

EATRIS-ERIC ACKNOWLEDGES WITH GRATITUDE THE SUPPORT OF:

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Grand Duchy of Luxembourg

Le Gouvernement du grand-Duché de Luxembourg



Republic of Portugal

INFARMED-National Authority of Medicines and Health Products



Kingdom of Sweden

Vetenskapsrådet

* The contribution in Norway is shared between University of Oslo (UiO), University of Bergen (UiB), Norwegian University of Science and Technology (NTNU), the Arctic University of Norway (UiT) and the four Regional Health Authorities in Southeastern, Western, Central and Northern Norway

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HÅKAN BILLIG

Chair of EATRIS Board of Governors

In 2020 EATRIS' activities were affected, as was the whole world, by the COVID-19 pandemic. While this presented challenges to working structures and activities, EATRIS responded, as so many people and institutions globally, both by rapidly adapting services to deal with the unprecedented changes to the working environment, and by working with many partners to help to fight the pandemic. More than 30 requests from academia and industry were supported that covered a wide range of needs, –from regulatory filing for a new vaccine candidate to mechanism-of-action studies for repurposed therapies. Both the range of high quality services delivered, as well as the advanced stage of development of the projects supported, are illustrative of EATRIS' key role in Europe's ability to advance knowledge into meaningful innovations.

All the members of EATRIS, twelve full Members and one Observer, constitute the heart of the infrastructure – EATRIS is inspired by and is the sum of all national life science agendas. All members are committed to cooperating towards the shared goal of accelerating and optimising translational research. The national nodes are a hugely important part of this, developing national coordination and spearheading awareness of and involvement with EATRIS. They have been actively increasing engagement within EATRIS and outwards, with the goal of increasing coordination and visibility. In February members from across the infrastructure gathered at the Annual Meeting at INFARMED in Lisbon to share best practices, to network, and to discuss how the capacities of the infrastructure will be used to best support the development of personalised medicine.

There was continued focus on advancing precision medicine R&D – illustrative events in 2020 were the kick-off of the flagship EATRIS-Plus project to develop a broad offering of multi-omics research tools and services, as well as the PERMIT project, launched in January, developing best practice in the use of preclinical models for the development of stratified medicines.

Moreover, throughout 2020 EATRIS continued to work collaboratively with institutions across Europe and globally on projects and activities promoting and contributing to the development of translational research. As 2020 has illustrated, it is very hard to know what the future will bring. Whatever happens, I am confident that EATRIS will show the adaptability and commitment demonstrated in 2020 to continue to increase its development and internal and external collaborations to continue to assist with the development and optimisation of translational research.

Sincerely,

Håkan Billig

The EATRIS Board of Governors (BoG) is the governance body of EATRIS-ERIC with full decision making authority. It is formed with representatives of ministries within EATRIS Member States. The BoG typically approves budget and yearly operational plans and approves new countries as members of the EATRIS Research Infrastructure.



CLAUDIA FARIA

Chair of EATRIS Board of National Directors

The year 2020 started with the EATRIS Annual Meeting at Infarmed in Lisbon. It was a successful meeting gathering a large number of participants from across Europe to discuss how to improve personalised medicine and how to best use the available tools for translational medicine. The meeting provided two exciting days for networking, sharing experiences and establishing fruitful collaborations.

The rest of the year was marked by the COVID-19 pandemic, which challenged Europe and the World. The COVID-19 pandemic changed our lives, challenged the healthcare systems of every country, but also created opportunities for cooperation among the scientific community, and strengthening the support and commitment of the Medical Research Infrastructures.

EATRIS has been particularly active in participating and disseminating initiatives related to COVID-19. EATRIS developed the COVID-19 Research Forum, a platform that facilitates the interaction between researchers, allowing the discussion of protocols, sharing resources and translational tools.

The joint efforts between the EATRIS coordination and support office and its members produced successful applications for EU funding. Two new Horizon 2020 projects were recently approved with EATRIS as a beneficiary, one to support the European Reference Network on Rare Diseases (ERICA) and the other to help developing a roadmap for health research data cloud (HealthyCloud).

