work with EATRIS and what is the added value of EATRIS for EPPIC?

EATRIS was central to setting up this project.

How do you work with EATRIS to push further the EPPIC project?

We are working on various invited talks and workshops on this idea, and also the setting up of an Innovation Hub.

1 Srinivas M, Heerschap A, Ahrens ET, Figdor CG, de Vries IJM. ^{19}F MRI for quantitative *in vivo* tracking of cellular therapeutics. Trends Biotechnol 28(7):363-70, 2010.

STRENGTHEN YOUR RESEARCH PROPOSAL WITH EATRIS

EATRIS offers a range of services to researchers preparing funding applications. The services described here can be provided for funding calls involving translational research. These are mainly H2020, IMI, ERA-NET calls, as well as calls published by national funders and charities.

Level 1: Forming a consortium

EATRIS can help you find the right European academic partner for your consortium thanks to a comprehensive database of the high-end capabilities and expertise of 90 top-tier member institutions. This service is free of charge. If you are a member of the infrastructure, EATRIS can also support you in identifying companies, charities, or patient organisations for your consortium. To benefit from this service, please fill in the request form available on our website. Our team will provide you with a report listing the potential matches among EATRIS members. Please note it is the PI's responsibility to then liaise with the institution or organisation of interest.

Level 2: Providing a Letter of support

EATRIS can provide coordinators with a letter of support for their proposal. To request a letter of support, please send the latest draft of your proposal, or at least a 3-page document including the composition of the consortium, a summary of the concept and foreseen impact, minimum four weeks before proposal submission. Please note that we are bound by confidentiality rules and will not distribute any drafts or project summaries to others without your explicit permission or request.

Level 3: Joining as partner

When relevant, EATRIS may participate in research funding proposals as full partner providing various centralised services with member institutions involved as linked third parties if necessary. EATRIS C&S office based in Amsterdam can provide the following services:

- **Innovation Management & industry partnering**

Activities can include: design of the dissemination and exploitation plan of the project; definition and implementation of a monitoring plan to capture intellectual property protection needs in a timely fashion; identification of industry partnering opportunities for co-development and/or out-licensing; follow-up financing opportunities.

- **Regulatory support**

EATRIS will leverage expertise from EATRIS affiliated institutions and perform dedicated tasks or work packages providing regulatory support by:

- Assessing the project's regulatory strategy and feasibility;
- Interacting with the relevant regulatory authorities;
- Answering any regulatory question arising during the project's lifetime;
- Ensuring the project fulfils all regulatory requirements.

- **Translational optimisation**

Activities can include: monitoring of the project to deliver a timely evaluation of the translational potential of the results generated during the project; full translational assessment to define follow-up validation route; early HTA support.

- **Training provider**

EATRIS can provide in-person workshops, tailor-made to the needs of your project, for example on:

- how to assess the translational potential of your project,
- how to develop collaboration with industry, or
- an introduction to translational medicine (particularly relevant for PhD students and postdocs).

These workshops typically can be offered as part of "Innovative Training Networks" proposals from the Marie Skłodowska-Curie work programme of Horizon 2020.

Level 4: Leading Flagship projects

From time to time, EATRIS will take a leading role in supporting the development and management of proposals coming from EATRIS member institutes. To be eligible for such support, the proposal has to be aligned with EATRIS' Strategic Plan 2019-22.

CASE STUDY

GSK IMMUNE INFLAMMATION IMAGING HUB

On June 4 2018, EATRIS announced a novel public-private collaboration for imaging method development in inflammatory diseases. The international multi-site collaboration hub will implement new clinical imaging tools and deliver several projects per year with enhanced speed and throughput.

PRESS RELEASE

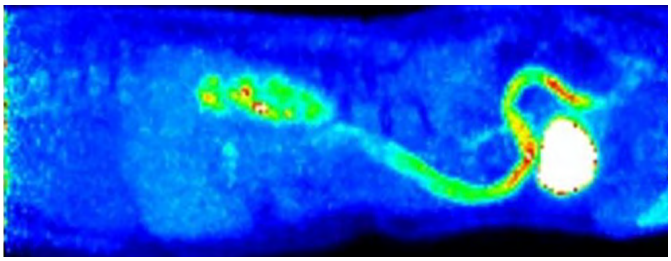
The European Infrastructure for Translational Medicine (EATRIS) has formed a collaboration with GlaxoSmithKline (GSK) to deliver a clinical and scientific expert network for the development and application of innovative imaging methods for inflammatory diseases.

While existing clinical imaging tools provide useful endpoints in clinical trials, they typically lack sufficient cellular and molecular information to fully understand drug response. Imaging has the potential to interrogate inflammatory cell populations, quantitatively in different tissues. This alliance aims to unlock this potential by delivering new clinical tools. Applying imaging in information-rich, small cohort studies can provide a high, immediate impact to enhance R&D productivity: developing our understanding of disease in the patient; enriching clinical trial cohorts; measuring therapeutic response.

Advanced imaging. The initiative is aimed at optimising existing imaging technologies for drug development and clinical translation of emerging probes.

The imaging hub aims to achieve these goals by; (1) optimising existing magnetic resonance imaging (MRI) and positron emission tomography (PET) technology for drug development; and (2) translating emerging PET and optical cell-specific probes towards the clinic. The first three projects with a focus around immune cell specific imaging have now been initiated.

The initiative creates a scientific bridge between GSK's clinical imaging scientists and five leading European imaging and experimental medicine research institutes within the EATRIS network: Academic Medical Center Amsterdam, Radboud University Medical Center, Nijmegen, University Medical Center Groningen, VU University Medical Center Amsterdam from the Netherlands, and Uppsala University and Uppsala University Hospital from Sweden. To enable experts in the alliance to fully focus on the scientific and technical challenges, EATRIS acts as portfolio manager, playing a key role in developing and administering the legal framework and operations, for optimal speed and efficiency. EATRIS will facilitate initiation of both independent and collaborative transnational projects under a master framework, with up-front auditing and quality agreements.



^{18}F-FDG PET Imaging of IBD. Whole body molecular imaging is available but current molecular probes like ^{18}F-fluorodeoxyglucose lack cellular specificity.

Anton Ussi, Operations and Finance Director of EATRIS comments:

"In Europe, EATRIS is in a unique position to construct bespoke international research collaborations from concept to execution of contracts. We are very excited about this novel collaboration format, combining GSK's wealth of knowledge around drug development with the clinical and technical expertise from EATRIS institutions having highly specialised molecular imaging and experimental medicine capacity, all supported with dedicated coordination staff within the EATRIS central support office."

EATRIS OUTREACH EFFORTS IN 2018

EATRIS services are typically promoted through business development dissemination channels, partnering events, promotion at workshops and through social media engagement.

In 2018, EATRIS was present at two partnering events with a booth and partnering meetings: the BIO International Convention (Boston, USA June 4 to 7) and the NordicLife Science Days (Stockholm, Sweden September 10 to 12) in collaboration with the Finnish, Swedish and Norwegian nodes. In addition, Chris Tieken, EATRIS Business Development Manager, attended BioFIT together with the EATRIS French Node, NeurATRIS (Lille, France December 4 and 5). Such engagement led to partnering meetings with 60+ companies.

We participated in additional events such as the Phacilitate Leaders World, (Miami, USA January 22 to 25) (EATRIS booth) and the Phacilitate Leaders Europe in September 11 and 12 in London, UK where David Morrow (Programme Manager EATRIS C&S) hosted a panel session on non-invasive imaging to track immune cells in cell therapy as a follow-up to the flagship proposal EPPIC.

In our effort to continue engaging with big pharma companies, contacts were initiated with Biogen's Imaging Group, Janssen Neurosciences, Lentigen/Miltenyi and Fresenius Kabi.

In addition, special effort to reach academia was undertaken in 2018 with, for example, the participation of EATRIS C&S together with our National Coordinator in Norway Laetitia Abdou-Garonne to the Horizon 2020 Health Partnering event organised in Oslo on September 3 and 4. For this occasion, a leaflet explaining our services to support academia was produced and was also disseminated at multiple additional occasions, including during our EATRIS Combined Platform Meeting (Ljubljana, Slovenia, December 12 and 13).

Toni Andreu, EATRIS Scientific Director, was also invited to chair the international panel sessions on Personalised Medicine at the 14th Personalized Medicine Conference: Preparing the New Possible, organised by the Personalized Medicine Coalition (PMC), (Boston, USA, November 14 to15); and at the 2nd European Alliance for Personalised Medicine (EAPM) Congress Forward as one: Integrating Innovation into Europe's Healthcare Systems (Milan, Italy November 26 to 28).

Publication from our nodes

RING TESTING TO ALLEVIATE PROCEDURE-INDUCED IRREPRODUCIBILITY

INTERLABORATORY PROFICIENCY PROCESSING SCHEME IN CSF ALIQUOTING: IMPLEMENTATION AND ASSESSMENT BASED ON BIOMARKERS OF ALZHEIMER'S DISEASE

Key messages:

In this study, Lewczuk et al. investigated the interlaboratory differences in SOPs (Standard Operating Procedures) for biobanking cerebrospinal fluid through a ring testing exercise. They identified duration of the preparation of the aliquots and the centrifugation force as two potential confounders influencing within-centre variability and biomarker concentrations respectively.

Standardisation and proficiency testing are essential to pinpoint main drivers of variability when specific analytes need to be quantified and to reduce the alarming rate of irreproducibility in biomedical sciences.

Synopsis:

In this study, we tested to which extent possible between-centre differences in standardised operating procedures for biobanking of cerebrospinal fluid (CSF) samples influence the homogeneity of the resulting aliquots and, consequently, the concentrations of the centrally analysed selected Alzheimer's disease biomarkers.

Proficiency processing samples (PPSs), prepared by pooling of four individual CSF samples, were sent to 10 participating centres, which were asked to perform aliquoting of the PPSs into two secondary aliquots (SAs) under their local SOPs. The resulting SAs were shipped to the central laboratory, where the concentrations of amyloid beta (Aß) 1–42, pTau181, and albumin were measured in one run with validated routine analytical methods. Total variability of the concentrations, and its within-centre and between-centre components, were analysed with hierarchical regression models.

We observed neglectable variability in the concentrations of pTau181 and albumin across the centres and the aliquots. In contrast, the variability of the Aß1–42 concentrations was much larger (overall coefficient of variation 31%), with 28% of the between-laboratory component and 10% of the within-laboratory (i.e., between-aliquot) component. We identified duration of the preparation of the aliquots and the centrifugation force as two potential confounders influencing within-centre variability and biomarker concentrations, respectively.