As the EATRIS community increases its visibility, we have also witnessed the strengthening of the national nodes and their growing capacity to support biomedical research and to disseminate the vision of EATRIS.

I am looking forward to the years ahead, to follow the achievements of EATRIS and the impact it will have on human health.

Sincerely,

Claudia Faria

The EATRIS Board of National Directors (BoND) is formed of national scientific representatives to ensure scientific excellence of the infrastructure and develop and implement the scientific strategy at national levels. The BoND reviews the participation of new institutions to the infrastructure. In several countries a National Coordinator provides support to the National Director for the day to day activities, fostering engagement and maintenance of a vibrant scientific community nationally.



CATHERINE LARUE

Member of the EATRIS Scientific Advisory Board

In order to serve the EATRIS strategy and operations in 2020, advice from the Scientific Advisory Board led to a number of improvements in the infrastructure. One of these improvements was better communication with the three other Research Infrastructures (BBMRI, ECRIN and ELIXIR), in alignment with Horizon Europe new research program priorities.

Scientific operations were well managed leading to new European grants won and other achievements were finalised with regards to education and training associated with a clearer communication which all together reinforced EATRIS mission and positioning as a lighthouse for a better biomedical and translational research in Europe.

All these efforts helped EATRIS reach a higher level of visibility throughout Europe, and positioned it as an important player to help researchers. The key is that EATRIS should do what researchers are not able to do by themselves.

Sincerely,

Catherine Larue
On behalf of the EATRIS Scientific Advisory Board

The EATRIS Scientific Advisory Board (SAB) is the advisory body to the Board of Governors that provides independent feedback and advice on the scientific strategy of the organisation. The SAB brings together multi-disciplinary expertise and a broad range of professional backgrounds to provide guidance on the development of EATRIS strategies and activities.



TONI ANDREU

EATRIS Scientific Director

Dear colleagues from the EATRIS family,

2020 will be a year that we will always remember for the impact that has had in our lives. The COVID-19 pandemic has represented a turning point in the development of our society, and many elements that we took for granted in daily life have been turned upside down. The SARS-CoV-2 virus forced us to look in the mirror and observe our contradictions and limitations but also our creativity, perseverance, resilience and, in a pure Darwinian perspective, our capacity to adapt to unprecedented challenging scenarios.

Science has been the driving force of a systemic and titanic effort to challenge the situation created by the pandemic. Thousands of researchers from all over the world, both from the public and private sectors, have been working ceaselessly to understand the biology of the SARS-CoV-2 virus, learn about the mechanisms of the virus-host interactions, developing efficient vaccines, setting and developing clinical trials repositioning known compounds and tackling the entire value chain of the translational medicine pipeline.

The EATRIS community has been a first-line actor in this journey. EATRIS institutions and scientists have provided essential contributions in the preclinical development pipeline of the COVID-19 translational process. Our fast access to key services and facilities process and our specific services for vaccine developers through the EU funded project TRANSVAC-2 are key examples of our commitment to the society in fighting the pandemic.

In addition to our services for supporting research and innovation on COVID-19, 2020 has been a year where EATRIS has intensified its presence in other key actions, programmes and activities that will reinforce the translational medicine landscape. Among these actions, EATRIS-Plus our infrastructure flagship project funded by the European Commission, has started its journey creating multiomic tools for the development and adoption of personalised medicine.

No one can predict what the future will look like, but I am sure that the energy, commitment and expertise of the EATRIS family will be able to tackle any challenge, overcome any barrier and successfully navigate in the translational seas.

We are going to keep working side by side with other scientific communities to bring scientific breakthroughs to people's lives with the conviction that science is the inspirational driving energy of a society based on the values of solidarity, equality, respect and protection of those that are vulnerable.

Sincerely,

Toni Andreu



ANTON USSI EATRIS Operations & Finance Director

Dear reader,

Reflecting on 2020, it's difficult to ignore the monolithic presence of the COVID-19 pandemic, which has had far-reaching effects on our professional, private and public lives. EATRIS is no exception, with all of us in the coordination office, nodes and research facilities heavily impacted. And yet in this time of public health crisis, the EATRIS family is very proud to be counted amongst the committed and tireless individuals and organisations that contributed substantially in the fight against SARS-CoV-2.