Proficiency processing schemes provide objective evidence for the most critical preanalytical variables. Standardisation of these variables may significantly enhance the quality of the collected biospecimens. Studies utilising retrospective samples collected under different local SOPs need to consider such differences in the statistical evaluations of the data.

Authors:

Piotr Lewczuk, Amélie Gaignaux, Olga Kofanova, Natalia Ermann, Fay Betsou, Sebastian Brandner, Barbara Mroczko, Kaj Blennow, Dominik Strapagiel, Silvia Paciotti, Jonathan Vogelgsang, Michael H. Roehrl, Sandra Mendoza, Johannes Kornhuber and Charlotte Teunissen, DOI: 10.1186/s13195-018-0418-3 Alzheimer's Research & Therapy, published on August 28 2018 [open access]

EATRIS QUALITY INITIATIVE

The EATRIS Quality Initiative (EQI) is an umbrella term for EATRIS activities addressing reproducibility, standards, and reference materials. Making use of its network, our infrastructure has engaged in several projects which address a range of biomedical needs. In 2018, we made significant progress towards publishing results of past and ongoing studies.

Harmonisation of multi-centre imaging studies: Antibody labelling with ^{89}Zirconium as diagnostic tool

Together with experts in the Imaging & Tracing Platform, the European Association of Nuclear Medicine (EANM) has developed the ^{89}Zirconium (^{89}Zr) PET/CT accreditation programme. Such accreditation programme is key to further exploit the potentials of this diagnostic tool and transfer it to clinical use. In this context, scanner calibration is pivotal to harmonise measurements and enable multi-site clinical studies. The work previously undertaken through a pilot phase involving four EATRIS sites was published in December 2018 in a technical note in EJNMMI Physics (doi: 10.1186/s40658-018-0226-7). In January 2019, the programme has opened to global sites, through EARL/EANM (http://earl.eanm.org/cms/website.php?id=/en/projects/fdg_pet_ct_accreditation/zr-pet_ct_accreditation.htm).

Development of best-practice process

The Biomarker Platform is involved in the FDA-driven community effort SEQC2 (Sequencing Quality Control Phase II)[2] 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 five sites, that provide sequencing data, and seven bioinformatics teams. Workshop participations, poster presentations (e.g. at the AACR 2018), as well as a first manuscript submission to Nature Biotechnology with eight EATRIS-co-authors resulted from the ongoing data analysis phase, with specific mentioning of their EATRIS membership. Several other manuscripts are under preparation and will be submitted during Spring/Summer 2019. All data will be available after publication of the analyses.

Pioneering pilot studies

Under the Translation Together (TT) initiative (see page 42), institutions within the Small Molecules Platform are participating in a high-throughput screening (HTS) system ring-testing pilot study. The aim of this ring testing exercise 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. A pilot phase constituted of four sites and led by NIH-NCATS (National Center for Advancing Translational Sciences, USA) was completed in 2018. Currently, 8 additional sites are involved in data generation and analysis. The results will be made available in 2019 together with guidelines and recommendations for HTS facilities (https://eatris.eu/insights/insightstranslationtogether-piloting-hts-reproducibility-study). In other platforms, quality related studies advanced quickly as well. EATRIS was involved in the FP7-funded EURIPRED infrastructure project for poverty related diseases, 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 SOPs for key immunological assays. The first outcome concerned the establishment of a SOP for the use of mycobacterial growth inhibition assays in TB vaccine development. The results were published in January 2019 in the Journal of Immunological Methods (https://doi.org/10.1016/j.jim.2019.01.006).

Further studies

Currently, EATRIS is exploring participation in further international consortia projects for process harmonisation. We will report on the progress once the contacts and project plans have developed further.

2 https://www.accessdata.fda.gov/scripts/fdatrack/view/track_project.cfm?program=nctr&id=NCTR-DBB-PM-SEQC2-Phase-II

OUR INFRASTRUCTURE AND THE INSTITUTIONS IN 2018

PARTICIPATING COUNTRIES:

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

EATRIS INSTITUTES

86 academic & non profit research institutes of excellence; more than half are university medical centres

EATRIS Coordination & Support located in Amsterdam

INSTITUTIONS OVERVIEW

- Platform participation
- Platform participation new institutions in 2018

Name	ATMP	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
CZECH REPUBLIC					
Central European Institute of Technologies (CEITEC)		●			
Charles University		●			
Institute of Chemical Technologies Prague				●	
Institute of Experimental Medicine AS CR	●				
Institute of Macromolecular Chemistry Prague (IMC ASCR)			●	●	
Institute of microbiology of the AS CR, v.v.i					●
Institute of Organic Chemistry and Biochemistry, Czech Academy of Sciences				●	
Masaryk University					
Nuclear Physics Institute of the ASCR/UJF, v.v.i.			●		
Palacký University - Institute of Molecular and Translational Medicine (IMTM)		●	●	●	
St. Anne's University Hospital Brno	●				
ESTONIA					
University of Tartu	●	●		●	
FINLAND					
Finnish Red Cross Blood Service	●	●			
University of Eastern Finland - National Virus Vector Laboratory (NVVL)	●				
University of Helsinki - Institute for Molecular Medicine Finland (FIMM)		●		●	
University of Tampere - Regea Cell and Tissue Center	●				
University of Turku and Turku University Hospital		●	●		
VTT Technical Research Centre of Finland (VTT)		●			
FRANCE					
NeurATRIS-Albert Chevalier-Henri Mondor Hospital	●		●	●	
NeurATRIS-Biotherapies Institute for Rare Diseases (BIRD)	●	●		●	
NeurATRIS-Brain & Spine institute IHU-A-ICM		●	●	●	
NeurATRIS-French Alternative Energies and Atomic Energy Commission (CEA)	●	●	●	●	
NeurATRIS-Neurosciences Bicêtre - Paris Sud (NBPS)	●		●		

● Platform participation
● Platform participation new institutions in 2018

Name	ATMP	Biomarkers	Imaging & Tracing	Small Molecules	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	●	●			
IRCCS Foundation Santa Lucia		●		●	
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)	●		●		
LUXEMBOURG					
Integrated Biobank of Luxembourg (IBBL)	●	●			●
Luxembourg Center of System Biomedicine		●		●	
NETHERLANDS					
Amsterdam UMC - Academic Medical Centre (AMC)					
Amsterdam UMC - VU Medical Center (VUmc)	●	●	●		●
Biomedical Primate Research Centre (BPRC)					●
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)		●	●		

- Platform participation
- Platform participation new institutions in 2018

Name	ATMP	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
University of Technology Eindhoven (TU/e)	●				
Wageningen Bioveterinary Research					●
NORWAY					
Norwegian University of Science and Technology (NTNU)		●	●	●	
University of Bergen (UiB) and Haukeland University Hospital			●	●	
University of Oslo (UiO) and Oslo University Hospital (OUH)	●	●	●	●	●
University of Tromsø (UiT) and University Hospital North Norway		●		●	
PORTUGAL					
INFARMED - National Authority of Medicines and Health Products, I.P., coordinating, consortium under construction					
SLOVENIA					
University of Ljubljana				●	
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)		●			
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					
Lund University			●		
Umea University					
University of Gothenburg				●	
Uppsala University and Uppsala University Hospital		●	●		

HIGHLIGHTS FROM OUR NODES

X-OMICS INITIATIVE

In 2018, a new large-scale scientific infrastructure project in the Netherlands focusing on further development of integrated omics technology was funded. The Netherlands X-omics Initiative is coordinated by Prof. Alain van Gool (Radboudumc, Chair EATRIS Biomarker Platform), is funded with €40 million and will last 10 years.

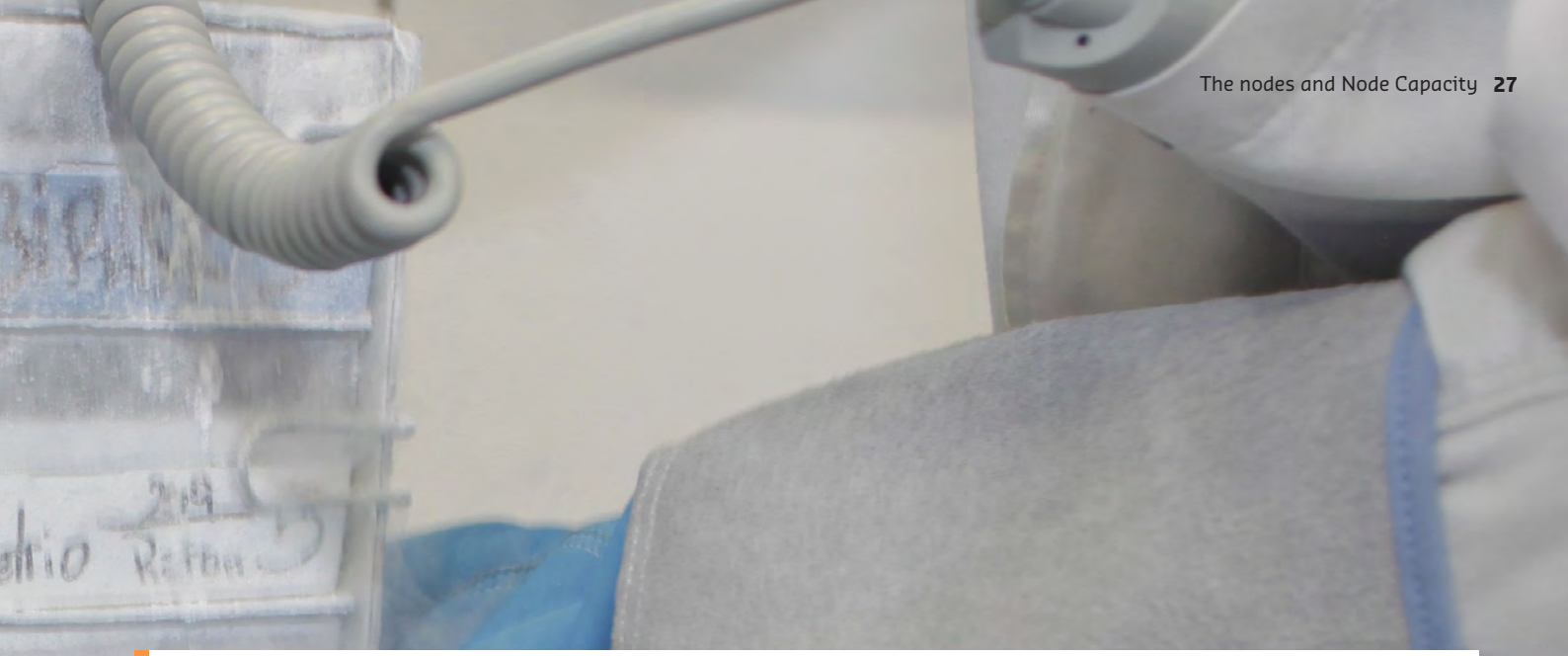
The project aims to establish an innovative and accessible X-omics research infrastructure across the Netherlands. It brings together existing world-leading facilities with expertise related to molecular biology research (genomics, proteomics, metabolomics and data integration & analysis), including laboratories that are part of EATRIS-NL.