Overnight our world was turned upside down, with our almost daily international travel abruptly halted, and transitioning to fully virtual teamwork within two weeks. Fortunately, our previous investments into the necessary IT architecture and reliable operational processes gave us the strength to meet the challenges head-on and emerge stronger. As a result, EATRIS had its strongest performance to date, both from a services provision and financial perspective. We are truly proud of the professionalism, commitment and positivism shown by the entire EATRIS team in this tumultuous and personally tortuous year.

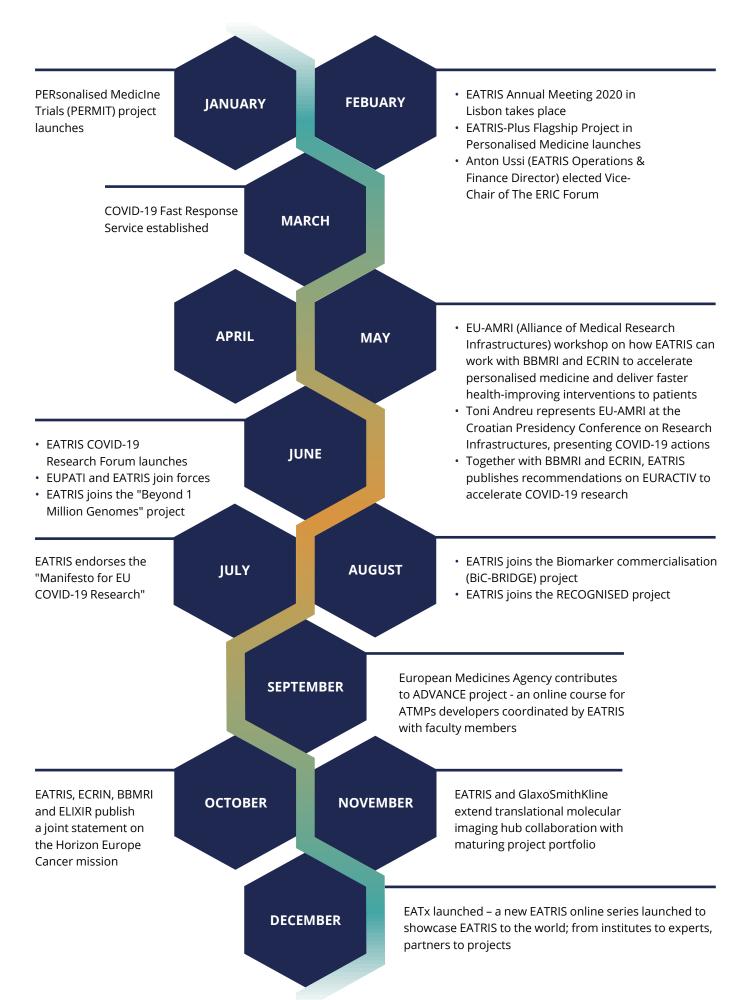
Happily, we can count some highlights in this Annual Report unrelated to COVID-19. One of my favourites is the highly successful mentoring programme that we developed for the European Joint Programme in Rare Disease, in which we coordinated industrial, regulatory and scientific mentoring for almost 20 transnational projects in rare diseases. The feedback from both mentors and the investigators was unanimously positive, and we continue in 2021 to scale out the programme. Further, in the ADVANCE programme funded by ERASMUS+, we have assembled a world class educational curriculum focused on advanced therapies such as cell and gene therapies, for which we have the good fortune to collaborate with the European Medicines Agency for content creation. Finally, EATRIS innovation in public-public collaboration models continues, with the services for charity and public funders - in the form of the Translational Assessment programme - growing in maturity and breadth.

We hope you enjoy the Annual Report 2020, and look forward to working with you in 2021.

On behalf of the whole Coordination & Support team,

Anton Ussi

EATRIS HIGHLIGHTS 2020



EATRIS 2020 IN NUMBERS





















MILLION EATRIS
WEBPAGE VIEWS
BY 545,224 WEBSITE
VISITORS





NEW FOLLOWERS





Participating countries: Bulgaria, Croatia, Czech Republic, Finland, France, Italy, Luxembourg, The Netherlands, Norway, Portugal, Spain, Slovenia, Sweden, Latvia (observer)

110+ academic and non-profit research institutes of excellence; more than half are university medical centres





OUR MEMBERS

Core Activities of Our Member States in 2020

BUI GARIA =

Member representatives:

Yanita Zherkova Milena Glavcheva

National Directors:

Rossitza Konakchieva Rumen Pankov

During 2020 many priorities were re-evaluated in the face of the global pandemic. National capacities in technology and human resources were urgently reorganised and new units established to create sufficient infrastructure to support the healthcare system. Due to the already granted access to funding instruments originating from the Operational programme 2014-2020 and the National Roadmap for Research Infrastructures, the actualisation of the national research infrastructure was accelerated as the community was already prepared and organised at the start of 2019.

The Ministry of Science end Education created a new webbased platform to map national research infrastructures and disseminate scientific results generated through investments of national funding.

The EATRIS node participated actively in the creation of a database dedicated to profiles of Bulgarian research teams in support of international cooperation to address the COVID-19 challenge. Participation in EATRIS events and activities raised great interest. The participation of PhD students from the MU-Sofia in the TMex Winter school was met with enthusiasm, as were other events dedicated to education and training, such as the ADVANCE course attended by two participants from Bulgaria.

The academic response to EATRIS activities is getting more intensive and we can expect to generate results due to closer collaboration. Intensive work was done to establish a framework agreement, map mutual interests and outline a strategic work plan with the other two participating ERIC - national nodes: BBMRI and EuroBioImaging. A series of virtual events and workshops were also organised by the Ministry of Education and Science together with the nodes and other stakeholders to prepare for concerted action and participation in Horizon Europe.

C7FCH REPUBLIC

Member representatives:

Marta Vandrovcová Marián Hajdúch

National Director:

Marián Hajdúch

National Coordinator:

Miroslav Hutňan

The Czech Republic is contributing to all five technology platforms of EATRIS, with the participating institutes being: Central European Institute of Technology (CEITEC); Charles University; University of Chemistry and Technology Prague; Institute of Experimental Medicine of the CAS; Institute of Macromolecular Chemistry of the CAS; Institute of Microbiology of the CAS; Institute of Organic Chemistry and Biochemistry of the CAS; Masaryk University; Nuclear Physics Institute of the CAS; Palacký University Institute of Molecular and Translational Medicine (IMTM); and International Center for Clinical Research of St. Anne's University Hospital Brno.

The node is coordinated by the Institute of Molecular and Translational Medicine (IMTM) at the Palacký University, in Olomouc, Czech Republic.



Sirpa Nuotio Riina Vuorento

National Director:

Seppo Ylä-Herttuala

EATRIS Finland has collaborated with other Nordic EATRIS nodes in Sweden and Norway in the ATMP area, rare diseases and COVID-19 vaccine projects with support from the EATRIS C&S team. New Biosafety level 3 animal facilities are under construction in the University of Eastern Finland to better serve the EATRIS network.

The Institute for Molecular Medicine Finland, or 'FIMM', within the University of Helsinki has continued to play an important role in many sequencing projects and also in the EATRIS quality initiative. A new EATRIS Finland consortium has been put together to provide personalised medicine services in Natural Killer cells reinforced with chimeric antigen receptors.

Increased visibility is achieved via a dedicated 'EATRIS Finland' LinkedIn page, which is maintained by colleagues within FIMM.

FRANCE **I**

Member representatives:

Eric Guittet Simone Mergui

National Directors:

Philippe Hantraye Simone Mergui

National Coordinators:

Lauranne Duquenne Emilie Hangen

NeurATRIS, the French node of EATRIS, is a French national research infrastructure dedicated to translational research in neuroscience and in particular neurodegenerative and neurodevelopmental diseases. Following its excellent evaluation by the French authorities and an international scientific jury in 2019, NeurATRIS obtained funding of €3.3m for the next five years, thus guaranteeing its sustainability until 2025.