Furthermore, it aims to advance X-omics technologies far beyond state-of-the-art, to analyse both single cells and thousands of samples. Most challenging is the integration of the various omics data to enable an integrated systems view of human health and disease, which is already in use for the diagnostic of rare pediatric metabolic diseases.

Access will be provided through http://www.x-omics.nl. State-of the art facilities can be used by researchers for the newest X-omics technologies in their projects and drive new insights in biology. A helpdesk will provide researchers with expert advice on X-omics approaches in general or specific omics-related sample or data analysis challenges. Training schools and meetings will be organised together with the national and international community on multi-omics technologies and innovation.

Alain van Gool (Coordinator of the X-omics project Radboudumc, The Netherlands):

"We aim at applying X-omics technology to achieve impact in science and translational medicine. This ambitious Dutch initiative is already becoming a landmark project and will be a strong component of the pan-European multi-Omics biomarker focus in EATRIS."



WELCOME BULGARIA

Rossitza Konakchieva, Sofia University
National Director of EATRIS Bulgaria

It is my strong belief, that the affiliation of Bulgaria to EATRIS will give precise focus and help accelerate bio-medical research and innovation in the country. With the support of EATRIS and new opportunities for multifaceted interaction, we feel more confident on our path to develop valuable and sustainable infrastructures in community service. The access to high-end technological and scientific expertise available among EATRIS member institutions will impact enormously on the performance of academic research and help increase the effectiveness of academia - industry partnerships in Bulgaria to meet social needs in the field of translational biomedical science.

WELCOME PORTUGAL

Cláudia Maria Coelho de Faria,
University of Lisbon
National Director of EATRIS Portugal

The Portuguese node for the European Translational Research Infrastructure has joined EATRIS in May 2018 aiming to foster translational research in Portugal. The participation in this European network will facilitate the integration of our national hospitals and research institutes in joint research projects and grant applications. The positive effects of joining EATRIS will be expected in capacity building, integration of best practices and their promotion with peers, together with the increase to the provision of scientific and technological services; access to international R&D funds and creation of qualified employment. The final goal is to improve citizens' access to innovative therapies, by attracting clinical trials to Portugal.


VX100

Publication from our nodes

OPEN ACCESS TOOL DEVELOPED IN LUXEMBOURG TO IMPROVE STRATIFICATION OF PARKINSON'S DISEASE PATIENTS

THE LUXEMBOURG PARKINSON'S STUDY: A COMPREHENSIVE APPROACH FOR STRATIFICATION AND EARLY DIAGNOSIS

Key Messages:

In this article published in Frontiers in Aging Neuroscience, the authors present the Luxembourg Parkinson's disease study, a comprehensive clinical, molecular and device-based approach to provide a large, longitudinally followed, set of patients and controls for clinical and fundamental research on PD. Through the implementation of an open-source digital platform that can be harmonised with international PD cohort studies, the authors alert the international research community to their willingness to collaborate with other centres.

Synopsis:

While genetic advances have successfully defined part of the complexity in Parkinson's disease (PD), the clinical characterisation of phenotypes remains challenging. Therapeutic trials and cohort studies typically include patients with earlier disease stages and exclude comorbidities, thus ignoring a substantial part of the real-world PD population. To account for these limitations, we implemented the Luxembourg PD study as a comprehensive clinical, molecular and device-based approach including patients with typical PD and atypical parkinsonism, irrespective of their disease stage, age, comorbidities, or linguistic background. To provide a large, longitudinally followed, and deeply phenotyped set of patients and controls for clinical and fundamental research on PD, we implemented an open-source digital platform that can be harmonised with international PD cohort studies. Our interests also reflect Luxembourg-specific areas of PD research, including vision, gait, and cognition. This effort is flanked by comprehensive biosampling efforts assuring high quality and sustained availability of body liquids and tissue biopsies. We provide evidence for the feasibility of such a cohort program with deep phenotyping and high quality biosampling on parkinsonism in an environment with structural specificities and alert the international research community to our willingness to collaborate with other centres. The combination of advanced clinical phenotyping approaches including device-based assessment will create a comprehensive assessment of the disease and its variants, its interaction with comorbidities and its progression. We envision the Luxembourg Parkinson's study as an important research platform for defining early diagnosis and progression markers that translate into stratified treatment approaches.

Authors:

Geraldine Hipp, Michel Vaillant, Nico J. Diederich, Kirsten Roomp, Venkata P. Satagopam, Peter Banda, Estelle Sandt, Kathleen Mommaerts, Sabine K. Schmitz, Laura Longhino, Alexandra Schweicher, Anne-Marie Hanff, Béatrice Nicolai, Pierre Kolber, Dorothea Reiter, Lukas Pavelka, Sylvia Binck, Claire Pauly, Lars Geffers, Fay Betsou, Manon Gantenbein, Jochen Klucken, Thomas Gasser, Michele T. Hu, Rudi Balling and Rejko Krüger on behalf of the NCER-PD Consortium, Frontiers in Aging Neuroscience, **DOI:** https://doi.org/10.3389/fnagi.2018.00326 published on October 29 2018

PRODUCT PLATFORM HIGHLIGHTS 2018

Multimodal Approaches in Translational Medicine. The EATRIS infrastructure expanded significantly in 2018 with Norway and Sweden continuing to strengthen their participation in the EATRIS product platforms, Portugal joining as a new full Member country and Bulgaria joining as an Observer. As a result, several high-quality research institutes entered the EATRIS product platforms, adding valuable expertise and facilities to the EATRIS-ERIC Research Infrastructure.

2018 was rich in activities and projects development for the EATRIS product platforms with the highlight of the year being the EATRIS Combined Product Platform meeting held in December in Ljubljana, Slovenia (page 38).

ATMP

Chairs
Maria Cristina Galli (ISS, Italy), Miguel Chillón Rodríguez (VHIR, Spain)
Platform Coordinator
David Morrow (Programme Manager EATRIS C&S)

2018 saw the ATMP Platform continue to increase its visibility and showcase its contribution to the Advanced Therapies community. Central to this was the EATRIS flagship Project EPPIC (page 12) which involved 7 EATRIS institutions amongst 19 partners to form a consortium for the Horizon 2020 Health call and develop a platform in Europe for cell tracking of immune cell therapies, specifically CAR Ts in solid tumours. This initiative is seen as integral to the advancement of CAR Ts and was presented at international conferences as well as at a workshop at the Phacilitate Leaders Europe in London, UK in September and was part of a successful breakout session at the EATRIS Combined Platform Meeting. EATRIS joined several other consortia for the same call as partner providing expertise on regulatory affairs or innovation management. The EATRIS ATMP platform was represented at different events such as the ISCT Meetings in Montreal and Florence and at the Phacilitate Leaders World in Miami where EATRIS attended with a booth. In late 2018, EATRIS C&S was approached by several of our ATMP research groups for support to begin proposal preparation for the Horizon 2020 call on Regenerative Medicine (SC1-BHC-07-2019).

BIOMARKERS

Chairs Alain van Gool (Radboudumc, The Netherlands), Andreas Scherer (FIMM, Finland), Laura García Bermejo (IRYCIS, Spain)
Platform Coordinator Florence Bietrix (Programme Manager EATRIS C&S)

In 2018, Norway expanded its contribution to the biomarker platform through the participation of University of Tromsø and University Hospital North Norway (also known as the Artic University of Norway), the Norwegian University of Science and Technology (NTNU), and Oslo University Hospital. With the addition of the Luxembourg Centre for Systems Biomedicine, and the IRCCS Fondazione Santa Lucia in Italy, the biomarker platform counts nowadays 50 state of the art institutions.

In 2018, the biomarker platform continues to position itself towards best biomarker practices enabling Personalised Medicine. Support was provided to help multiple forming consortia looking to add capabilities towards biobanking, access to high quality clinical data sets and various analytical pipelines. Under the CORBEL Open call, EATRIS, the Biobanking and BioMolecular resources Research Infrastructure (BBMRI), and the European Clinical Research Infrastructure Network (ECRIN) offered an integrated pipeline for complex multimodal biomarker profiling.

The Handbook of Biomarkers and Precision Medicine, edited by Alain van Gool (Radboudumc, the Netherlands), was compiled in 2018. Andreas Scherer (FIMM, Finland) and Laura García Bermejo (IRYCIS, Spain) provided chapters to the book, and Anton Ussi and Florence Bietrix contributed a chapter on The Need for Global Collaboration in Translational Medicine. The book is available from 2019.

Through the COST action CliniMARK, Andreas Scherer, co-chair of the Biomarker Platform, (FIMM, Finland) applied for a Short-Term Scientific Mission to develop a quality framework through ring testing for omics technologies which was granted towards the end of the year.

Platform members were able to network and exchange vision on the development of the biomarker platform during the break-out session on “Multimodal approaches for patient stratification” held during the Combined Platform Meeting in Ljubljana. The session highlighted the current achievements and challenges in patient stratification. The participants had the opportunity to join as speakers by submitting their abstracts. Subsequently, three speakers from EATRIS institutions were selected.

IMAGING & TRACING

Chairs Cyril Poupon (CEA / NeuroSpin, France), Albert Windhorst (VUmc, The Netherlands)
Platform Coordinator Martin de Kort (Programme Manager EATRIS C&S)

The Imaging and Tracing Platform welcomed Lund University (Sweden) and the University of Tromsø (Norway) as new institutions, yielding now a total of 35 high-end translational (molecular) imaging facilities within EATRIS that are dedicated to advanced nuclear and magnetic (multimodal) imaging in supporting the translation of new therapeutics and interventions into humans.

The Platform also welcomed its new chair, Dr. Cyril Poupon (CEA/NeuroSpin, France), who brings in ultra-high field MRI expertise for improved patient stratification. Development of harmonised imaging protocols and data analysis will bring new opportunities to deploy novel contrast mechanisms observed at such ultra-high fields, revealing details in vivo at unprecedented resolutions that are not visible at lower fields.

In 2018, the GSK Immune Inflammation Imaging Hub matured with a growing portfolio of projects to develop imaging tools to support drug development towards various inflammatory targets.

Another area of interest for the platform is translational neuroimaging. Together with NeurATRIS, a webinar series was organised informing the community about the capabilities of CEST MRI, PET and optical imaging, to study metabolic pathways, brain cells and neurodegenerative diseases (see page 33). Underscoring the operational aspects of the RI in this domain, two small/medium enterprises from Israel and France were matched to expert centres in France and Czech Republic to implement advanced translational imaging methods in their R&D programs. The extensive experience EATRIS has gained over the recent years in setting up such collaborations was shared in the CORBEL workshop on best practices in Public-Private Research Collaborations (see page 50).

The annual congress meeting EANM’18 took place in 2018 in Düsseldorf, Germany where several EATRIS sites participated in discussions with the nuclear medicine community. The feasibility of PET/CT system performance harmonisation for quantitative multi-centre ^{89}Zr studies was presented by EARL/EANM (see page 21) and the formal start of the EARL ^{89}Zr accreditation program, co-developed with EATRIS expert centres, was announced for 1 Jan 2019.

EATRIS – NEURATRIS NEUROIMAGING WEBINARS

In November of 2018, EATRIS and NeurATRIS launched a series of webinars on Neuroimaging. The series covered the usage of CEST-MRI, optical and PET imaging in neurodegenerative diseases and their potential application in translational medicine.

The first webinar entitled Translational Metabolic Imaging using CEST MRI in Neurodegenerative Diseases introduced the theoretical background of Chemical Exchange Saturation Transfer (CEST) imaging. In this webinar, Dr. Julien Flament of Molecular Imaging Research Center (MIRCen, CEA), Fontenay-aux-Roses, France, outlined how CEST has been introduced in both clinical and preclinical investigations and how it works and illustrated its potential for translational research and future possibilities, particularly as they relate to degenerative diseases.

The second webinar featured Basile Gurchenkov of ICM (Brain & Spine Institute) located at the Pitié Salpêtrière Hospital in Paris. He addressed in this webinar how to choose the most suitable type of microscope to study neurological mechanisms and cells of interest and shared his insights about multiphotonic, light-sheet, confocal, transmission electron microscopes and spinning disks.

In the third webinar "PET imaging to investigate neurodegenerative diseases", Sonia Lavisse and Nadja Van Camp, both permanent researchers at MIRCen, introduced PET modality and how it plays a pivotal role in visualising neuroanatomical and functional signatures, as well as identifying disease-specific biomarkers of underlying neurodegenerative processes. The prominent preclinical and clinical application of this well-established and promising imaging tool in neurodegenerative diseases was illustrated with several applications in Parkinson's, Huntington's and Alzheimer's Diseases.

All the webinars including the audience Q&A session with the experts were recorded and made available on the EATRIS website: (https://eatris.eu/solutions/transmedacademy)

SMALL MOLECULES

Chairs Maria Salmona (Mario Negri Institution, Italy), Alfredo Budillon (Fondazione IRCCS, Fondazione Pascal, Italy)
Platform Coordinator Martin de Kort (Programme Manager EATRIS C&S)

In 2018, the IRCCS Fondazione Santa Lucia (Italy) became affiliated as a new member of the platform, as well as the Norwegian University of Science and Technology NTNU (Norway). These advanced research facilities complement the EATRIS academic drug discovery centre capabilities infrastructure now totalling 27 institutions.

Platform members gathered at the annual EATRIS Combined Platform Meeting to network and exchange case studies in a thematic session entitled "Connecting Atoms to Anatomy". The session brought together expertise in targeted drug development, systems medicine and multi-modal imaging platforms. Emerging theragnostic approaches were discussed where a deep molecular understanding of target modulation is combined with novel integrated, systemic therapeutic strategies.

As part of the global translational medicine initiative "Translation Together", the HTS ring testing pilot phase to investigate drivers of variability at screening facilities was completed with the participation of four centres (two academic sites, NIH-NCATS and IMTM in Czech Republic, two pharma companies, Eli Lilly and Pfizer). 8 additional discovery centres are currently expanding the initial pilot phase, producing data to be centrally analysed at NIH-NCATS (Maryland, USA) and compared to results generated from individual analytical pipelines. Five of the recruited centres contribute to the Small Molecules platform (IMTM Olomouc CZ, CNCCS-IRBM Rome IT, FIMM Helsinki FI, NCMM Oslo NO, IRCCS Pascale Naples IT). https://eatris.eu/insights/insightstranslationtogether-piloting-hts-reproducibility-study/

The platform further engaged with its user community by a contribution of Toni Andreu to the International Conference on Nanomedicine and Nanobiotechnology (ICONAN2018, September 26 to 28 in Rome, Italy) entitled "Translational Research in medicine – Navigating the maze from lab to patient".

Alfredo Budillon co-chair of the Small Molecules platform and director of the Experimental Pharmacology Unit of The Pascale Cancer Institute in Naples, hosted a seminar between EATRIS and ESMO, the European Society for Medical Oncology. Together with current president Prof. Tabernero and former president Prof. Ciardiello the current open challenges in translational cancer research were discussed. These include the patient access to medical innovation on global level and the training of the medical oncologists to keep up with the latest technological advances in the field. http://www.quotidianosanita.it/regioni-e-asl/articolo.php?articolo_id=59832

VACCINES

Chairs Jan Langermans (BPRC, The Netherlands), Lucia Gabriele (ISS, Italy)
Platform Coordinator David Morrow (Programme Manager EATRIS C&S)

In 2018, EATRIS continued its work in the TRANSVAC2 project which included delivering an updated Regulatory Information System (RIS) with information on the Vaccines regulatory landscape. This resource was shared with the TRANSVAC2 community and is now available to all our EATRIS institutions.

Early discussions took place in 2018 on how to restructure the vaccine platform to offer more integral and relevant services to the vaccine developers. It involves highlighting the capacity and expertise of the platform in developing standardised immunomodulation and immunomonitoring services. Vaccine Co-chair Lucia Gabriele (ISS, Italy) spearheaded this initiative with a dedicated breakout session at our combined meeting together with collaborators from IdiPAZ (Spain) and the University of Oslo (Norway). These EATRIS institutions began to work together with the submission of a proposal to the ERA PerMed JTC 2019 call. EATRIS also attended the World Vaccine Congress Europe in Lisbon in October where multiple meetings took place to present the capacity of the platform to the vaccine community.

Publication from our nodes

EXPLORING THE THERAPEUTIC POTENTIALS OF THIRD GENERATION CAR T CELLS

A PHASE I/IIA TRIAL USING CD19-TARGETED THIRD-GENERATION CAR T CELLS FOR LYMPHOMA AND LEUKEMIA

Key Messages:

This study from research groups at the EATRIS Swedish institutions of the University of Uppsala and Karolinska, in addition to collaborators from Baylor College (Houston, TX) shows how preclinical development of third-generation CAR T cells can be translated into a clinical study and their clinical benefit potentially provided to patients in Sweden for the treatment of Lymphoma and Leukemia. This research highlights the major importance of the immune status of the patient for CAR T cells to be effective. Furthermore, this study provides insight for the design of future studies of CAR T cells and as a result, supports the future development of this promising therapy.

Synopsis:

PURPOSE: The chimeric antigen receptor (CAR) T-cell therapy has been effective for patients with CD19+ B-cell malignancies. Most studies have investigated the second-generation CARs with either CD28 or 4-1BB costimulatory domains in the CAR receptor. Here, we describe the first clinical phase I/IIa trial using third-generation CAR T cells targeting CD19 to evaluate safety and efficacy.

PATIENTS AND METHODS: Fifteen patients with B-cell lymphoma or leukemia were treated with CAR T-cells. The patients with lymphoma received chemotherapy during CAR manufacture and 11 of 15 were given low-dose cyclophosphamide and fludarabine conditioning prior to CAR infusion. Peripheral blood was sampled before and at multiple time points after CAR infusion to evaluate the persistence of CAR T cells and for immune profiling, using quantitative PCR, flow cytometry, and a proteomic array.

RESULTS: Treatment with third-generation CAR T cells was generally safe with 4 patients requiring hospitalisation due to adverse reactions. Six of the 15 patients had initial complete responses [4/11 lymphoma and 2/4 acute lymphoblastic leukemia (ALL)], and 3 of the patients with lymphoma were in remission at 3 months. Two patients are still alive. Best predictor of response was a good immune status prior to CAR infusion with high IL12, DC-Lamp, Fas ligand, and TRAIL. Responding patients had low monocytic myeloid-derived suppressor cells (MDSCs; CD14+CD33+HLA-DR-) and low levels of IL6, IL8, NAP3, sPDL1, and sPDL2.

CONCLUSIONS: Third-generation CAR Tcells may be efficient in patients with advanced B-cell lymphoproliferative malignancy with only modest toxicity. Immune profiling pre- and post-treatment can be used to find response biomarkers.

Authors:

Gunilla Enblad, Hannah Karlsson, Gustav Gammelgård, Jessica Wenthe, Tanja Lövgren, Rose Marie Amini, Kristina I. Wikstrom, Magnus Essand, Barbara Savoldo, Helene Hallböök, Martin Höglund, Gianpietro Dotti, Malcolm K. Brenner, Hans Hagberg and Angelica Loskog, Clinical Cancer Research, **DOI:** 10.1158/1078-0432.CCR-18-0426 published in December 2018 [open access]

Publication from our nodes

MINIMALLY INVASIVE TRACERS TO MONITOR EFFICACY OF IMMUNOTHERAPY AND PREDICT OUTCOME

WHOLE BODY PD-1 AND PD-L1 POSITRON EMISSION TOMOGRAPHY IN PATIENTS WITH NON-SMALL-CELL LUNG CANCER.