In 2020, the COVID-19 crisis strongly impacted NeurATRIS activities. Training activities suffered from the cancellation of numerous scientific events: workshop, supported courses, national and international scientific events/ courses attended by young scientists. Only three scientific events occured: (i) the 2nd edition of the conference 'Physiopathology Of Parkinson's disEase', which gathered 150 participants over 3 days in Paris, and (2) two webinars entirely dedicated to glial cells (81 and 132 participants).

Partnership development was not spared by the pandemic, as the 4th edition of "Translational Neuroscience day", annually organised by NeurATRIS to gather experts in neurodegenerative diseases and foster interactions, was also cancelled. This event was postponed until December 2021, and held as a joint event with BioFIT 2021.

Despite the situation, NeurATRIS research activities remained strong with an increased number of publications (150 in total, 29% with an impact factor >7).



Maria Ferrantini Francesca Capone

National Directors:

Franca Moretti Francesca Capone

Italian activities in 2020 were deeply affected by the COVID-19 pandemic and by the resulting restrictions implemented by the Italian government. In 2019 EATRIS in Italy focused mostly on education and training activities that were extremely appreciated by the Institutes as they stimulated the development of a sense of belonging and identity in EATRIS.

In much of 2020, due to the COVID-19 pandemic, we were unable to continue with these activities as planned and we began the process of converting the scheduled face-to-face events into virtual ones.

Nevertheless, we were able to hold the second edition of the course "Biomarkers and Techniques of Diagnostics for Images in the Assessment of Inflammation in Oncology" and the fifth edition of the EATRIS Workshop "Intellectual property and technology transfer".

At the same time the following activities were performed: facilitation of the development of common projects around priority biomedical research topics, promotion of the participation of Italian institutes in EATRIS, participation in EATRIS projects and collaborations developed with the contribution of EATRIS and publication of a special issue of The International Journal of Biological Markers on "Biomarkers and Imaging in the Evaluation of Inflammation in Oncology."



Member representative:

Uldis Berkis

National Directors:

Liene Nikitina-Zake **Uldis Berkis** Zaiga Nora-Krukle

In 2020, the EATRIS-Latvia National Contact Point continued work on the initiated activities in order to increase the consortium's recognition and interest in the services provided both in Riga Stradiņš University, as the contact point for host and partner institutions. The joint annual meeting of the EATRIS consortium was attended by the National Director, coordinator and representatives from the Latvian Institute of Organic Synthesis and the University of Latvia. The National Coordinator participated in the EATRIS-PLUS kick off meeting in February 2020 in Lisbon.

In the first half of 2020 a "Questionnaire for National European Strategy Forum on Research Infrastructures (ESFRI) *Infrastructure Node Coordinators*" was prepared with the aim to increase the research and innovation capacity of Latvian research institutions and the ability to attract external funding by investing in human resources and infrastructure. The questionnaire was submitted to the Ministry of Education and Science to update the Latvian ESFRI roadmap.

An international online seminar was held on 24 November 2020. The following experts shared their experience in realising translational medicine - Yehuda Shoenfeld from Tel Aviv Sheba Medical Center, Rejko Kruger from the University of Luxembourg, Pawel Zalewski from Nicolaus Copernicus University in Torun and Anton Ussi, EATRIS Operations and Finance Director. Two participants from Latvia participated in the "TMex - Translational Medicine Explained" digital course that ran between 26-30 October 2020. Meanwhile, representatives of the National Contact Point also participated in teleconferences, webinars and online workshops organised by EATRIS.

Jean-Claude Milmeister

National Director:

Frank Glod

National Coordinator:

Iris Egner

2020 was a very successful year for the Luxembourg EATRIS node. In January 2020, the EATRIS Plus flagship project started and in June the first National Coordinator was appointed.

The National Centre of Excellence in Research on Parkinson's Disease (NCER-PD) entered its second phase. Exemplifying existing research efforts spanning the entire translational pipeline are now used to investigate a GBA and a Nationwide sleep behaviour disorder subcohort.

The established translational collaborations between research institutes, hospitals and laboratories furthermore allowed Luxembourg to launch CON-VINCE and Predi-COVID in April 2020 to better predict infection rates and disease outcome during the COVID-19 pandemic.

As part of the IMI2 call 23, UL/LCSB and LIH/IBBL joined the European Platform for Neurodegenerative Diseases, which was nominated for the second stage. The proposal is composed of 28 partners and is led by the University of Maastricht. The objective of this proposal is to develop a platform that improves access to samples and data in the neurodegenerative field. It aims to integrate existing initiatives and build, grow and deliver a scalable and self-sustainable platform.

Luxembourg's unique research landscape ensured that Luxembourg could continue with existing research programmes in 2020 while successfully responding to the COVID pandemic.

THE NETHERI ANDS



Member representative:

Saco de Visser

National Directors:

Gerrit Meijer Jan-Willem Boiten

Health-RI is a joint initiative of the Dutch nodes of EATRIS, ELIXIR, and BBMRI, the Dutch university medical centers, together with a broad coalition of other organisations. Health-RI builds a National Health Research Infrastructure for optimal access to knowledge, tools, facilities, health data and samples. For sustainable and affordable personalised medicine and health.

The strategy of Health-RI follows three lines of action:

- 1. Collective action: optimising the conditions for building and maintaining a national health data infrastructure
- 2. Building a national health data infrastructure: fostering and facilitating initiatives and collaborations directed at developing health data infrastructure
- 3. Providing mature services: supporting researchers and data managers by making infrastructure services, tools and data easy to locate, access and use

KEY RESULTS 2020:

- 2020 was the founding year of the legal entity for Health-RI, the Health-RI foundation
- Proposal submitted for a National Health Data Infrastructure for research and innovation to be funded from the economic stimulation funds ("Groeifonds")
- Supporting activities for COVID-19 research
- Project with Ministry of Health, Welfare and Sport on national consent register for secondary use of data
- Development of a COVID-19 data portal in collaboration with the Dutch UMCs and ZonMw
- Development of radiology repository
- Established a national community organisation for further implementation and support of Health-RI
- In 2020, Health-RI has acquired a central place in the landscape of health data infrastructure in the Netherlands

Marianne Gronsleth

National Director:

Janna Saarela

National Coordinator:

Anita Kavlie

EATRIS Norway has focused on membership renewal after the initial five-year period. We have presented EATRIS to the Research Council of Norway, the Universities of Oslo, Bergen, NTNU and Tromsø and the corresponding four health regions. Outreach has been initiated towards the University research administrations to update relevant contact information, inform about educational possibilities and services to strengthen research proposals for the Horizon Europe program (2021-2027).

EATRIS Norway are involved in theH2020 project European Joint Program on Rare Diseases, where the national coordinator participated in coordination of mentoring for JTC2020 applicants invited to submit a second-stage proposal. We contributed to marketing content to disseminate this service. In addition, the national coordinator presented in the EJP-RD General Assembly meeting in September.

Norway is partner in the H2020 EATRIS-Plus project, and we contributed with a lecture for the TMex course in October. The institutions Oslo University Hospital/University of Oslo joined a consortium (Platform dementia) in partnership with several other EATRIS institutions, and this IMI2 application was selected to submit a second-stage proposal.

The University of Oslo has also joined a COST action consortium building (with Spain as the coordinator), and were selected to participate in an Erasmus+ consortium.

Member representatives:

Rui Santos Ivo

Helena Baião

National Director:

Claudia Maria Coelho de Faria (Chair)

National Coordinators:

Dinah Duarte Helena Baião

Despite the challenging year of 2020 to Europe and the World, the recently created EATRIS-PT has been particularly active pursuing the main goals of EATRIS. The National Hub was formally accepted in July 2019, includes 14 specialised centres that have joined the 5 platforms of EATRIS and Infarmed is the coordinating institution.