Key Messages:

This public-private collaboration between research groups from Bristol-Meyers Squibb, Dutch EATRIS institutions from Amsterdam UMC and the Netherlands Cancer Institute illustrates the power of molecular (PET-CT) imaging as a non-invasive technique to provide key insight in the intra- and interpatient heterogenic responses to immune-therapy involving PD-(L)1 targeting. EATRIS infrastructure provided the translational capacity to develop clinical grade ^{89}Zr-labelled and ^{18}F-labelled therapeutic antibodies and the expertise to analyse the imaging data.

Synopsis:

PD-L1 immunohistochemistry correlates only moderately with patient survival and response to PD-(L)1 treatment. Heterogeneity of tumor PD-L1 expression might limit the predictive value of small biopsies. Here it is shown that tumor PD-L1 and PD-1 expression can be quantified non-invasively using PET-CT in patients with non-small-cell lung cancer. Whole body PD-(L)1 PET-CT reveals significant tumor tracer uptake heterogeneity both between patients, as well as within patients between different tumor lesions. The study comprised a head-to-head comparison of ^{89}Zr-nivolumab and 18F-BMS986192 in the same NSCLC patients (n=13), against immunohistochemistry. This proof-of-principle study shows that in vivo molecular imaging of the PD-1/PD-L1 axis in NSCLC using 18F-BMS-986192, and ^{89}Zr-nivolumab is feasible and safe in humans. 18F-BMS-986192 tumor uptake correlated with PD-L1 expression by IHC, and ^{89}Zr-nivolumab uptake correlated with PD-1 expression on lymphocytic aggregates by IHC. This implies that these tracers could potentially be used to longitudinally and non-invasively quantify PD-(L)1 expression in future immunotherapy studies. Larger datasets are needed to validate these results.

Authors:

Niemeijer AN, Leung D, Huisman MC, Bahce I, Hoekstra OS, van Dongen GAMS, Boellaard R, Du S, Hayes W, Smith R, Windhorst AD, Hendrikse NH, Poot A, Vugts DJ, Thunnissen E, Morin P, Lipovsek D, Donnelly DJ, Bonacorsi SJ, Velasquez LM, de Gruijl TD, Smit EF, de Langen AJ., Nature Communications,
DOI: 10.1038/s41467-018-07131-y Published November 2018 [open access]

Publication from our nodes

THE GUARDIAN OF THE GENOME, P53, ACTIVATED AND TURNED INTO A NATURAL TUMOUR CELL KILLER

A DHODH INHIBITOR INCREASES P53 SYNTHESIS AND ENHANCES TUMOR CELL KILLING BY P53 DEGRADATION BLOCKAGE

Key Messages:

This publication illustrates how several EATRIS sites have worked together in a multidisciplinary setting to unravel a new pathway towards p53 activation to suppress tumours. Among others, Karolinksa Institute, Haukeland University Hospital and Uppsala University jointly set up a phenotypic screening campaign of a library of 20,000 compounds to identify new (classes of) inhibitors of dihydroorotate dehydrogenase (DHODH). This target was deconvoluted as a protein that augments the action of P53 as a tumor suppressor, and inhibition of which is proposed as an alternative strategy to treat resistant tumors.

Synopsis:

The development of non-genotoxic therapies that activate wild-type p53 in tumors is of great interest since the discovery of p53 as a tumor suppressor. This paper reports the identification of over 100 small-molecules activating p53 in cells. The mechanism of action of a chiral tetrahydroindazole (HZ00) was elucidated, and through target deconvolution, its active enantiomer (R)-HZ00 was deduced, inhibiting dihydroorotate dehydrogenase (DHODH). The chiral specificity of HZ05, a more potent analog, is revealed by the crystal structure of the (R)-HZ05/DHODH complex. Twelve other DHODH inhibitor chemotypes are detailed among the p53 activators, which identifies DHODH as a frequent target for structurally diverse compounds. It was observed that HZ compounds accumulate cancer cells in S-phase, increase p53 synthesis, and synergise with an inhibitor of p53 degradation to reduce tumor growth in vivo. A new strategy is proposed to promote cancer cell killing by p53 instead of its reversible cell cycle arresting effect: the discovery of new DHODH inhibitors, as well as a novel strategy to increase p53 activation and synergism with mdm2 inhibitors offers an exciting prospect to bring p53 therapy to fruition and may allow the cure of diseases like chronic myeloid leukemia (CML) that retain resistance to elimination via a p53 sensitive stem cell population.

Authors:

Marcus J. G. W. Ladds, Ingeborg M. M. van Leeuwen, Catherine J. Drummond, Su Chu, Alan R. Healy, Gergana Popova, Andrés Pastor Fernández, Tanzina Mollick, Suhas Darekar, Saikiran K. Sedimbi, Marta Nekulova, Marijke C. C. Sachweh, Johanna Campbell, Maureen Higgins, Chloe Tuck, Mihaela Popa, Mireia Mayoral Safont, Pascal Gelebart, Zinayida Fandalyuk, Alastair M. Thompson, Richard Svensson, Anna-Lena Gustavsson, Lars Johansson, Katarina Färnegårdh, Ulrika Yngve, Aljona Saleh, Martin Haraldsson, Agathe C. A. D'Hollander, Marcela Franco, Yan Zhao, Maria Håkansson, Björn Walse, Karin Larsson, Emma M. Peat, Vicent Pelechano, J ohn Lunec, Borivoj Vojtesek, Mar Carmena, William C. Earnshaw, Anna R. McCarthy, Nicholas J. Westwood, Marie Arsenian-Henriksson, David P. Lane, Ravi Bhatia, Emmet McCormack & Sonia Laín, Nature Communications,
DOI: 10.1038/s41467-018-03441-3 Published March 2018 [open access]

EATRIS' COMBINED PLATFORM MEETING 2018

A TWO-DAY CROSS-PLATFORM INTERACTIONS AND NETWORKING EVENT

Last December our annual platform meeting, offered exclusively to EATRIS members, was hosted in the beautiful city of Ljubljana, Slovenia with great success. Tim Hubbard, Head of Genome Analysis at Genomics England, kicked-off the meeting with a presentation of the 100,000 Genomes project while Toni Andreu, EATRIS Scientific Director, officially presented our Strategic Agenda 2019 - 2022.Our theme "Multimodal approaches in Translational Medicine" was selected to reflect the multidisciplinarity of scientific and technological approaches needed to develop new tools and solutions for the advancement of Translational Research.

Over 100 participants, joining from 13 countries, had the opportunity to discuss with keynote speakers on specific topics divided into three parallel Breakout Sessions.

Multimodal approaches connecting Atoms to Anatomy; Keynote Prof. Emmet Mc Cormack, Professor Pharmaceutics & Pharmaceutical Technology, University of Bergen, Norway

Multimodal approaches for immunomodulation and immunomonitoring; Keynote Dr. Eduardo Lopez Collazo, Scientific Director, IdiPAZ, Madrid, Spain

Multimodal approaches for patient stratification; Keynote Prof. Alain van Gool, Head Translational Metabolic Laboratory, Radboudumc, Nijmegen, The Netherlands, Chair EATRIS Biomarker Platform

Toni Andreu, Scientific Director, EATRIS

"Our goal is to create an environment where the capacities of the EATRIS scientific community would emerge as an integrated and powerful tool. The EATRIS Combined Platform Meeting acted as a carrier where through discussions, interactions, networking possibilities this goal can be achieved."

The encouraging feedback from the post-meeting survey allows us to look to the next EATRIS annual meeting with great anticipation. We would like to thank all speakers and attendees for their tireless work towards the transformation of scientific breakthroughs into life-altering interventions for patients.

Please specify the main reason for attending this meeting:
70% joined for Networking opportunities.
20% for the Programme.
10% for Personal growth and development.

Did the meeting fulfil the reason for attending?
99% responded with a yes.

Were you satisfied with the themes developed at the Breakout Sessions on day 1?
92% responded with a yes

Were you satisfied with the content of the plenary sessions?
98% responded with a yes.

How would you rate the meeting content?
90% would rate the content from Good to Excellent.

How likely is it that you would recommend this meeting to a friend or colleague?
90% would Likely or Very likely recommend this meeting.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PARTNERSHIPS AND LONG-TERM INITIATIVES

Engaging with key global stakeholders to collectively address bottlenecks currently hampering translational medicine development is essential to successfully introduce cost-effective, patient-centered interventions. It requires coordinated collaboration between multiple sectors and stakeholders, namely from academia, industry, funding bodies, hospitals, regulators and patient organisations. In 2018, EATRIS continued to link with actors in this ecosystem from the European Medicines Agency and the European Federation of Pharmaceutical Industries and Associations, to ensure that RIs' innovation potential is fully exploited in the ERA.

Working closer with other Research Infrastructures

Alliance of Medical RIs

In 2018, EATRIS has established stronger ties with two other ESFRI patient-centred RIs: BBMRI and ECRIN. All three RIs expressed joint interest in working more closely together to provide even better services to the biomedical community and to support a more cost-effective research process.

As a first step towards long-term collaboration, the three medical RIs published a joint statement on the next funding programme, Horizon Europe, that was handed to Carlos Moedas, European Commissioner for Research, Science and Innovation, in person during the International Conference on Research Infrastructures (ICRI) in Vienna in September 2018. In that statement, EATRIS, BBMRI and ECRIN have identified four critical success factors for optimal outcomes in the next funding period: avoiding undesired duplication and fragmentation; safeguarding quality and enhancing reproducibility; supporting public engagement by promoting responsible research policies; enabling rigorous innovation management.

A long-term collaboration agreement, laying the ground for facilitating user access and supporting the development of tools, joint services and common approaches on quality, standards and advocacy was in preparation in the end of 2018. The three RIs aim to publish an implementation plan in 2019.

Anton Ussi, EATRIS Operations and Finance Director, nominated Chair of the Biological and Medical Sciences Research Infrastructures Strategy Board

In October 2018, Anton Ussi succeeded Ilaria Nardello (EMBRC) as Chair of the BMS RI Strategy Board. The Board, in place since 2015, enables 13 BMS RIs to find alignment on strategic topics and coordinate joint advocacy actions. As a first action as Chair, EATRIS coordinated the preparation of a joint publication from all 13 RIs to express support for a strong and coherent road mapping process and close dialogue with ESFRI, particularly when new infrastructure projects in the Health & Food domain apply for future ESFRI Roadmaps.