In early 2020 we organised at Infarmed (Lisbon) the EATRIS Annual Meeting, a highly successful meeting, gathering participants across Europe and with an outstanding scientific quality.

Several institutions of the Portuguese node participate in European funded projects including EATRIS-Plus (Infarmed leads a work package in training and it is actively organising yearly summer schools in Personalised Medicine), RECOGNIZE (Retinal and cognitive dysfunction in type 2 diabetes), TRANSVAC 2 (to develop a malaria vaccine) and EPND (Alzheimer and Parkinson Biomarker platform).

In line with the European Infrastructures Alliance, EATRIS-PT has established fruitful collaborations with national partners including ptCRIN (Portuguese Clinical Research Infrastructure Network), AICIB (Portuguese Agency for Clinical Research and Biomedical Innovation), FCT (Portuguese Foundation for Science and Technology) and HCP (Health Cluster Portugal). Joint initiatives were developed including seminars, workshops, educational activities and the contribution to the elaboration of a national strategic plan.

Finally, the National Director Claudia Faria was appointed the new Chair of the Board of National Directors.

SLOVENIA ===

Member representatives:

Albin Kralj

Irena Mlinaric-Rascan

National Director:

Irena Mlinaric-Rascan

National Coordinator:

Žiga Jakopin

2020 saw the formation of an umbrella consortium EATRIS-TRI.si with KI, UL FFA and MF UM as members. The EATRIS Slovenia website was updated and the following new people were onboarded: Maša Kandušer, Žane Temova Rakuša and Dunja Urbančič.

INFRASTRUCTURE INVESTMENT - UPGRADE OF RESEARCH INFRASTRUCTURE

Next generation sequencer, MiSeq Ilumina. Raman Spectrometer - Confocal Raman Microscope XploRA PLUS-OmegaScope. Biobanking storage systems: ARPEGE Cryopal, freezer PHCBi. HRMS-nHPLC (University of Maribor, Medical Faculty).

PARTNERSHIPS AND COLLABORATIONS THROUGH EATRIS

- a) EATRIS-Plus (UL FFA lead, Professor Mlinaric-Rascan)
- Survey on EATRIS community training needs in personalised and translational medicine.
- WP7 Summer School role of UL FFA part of the curriculum committee and organising committee;
 Partners INFARMED (organiser), EATRIS and UL FFA.
- WP7 Workshop on Private-Public partnership: kick-off meeting of the organising committee.
- b) Erasmus+ ADVANCE (UL FFA; Professor Mlinaric-Rascan)
- Coordination of workshop curriculum and organisation.
- Offering scientific support for online courses (Professor Urban Svajger from UL FFA; lecturer on two scientific online courses).

MEETINGS, WORKSHOPS, EDUCATION AND TRAINING ACTIVITIES

Meeting ERASMUS+ ADVANCE, Intellectual property rights management.

COMMUNICATION AND OUTREACH

- The ADVANCE project was presented at the EAFP conference in November 2020.
- Training and education was advertised on the EATRIS Slovenia website and mailing lists of Slovenian biochemical and pharmaceutical societies.

The meetings, workshops, education and training activities organised in 2020, plus our communication outreach and organisation of partnering activities resulted in increased awareness of benefits from EATRIS membership.



Member representatives:

Gonzalo Arévalo Nieto

Cristobal Belda

National Directors:

Joan Comella

Fatima Nunez

National Coordinator:

Marta Marin

The COVID-19 pandemic undoubtedly left a mark on the 2020 activities of EATRIS Spain, especially given that all Spanish institutes are Health Research Institutes and therefore were overwhelmed by their medical activity. In that sense, the Spanish Institutes have been heavily involved in the COVID-19 research and contributed to the EATRIS COVID-19 Research Forum.

The priority of 2020 was to strengthen communication with the EATRIS institutes and to connect with other researchers. We participated in the XXIV Meeting of the International Department of the Health Institute Carlos III with the autonomous regions (23 June 2020), where EATRIS was presented and we have set up a newsletter for our node.