Strengthening EATRIS' role in the global research environment

Expansion of Translation Together

Following the successful launch of Translation Together on September 25, 2017 during EATRIS' Translational Medicine 2017 Conference, the initiative continued to grow in 2018. AMED, the Japan Agency for Medical Research and Development, joined the partnership already formed by five of the world's top translational science organisations; 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.

The group met in Boston on June 3 next to the BIO International Convention to review and discuss the progression made toward achieving Translation Together's objectives:

- Coordinate and develop programs and resources for educating and training the next generation of translational scientists and other key stakeholders;
- Advocate for a broad understanding of and appreciation for translation and translational science among diverse stakeholders;
- Assist investigators in the conduct of translation and translational science by connecting them to resources, tools, technologies, and expertise;
- Conduct collaborative research projects to remove systemic barriers and catalyse translation.

Among others, Marian Hajdúch, Director of IMTM in Olomouc, Czech Republic presented the results obtained from the HTS ring testing pilot phase completed during the spring with the participation of four screening centres.

In addition, further discussions took place around the drafting of an article on the fundamental characteristics of a translational scientist to be published Q2 2019 and the production of a short introductory video to Translational Medicine and the expansion of EATRIS' e-learning platform with TT content. Prof. Masatoshi Hori from Tokyo, Japan University presented his plan to create a new online publication "Journal of Translational and Regulatory Sciences" with TT members as the journal's Editorial Board.

The group will meet in Philadelphia on June 2, 2019. Translation Together's mission is to conduct collaborative research projects to systematically remove barriers, catalyse translation and foster a broad understanding of and appreciation for translational science among diverse stakeholders.

Visit the website: translationtogether.org

EATRIS becomes a member of the Personalized Medicine Coalition (PMC)

The PMC brings together innovators, scientists, patients, providers and payers, to promote the understanding and adoption of personalised medicine concepts, services, and products to benefit patients and the health system. This international and multi-stakeholder organisation also supports investment in and adoption of personalised medicine through education, advocacy, and evidence development.
The infrastructure's joining forces with PMC demonstrates the EATRIS community's growing commitment to actively contribute to the evolving field of personalised medicine and the leading role played by the translational research approach to make personalised medicine a reality for patients and health systems around the world.

As a member, EATRIS will have the opportunity to raise the voice of the European translational community in shaping the future strategic agenda of the Coalition, will participate in joint education and advocacy activities to raise the profile and scope of personalised medicine, and will engage with regulators and other policymakers. The current members of the coalition also include representatives from patient advocacy groups, venture capital, pharmaceutical companies, and diagnostic companies, among others.

Visit the website:
http://www.personalizedmedicinecoalition.org/

Fostering multi-stakeholder engagement

EATRIS maintains close dialogue with regulatory authorities

In November 2018, EATRIS was invited to participate in a workshop organised by the European Medicines Agency (EMA) and the EU Innovation Network in London. Within the EMA framework of interaction with academia and the mandate of the EU Innovation Network, this workshop was convened to catalyse synergies for reinforced support to innovation in medicines development, for effective collaborations between regulators and academia, and to advance regulatory science.

Participants included representatives from academic centres, European research infrastructures, the European Commission Directorate-General for Research and Innovation and the medicines regulators from EMA and the Innovation Offices in the national competent authorities - the EU-Innovation Network (EU-IN).

The first part of the workshop was dedicated to presenting current activities and ambitions on how to further support academia in translating research and innovation in future medicines and tools for their development. The second part allowed the participants to work in breakout sessions and address key questions relevant to challenges and opportunities for advancing academic research for medicines. As an integral part of the EU research landscape, four EU research infrastructures, including EATRIS, contributed their experience in regulatory science as well as the services they can offer to innovators and regulators alike.

This workshop was the opportunity for EATRIS to maintain an open dialogue with EMA and National Competent Authorities (NCAs) and support the implementation of their framework of interaction with academia. EATRIS' participation helped raise the voice of academic translational research by highlighting a series of challenges in regulatory science from an academic point of view. Further interactions are foreseen in 2019 as part of the H2020-funded STARS project.

Furthermore, EATRIS continues to build trust and partnerships with regulatory NCAs in Europe. In October 2018, EATRIS joined an informal meeting with the Medicines Evaluation Board in the Netherlands, to discuss regulatory challenges in paediatrics. In addition, the Portuguese NCA, INFARMED, has become the EATRIS national node as of 2018 and will further support EATRIS' further engagement with regulatory authorities in the future.

Accelerating collaboration with industry: kick-off of a series of workshops with the European Federation of Pharmaceutical Industries and Associations (EFPIA)

In November 2018, EATRIS was invited by EFPIA and its Innovative Medicines Working Group to discuss how to better structure interactions and engagement between EFPIA and RIs, and how the Innovative Medicines Initiative (IMI) could better utilise RI services in current and future projects.

This workshop was the initial kick-off of a series of workshops to be held in 2019 between RIs, EFPIA and large pharma representatives to further strengthen interactions and build a joint agenda. As Europe is moving to a new and mission-oriented work programme - Horizon Europe, supporting health research public-private partnerships and rethinking and evolving the role of European Research Infrastructures in this new system is an important step.

A joint statement is foreseen for publication in 2019 highlighting the following:

- For efficiency and for the sake of standardisation: the existing infrastructures should be adequately resourced and used as preferred service providers in EU funded projects whenever they are fit for purpose;
- For sustainability: stable infrastructures will secure the preservation and long-term quality of assets generated through publicly and privately funded projects that are useful for the entire scientific community including data and sample collections, clinical trial networks, etc;
- Public-Private-Partnerships (PPPs) are an important tool for infrastructures to reinforce their role as enablers of translational research.

EC FUNDED PROJECTS: FOUR NEW INITIATIVES APPROVED

EJP- RARE DISEASES NEW

Funding programme: H2020 (Health)
Total budget: € 55,073,831
Budget EATRIS: € 376,678
Coordinator: INSERM (France)
Starting - end date: January 2019 – December 2023
EATRIS participating institutions: VHIR (ES), University of Oslo (NO)
EATRIS role: Co-leader of Pillar IV "Accelerating Translation"; WP19 Leader - "Facilitate partnerships and accelerate translation for higher patient impact"

Project description: The European Joint Programme on Rare Diseases (EJP RD) has two major objectives: (i) To improve the integration, the efficacy, the production and the social impact of research on RD through the development, demonstration and promotion of European/ world-wide sharing of research and clinical data, materials, processes, knowledge and know-how; (ii) To implement and further develop an efficient model of financial support for all types of research on RD (fundamental, clinical, epidemiological, social, economic, health service) coupled with accelerated exploitation of research results for benefit of patients. To this end, the EJP RD actions will be organised within four main Pillars assisted by the central coordination: (P1): Funding of research; (P2): Coordinated access to data and services; (P3): Capacity building; (P4): Accelerated translation of research projects and improvement outcomes of clinical studies. Among the activities planned under the P4, EATRIS will be responsible for assembling an Innovation Management Toolbox, assessing the translational potential of research projects and providing real-time mentoring. We will also contribute to other parts of the proposal related to education and sustainability strategy.

EOSC-LIFE NEW

Funding programme: H2020 (Research Infrastructures)
Total budget: € 23,745,978
Budget EATRIS: € 1,734,523
Coordinator: ELIXIR
Starting - end date: March 2019 – February 2023
EATRIS participating institutions: University of Helsinki (FI), IMTM (CZ), Lygature (NL), VHIR (ES), Mario Negri Institute (IT)
EATRIS role: WP3 co-lead "Open Call on Sensitive Data"; co-lead WP8 "International Impact", "Innovation and Sustainability"; co-lead WP9 "Training of the EOSC Life Community", Partner WP10 "Dissemination and Outreach"

Project description: EOSC-Life is the project regrouping the 13 BMS RIs in Europe into the European Open Science Cloud (EOSC) and joining forces to create an open collaborative digital space for life science. Under EOSC-Life the 13 BMS RIs will publish their data as FAIR Data Resources, link reusable Tools and Workflows to standardised computing services in national life-science clouds, and connect with their scientific users across Europe to a single login authentication and resource authorisation system. By the end of the project EOSC-Life will be established as the new norm for digital biology in Europe – accessible by Europe's 500,000 life scientists. Under EOSC-Life, EATRIS C&S will work closely with EATRIS data core team formed by five EATRIS linked third parties: University of Helsinki (FI), IMTM (CZ), Lygature (NL), VHIR (ES), and Mario Negri Institute (IT). EATRIS linked third parties will contribute to the project through WP1 Publishing FAIR RI data resources in EOSC; WP2 Make tools and workflows interoperable and reusable in the EOSC across RIs and WP4 Policies, specifications and tools for the management of data for biological and medical research. Under WP8, Mario Negri Institute will lead a task on assessing the impact of life-science open data in the cloud on data reproducibility.

ERIC-FORUM NEW

Funding programme: H2020 (Research Infrastructures)
Total budget: € 1,495,281
Budget EATRIS: € 77,916
Coordinator: BBMRI-ERIC
Website: https://www.eric-forum.eu/
Starting - end date: January 2019 – December 2021
EATRIS role: WP3 Leader – "Operations, Administrative", "Human Resources" and "Finance ERICs"

Project description: ERIC-Forum aims to strengthen the coordination and networking of the established European Research Infrastructure Consortia (ERICs). It will support the organisation of specific meetings, targeted thematic workshops focusing on shared challenges such as the development of internal procurement rules, harmonised reporting, VAT exemption practices, insurances and pensions policies and training of governance bodies

representatives. The project will also facilitate common outreach activities and strengthen the external representation of ERICs.

RI-VIS NEW

Funding programme: H2020 (Research Infrastructures)
Total budget: € 1,500,000
Budget EATRIS: € 24,625
Coordinator: INSTRUCT-ERIC
Website: https://ri-vis.eu/network/rivis/home
Starting - end date: February 2019 – July 2022
EATRIS role: Partner in all work packages

Project description: RI-VIS aims to increase the visibility of European RIs to new communities in Europe and beyond. The consortium is composed of 13 partners from 12 RIs working in the fields of biomedical sciences, social sciences and environmental sciences.
The objectives of RI-VIS are to map RI services to new target communities and identify routes to maximise exchange of information and bases for new partnerships, create an outreach programme to provide information, bring RIs together with new target communities and facilitate collaborative engagement; create a collection of tools that are freely available to all research infrastructures that have demonstrated efficacy and impact in facilitating new cooperative relationships.

ID-EPTRI

Funding programme: H2020 (Research Infrastructures)
Total budget: € 3 M
Budget EATRIS: € ~200K
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"

Project update: In 2018, EATRIS attended the first and second General Assemblies in Rome and in Athens. Along with close involvement in identifying unmet needs in paediatric research and drug development in Europe, EATRIS developed draft governance models and business plans for the project and presented alternative models for discussion with stakeholders. The ongoing gap analysis and discussion with stakeholders is enabling further development of a business and sustainability plan designed to harness efficiency and delivery of paediatric research activities services. The design will strengthen collaborations within the scientific paediatric community and will be complementary to the existing RIs, while avoiding any duplication. These factors will be key to instituting a one-stop-shop and common services for the advancement of paediatric drug development.

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" WP18 – Partner "Training"

Project update: 2018 marked the second year of the TRANSVAC2 Project where EATRIS completed its first update of the Regulatory Information System (RIS) to now include information on Vaccines. Webinars were held in December to demonstrate the RIS to TRANSVAC Partners. The system remains open for use by EATRIS institutions and TRANSVAC Partners. Opportunity to open the repository to the entire scientific community is under discussion. Work continued to identify a panel of regulatory experts in vaccines in addition to developing a survey for the TRANSVAC consortium to identify the real bottlenecks in the regulatory landscape of vaccine development. The annual meeting was attended by EATRIS C&S in Brussels in May where a fruitful discussion took place to identify the current gaps in the vaccine development field.

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 (Project extension until March 2020 without additional funding)
EATRIS role: Partner WP2 "Definition of competencies" and WP5 "Continued professional development"

Project update: The Research Infrastructure Training Programme (RItrain) aimed at improving and professionalising the training of managerial and leadership staff in RIs. The tailored training comprises: 1) Executive Masters in Management of Research Infrastructures; 2) A series of webinars with experienced leaders in research infrastructures; 3) Staff Exchanges to access managerial and leadership expertise directly from leading RIs. In 2018 EATRIS organised a 2-day staff exchange "Governance, business context and operational planning for hubs & nodes". EATRIS welcomed six Research Infrastructure managers to Amsterdam to exchange knowledge and experiences through a mix of lectures from EATRIS on best practices and lessons learnt, and structured break-out groups where participants discussed their user cases. The feedback from the participants was extremely positive and for EATRIS hub and node staff it was a great opportunity to reflect on achievements and challenges so far, and to gain new insights and ideas from the participating RIs. In addition, EATRIS C&S staff continued to follow the Executive Masters in Management of Research Infrastructures, one of RItrain's training opportunities to deepen their knowledge and gain additional competencies in a broad range of topics including strategy, financial management and communication.

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

Project update: In 2018 the Innovation Help Desk coordinated by EATRIS continued to provide support for industry partnering and legal assistance. For the third consecutive year, CORBEL was present at the BIO International Convention in Boston (USA) and represented three RIs in making contacts with potential industry partners. EATRIS developed additional guidelines to support the RI with preparing material transfer and research collaboration agreements and made them available on the CORBEL website for any academic party. EATRIS also organised a two-day workshop on "Best Practices in Public-Private Research Collaborations" : Network Development, Legal Planning & Project Management" in Ljubljana, Slovenia, on 12 and 13 December 2018. The workshop aimed to offer practical tools and insights to academic groups as well as staff from BMS RI to accelerate their partnerships with industry and increase the innovation potential of their RI.

INNOVATION PARTNERSHIP FOR A ROADMAP ON VACCINES IN EUROPE (IPROVE): **A VISION FOR THE VACCINES OF TOMORROW**

Key Messages:

This article discusses the strategy of the Innovation Partnership for a Roadmap on Vaccines in Europe (IPROVE) and the rationale behind that, with a view to lead the next generation of vaccines. The approach presented in this publication covers the developmental pipeline of vaccines and moves further suggesting actions on European level. Furthermore, it highlights the need for advanced courses in Vaccinology as well as campaigns to mitigate vaccine hesitancy. This roadmap plans to encourage the development of networks of collaboration in EU and worldwide, create a vibrant, multi-disciplinary vaccine research community and avoid any duplication of efforts.

Synopsis:

A clear vision for vaccines research and development (R&D) is needed if Europe is to continue to lead the discovery of next generation vaccines. Innovation Partnership for a Roadmap on Vaccines in Europe (IPROVE) is a collaboration between leading vaccine experts to develop a roadmap setting out how Europe can best invest in the science and technology essential for vaccines innovation. This Framework Programme FP7 project, started in December 2013, brought together more than 130 key public and private stakeholders from academia, public health institutes, regulators, industry and small and medium-sized enterprises to determine and prioritise the gaps and challenges to be addressed to bolster innovation in vaccines and vaccination in Europe. The IPROVE consultation process was structured around seven themes: vaccine R&D, manufacturing and quality control, infrastructure, therapeutic vaccines, needs of small and medium-sized enterprises, vaccines acceptance and training needs. More than 80 recommendations were made by the consultation groups, mainly focused on the need for a multidisciplinary research approach to stimulate innovation, accelerated translation of scientific knowledge into technological innovation, and fostering of real collaboration within the European vaccine ecosystem. The consultation also reinforced the fact that vaccines are only as good as their vaccine implementation programmes, and that more must be done to understand and address vaccination hesitancy of both the general public and healthcare professionals. Bringing together a wide range of stakeholders to work on the IPROVE roadmap has increased mutual understanding of their different perspectives, needs and priorities. IPROVE is a first attempt to develop such a comprehensive view of the vaccine sector. This prioritisation effort aims to help policy-makers and funders identify those vaccine-related areas and technologies where key investment is needed for short and medium-long term success.

Authors:

Donata Medaglini, Magdalena R. De Azero, Odile Leroy, Florence Bietrix, Philippe Denoel, Vaccine, Volume 36, Issue 9, 21 February 2018, Pages 1136-1145 [open access]
DOI 10.1016/j.vaccine.2017.11.069

EDUCATION & TRAINING

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

Guest lectures from staff members of EATRIS C&S

Florence Bietrix and Rosan Vegter (Training Manager) were invited speakers at Kyushu University, Japan, in January (see page 51) and August. They discussed how EATRIS operates in the European scientific landscape and its involvement in European and global initiatives.

Anne-Charlotte Fauvel (Head of European Affairs) was a guest speaker at the training seminar "Funding Strategies & Sources for International Research Cooperation" organised by the European Academy for Taxes, Economics & Law in Berlin, Germany in August. She gave lectures on 'Avoiding Pitfalls and Red Flags in Your Proposal Writing' and 'Optimising Research's Fundability Through Private Partnerships and Translational Research'.

David Morrow (Programme Manager) was involved as panel member and guest speaker at several occasions such as the Phaciliate Leaders World (Miami, USA January), ISCT Europe (Florence, Italy September), ProMIS - Mattone Internazionale Salute Programme on personalised medicine (Naples, Italy September), discussing cell tracking and personalised medicines.

Onboarding new capabilities at EATRIS C&S

As part of EATRIS' continuous development and on-boarding of new expertise and capability, EATRIS team followed several training and learning modules.
David Morrow, Tamara Carapina, Anne-Charlotte Fauvel, Spyridon Goudelis, Martin de Kort and Ben Lydall enrolled as a team in the EMMRI programme (Executive Masters in Management of Research Infrastructures) while Florence Bietrix joined the second edition with a view to complete the full programme. In addition, Lisa Williams and Anne-Charlotte Fauvel received training on Financial Management of H2020 Projects.

Supporting capacity-building and skill development of fellow RIs

Train the trainer
This workshop was organised under WP9 of the CORBEL project in July. The main goal was to support trainers, educators, training coordinators and work package leaders by providing them with new ideas and tools to make their training events even better and easier to run and prepare. The workshop was followed by a 1-day course development hackathon in which participants were enabled to turn new ideas into practice and work on their own training concepts with input from colleagues.

Twelve participants from different RIs joined the event in the Lloyd Hotel in Amsterdam. The workshop was very interactive, content was focussed on the needs of the participants and based on many practical exercises.

Best Practices in Biomedical Public-Private Research Collaborations: Network Development, Legal Planning & Project Management

On December 12 and 13, a best practice workshop in Public-Private collaboration was held at the Faculty of Pharmacy of the University of Ljubljana under CORBEL's WP8 "Accelerating Innovation". The workshop aimed to offer practical tools and insights to academic groups as well as staff from BMS RIs to accelerate their partnerships with industry and increase the innovation potential of their RI. The two-day training covered the many aspects of setting up public-private collaborations (business development strategy, legal frameworks, project management), and was followed by an interactive group exercise featuring a realistic case study. The programme and exercise looked from the perspective of the academic researcher required to take an active role in setting up public-private collaborations. EATRIS and other BMS RIs gave highlights from their experience in reaching out to industry, and a pharmaceutical consultant also gave a talk on the industry point of view. Judging by the high level of enthusiasm and the positive comments received, the workshop fulfilled a clear need in academia. We hope to repeat the workshop during the remainder of the CORBEL project.

RI-train Staff Knowledge Exchange

On June 12 and 13, EATRIS welcomed six Research Infrastructure managers in Amsterdam, The Netherlands to exchange knowledge and experiences with respect to Governance, Business and Operational planning for hubs & nodes. The two-day programme provided a mix of lectures from EATRIS on best practices and lessons learnt as well as structured break-out groups where participants discussed their user cases.

The knowledge exchange workshop proved to be a very valuable opportunity not only for the participants but also EATRIS' staff to reflect on achievements and challenges so far and make plans for the steps forward. Participants' feedback was extremely positive (all participants strongly agreed that the staff exchange was a valuable experience):

"Many thanks for organising this excellent workshop and for sharing the resources. It was extremely useful and a good networking opportunity".

"Great and valuable meeting. Would be great to be continued for others!"

"It was a rewarding and helpful opportunity to get a more in-depth understanding of RI best practices and structural characteristics. I learned a lot!"

Training the next generation of translational scientists

ENLIGHT-TEN Summer School

From April 16 to 20, 2018, thirty early-career scientists came together at Bayer headquarters in Berlin, Germany for the ENLIGHT-TEN summer school on translational research and medicines development. The summer school introduced the participants to the knowledge, philosophy and tools needed in translational research and medicine development, empowering them to make a difference in translational medicine. During this exciting week, participants enjoyed both the scientific workshops and the career related activities. A faculty of 13 high profile professionals from Industry, Academia and Biotech introduced the basics of the medicines development process including real life case studies. After the course all 30 participants stated that they would recommend the course to their peers. Next edition, entitled Translational Medicine Explained (TMex) Winter school, is kindly supported by VHIR and "la Caxia" Banking Foundation and will be held at the Palau Macaya (Barcelona, Spain) from November 11 to 15, 2019.

LECTURING IN JAPAN

2018 started for me in Fukuoka in Japan. I had been invited by Prof. Sugiyama to give a series of lectures at Kyushu University and a three-hour seminar on Translational Research in French at the Nihonbashi Life Science Building in Tokyo.

Needless to say, I was extremely excited by the adventure, but also slightly stressed about the challenge ahead of me: providing lectures on Translational Research to Japanese students in a country I had never before visited.

Through four lectures of 90 min, I tried my best to provide an overview of key concepts in Translational Medicine at the heart of EATRIS such as the key components beyond scientific excellence dictating feasibility and chances of success; the need for validated biomarkers and better predictive models but also European R&D and the role of Research Infrastructures in Europe to promote innovation.

Designing your research for maximum impact : The translational research pipeline

This first lecture provided a basic introduction to translational research and a review of the main components of the development pipeline that affect the feasibility of translational research.

Designing your research for maximum impact: Building a data package fit for investment

The second lecture focused on providing a strong understanding about the level of research data necessary to secure interest from investors from target validation to predictive models.

The rise of biomarkers

In the era of Personalised Medicine, biomarkers are instrumental; however, many biomarkers are published in peer-reviewed journals and only few biomarkers progress to subsequent clinical validation and into a clinical test. The third lecture investigated the biomarker innovation gap by identifying key components of the biomarker development pipeline and the prerequisites for their implementation for Personalised Medicine.

Global trends in Europe

The last lecture dealt with the European landscape in translational medicine and its latest trends. Topics covered included how academic research infrastructures are being deployed to improve access to and utilisation of resources for biomedical research and innovation; the large investments currently being made in exploiting (big) data and the concept of FAIR data; how academia and regulators are starting to work more closely together to develop transparent standards in advanced therapies development; and the need to improve public-private collaboration in translational medicine, for better validated tools and biomarkers for personalised medicine.

While in Japan, I had the chance to share an office with our colleagues at NIH-NCATS: Gurusingham Sittampalam, Nathan Coussens and Samarjit Patnaik. They had been invited to give a series of lectures and workshops at the same time as me at both Kyushu University and Tokyo University. Being in the company of such brilliant and friendly scientists gave me the opportunity not only to attend their two-day workshop on Translational Science & Medicine but also to exchange knowledge on best practices and to discuss projects and challenges around Translational Medicine. Overall, this month in Japan was a formidable adventure and the opportunity to experience teaching, learn and exchange with our colleagues in Japan and in the US together with a deep dive in a new culture.

Many thanks to Prof. Sugiyama for his invitation and warm welcome and to Nao Tsuruya who waited for me at the airport when I arrived, helped me settle in and became a dear friend over the weeks I stayed in Fukuoka.

Florence Bietrix
Operations and Programme Manager

FINANCIAL SUMMARY

Development in income and expenses result:
Compared to the previous year, contribution and subsidy income increased, core projects income decreased due to discontinuity in staff. The negative operating result of €80K for 2018 was anticipated and covered by the reserves as pre-approved by the Board of Governors. An extra €43K was added to the negative operating result due to unforeseen HR costs and lower projects income. Otherwise, resource allocation was in line with the budget approved by the Board of Governors and in accordance with the Board's final approval of the annual accounts.

	Annual report 2018 €	Approved budget 2018 €	Annual report 2017 €
Contributions income	1,412,764	1,385,000	1,369,937
Catch up budget		80,000	
Subsidy income	309,768	79,000-	261,505
Total income	**1,722,532**	**1,544,000**	**1,631,442**
Salaries and wages	857,037	787,042	835,482
Sub total staff	187,488	379,335	213,131
Personnel expenses	**1,101,345**	**1,166,377**	**1,048,613**
Depreciation	6,782	-	8,552
Other expenses	738,140	377,500	784,598
Total expenses	**1,846,267**	**1,543,877**	**1,841,763**
Total operating result	**-123,735**	**123**	**-210,321**

	2018	2017	Analysis
Activa	x € 000	x € 000	
Tangible fixed assets	15	18	The book value of the tangible fixed assets decreased as a result of a higher amount of deprecation than investments.
Current receivables	350	605	The decrease is mailnly due to less outstanding contributions at year-end compared to last year. Therefore less contribution income is still a receivable at year end rather than received as a cash position.
Cash at banks	394	303	Cash at banks increased due to a bigger decrease in current receivables than the decrease in current liabilities.
	759	**926**	

	2018	2017	Analysis
Equity & Liabilities	x € 000	x € 000	
Reserves	345	469	The reserve was adjusted with a net of € 124 K, equal to the negative result of the financial year.
Current liabilities	414	457	The decrease is caused mainly by the other liabilities and accrued expenses. Primarily due to a lower amount in advance receipts of subsidy money in 2018 compared to 2017.
	759	**926**	

MEET THE COMMUNITY

COUNTRY	Board of Governors	Board of National Directors
BULGARIA		
	Yanita Zherkova	Rossitza Konakchieva
		Rumen Pankov
CZECH REPUBLIC		
	Petr Ventluka	Marian Hajdúch
		Miroslav Hutňan
ESTONIA		
	Priit Tamm*	Sulev Koks*
	Toivo Raim*	
FINLAND		
	Riina Vuorento	Seppo Ylä-Herttuala
	Sirpa Nuotio	
FRANCE		
	Alix de la Coste	Philippe Hantraye
	Eric Guittet	Simone Mergui
		Lauranne Duquenne
ITALY		
	Maria Ferrantini	Franca Moretti
	Francesca Capone	
LATVIA		
	Uldis Berkis	Ilmars Stonans
	Ilmars Stonans	Uldis Berkis
LUXEMBOURG		
	Lynn Wenandy	
	Jean-Claude Milmeister	Frank Glod
THE NETHERLANDS		
	Martijntje Bakker	Peter Luijten
		Gerrit Meijer
NORWAY		
	Marianne Gronsleth	Janna Saarela
		Laetitia Abdou-Garonne
PORTUGAL		
	Maria do Céu Machado	Cláudia Maria Coelho de Faria
		Dinah Duarte
SPAIN		
	Rafael Andres de Medina	Joan Comella
		Fatima Nunez
SLOVENIA		
	Albin Kralj	Irena Mlinaric-Rascan
	Irena Mlinaric-Rascan	
SWEDEN		
	Hakan Billig	Mats Larhed
	Maria Nilsson	Ulrika Bäckman

*Member of the BoG and BoND until 2018

MEET THE C&S TEAM

Anton Ussi
Operations & Finance Director

Toni Andreu
Scientific Director

Giovanni Migliaccio
Senior Advisor

Frank de Man
Governance & Finance

Florence Bietrix
Operations & Programme Manager Biomarker platform

Anne-Charlotte Fauvel
Head of EU Affairs

David Morrow
Programme Manager ATMP & Vaccines platform

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

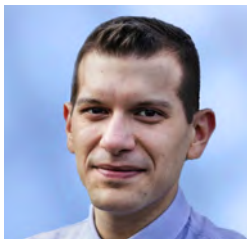
Chris Tieken
Business Development Manager

Rosan Vegter
Training Manager

Tamara Carapina
Legal Counsel

Lisa Marie Williams
Office Manager

Ben Lydall
Finance & Sustainability Specialist



Spyros Goudelis
Communications Manager

Laure Boudaud
IT & Platforms Coordinator

Rebecca Ludwig
Training Advisor

Erika Groenink
Finance Officer**

Nigel Wagstaff
Advisor Innovation Support

Jean-Baptiste Trannoy
Finance Officer

** Until the end of 2018

LIST OF ABBREVIATIONS

A	**ATMP**	Advanced Therapy Medicinal Products
B	**BBMRI-ERIC**	Biobanking and BioMolecular Resources Research Infrastructure
	BMS RI	Biological and Medical Research Infrastructures
	BPRC	Biomedical Primate Research Centre
C	**CAR T-Cell**	Chimeric Antigen Receptor T-Cell
	C-COMEND	Competency-based course on Translational Research and Medicines Development
	CDRD	Centre for Drug Research and Development
	CEST MRI	Chemical Exchange Saturation Transfer – Magnetic Resonance Imaging
	CORBEL	Coordinated Research Infrastructures Building Enduring Life-Science Services
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
	ECRIN	European Clinical Research Infrastructure Network
	EMA	European Medicines Agency
	EMMRI	Executive Masters in Management of Research Infrastructures
	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
	ESMO	European Society for Medical Oncology
	EU	European Union
	EURIPRED	European Infrastructure for Poverty-Related Diseases
H	**HESI**	Health and Environment Sciences Institute
	HTA	Health Technology Assessment
	HTS	High Throughput Screening
I	**IBBL**	Integrated BioBank of Luxembourg
	ICM	NeurATRIS Imagin webinar?
	IMI	Innovative Medicines Initiative
	ISCT	International Society for Cellular Therapy
J	**JTC**	Joint Transnational Call
L	**LoE**	Letter of Engagement
	LTP	Linked Third Party

M	**MIRCen**	Molecular Imaging Research Center
	MoU	Memorandum of Understanding
	MRCA	Master Research Collaboration Agreement
N	**NIBSC**	National Institute for Biological Standards and Control
	NTNU	Norwegian University of Science and Technology
	NIH-NCATS	US National Institutes of Health – National Center for the Advancement of Translational Science
P	**PET/CT**	Positron Emission Tomography – Computed Tomography
	PET/MRI	Positron Emission Tomography – magnetic resonance imaging
	PI	Principal Investigator
	PPP	Public-Private-Partnership
R	**R&D**	Research and Development
	RI	Research Infrastructures
	RIS	Regulatory Information System
	RITRAIN	Research Infrastructures Training Programme
S	**SMEs**	Small and medium-sized enterprises
	SOP	Standard Operating Procedure
T	**TIA**	Therapeutic Innovation Australia
	TT	Translation Together
	TRANSVAC2	European Network of Vaccine Research and Development
W	**WP**	Work Packages
V	**VHIR**	Vall d'Hebron Research Institute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G1


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