Five new institutes joined EATRIS (IMIM, Ibs.Granada, IDIVAL, Irb Lleida and IIS Aragón) and have constituted a Scientific Committee composed of six researchers from different institutes (IGTP, Biodonostia, IDIPAZ, IIS LA FE, IBIS and IIS-FJD) to reinforce our strategic agenda and to boost the participation of the Health Research Institutes in international activities.

In line with the EU-AMRI alliance, we have established a working group with the different RIs in the life science field within the Spanish node (ECRIN, ELIXIR, EU-OPENSCREEN, INSTRUCT and INFRAFRONTIER) to foster collaboration between RIs at a national level and perform dissemination activities.



Maria Nilsson Håkan Billig (Chair)

National Director:

Pontus Aspenström

National Coordinator:

Ulrika Bäckman

This year, the Swedish node appointed a new national director - Professor Pontus Aspenström. With an excellent research background, Pontus will further develop the node with a strong scientific focus, a new strategic agenda and also help to increase the EATRIS visibility to the community in Sweden.

As for the rest of the world, outreach activities were a great challenge due to the COVID-19 pandemic. Most of the planned physical meetings were cancelled in early 2020 but gradually the events began to go digital and the Swedish node represented EATRIS in several events such as:

- The yearly Park Annual meeting with the theme Sector Convergence – hosted by Sahlgrenska Science Park.
- The future of Swedish and Danish Life Science, an event organised by Life Science Sweden with Kemivärlden and Medicon Village.
- SwedenBio events, a great opportunity to participate in inspirational meetings, workshops and digital events throughout the year.
- BIO-Europe®Digital, a global partnership meeting with an opportunity to meet small and midsize companies.
- Other important outreach activities have been made to the Swedish EATRIS institutes, biotech clusters, presentations to SciLifeLab organisation, and participation in Grants Day with the opportunity to meet representatives from all the large funding agencies in Sweden.

As one of the pilot nodes, Sweden takes part in the evaluation of a new reporting tool for the EATRIS community called Researchfish. This platform will help the nodes to report their research impact for the country as well as individual projects and grants. To be a partner in the EU-funded project EATRIS plus, this first year has given us an ability to show our strong focus in precision medicine. This project has led to a great interest and branding of EATRIS which looks promising for future collaborations and consortium building.

Also new project collaborations have been initiated. The Immuno Inflammation Imaging Hub projects are ongoing and new projects in other areas are being discussed. This hub concept creates a great opportunity for Swedish researchers that have an important role in this EATRIS flagship initiative.

The year ended by kicking of the EATRIS EATx online series that showcases the EATRIS community. The first episode of the series featured the Testa Center in Sweden, an initiative between the Swedish government and Cytiva to secure the growth of life science industry and its manufacturing capabilities.

The Swedish node is growing and after a positive evaluation, the Swedish research council decided to continue the membership for the next two years. This gives us time to further strengthen the node, start new collaborations and be a strong partner in the European arena.

INSTITUTIONS OVERVIEW

 Platform participation Platform participation new institutions in 2020 Name	АТМР	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
BULGARIA					
National Center of Infectious and Parasitic Diseases (NCIPD)					•
CZECH REPUBLIC					
Central European Institute of Technologies (CEITEC)		•			
Charles University	•	•	•	0	•
University of Chemistry and Technology Prague	•		•	•	
Institute of Experimental Medicine of the CAS	•	•	•	•	•
Institute of Macromolecular Chemistry of the CAS	•	•	•	•	
Institute of Microbiology of the CAS	•		•	•	•
Institute of Organic Chemistry and Biochemistry of the CAS	•	•	•	•	
Masaryk University	•		•	•	
Nuclear Physics Institute of the CAS	•		•	•	•
Palacký University - Institute of Molecular and Translational Medicine (IMTM)	•	•	•	•	•
International Center for Clinical Research of 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)	•		•		
ITALY					
Centro di Riferimento Oncologico di Aviano (CRO Aviano)	•	•			
Centro Medicina Rigenerativa (CMR)	•	•	•	•	•
CNCCS - IRBM Science Park	•	•	•	•	•
Fondazione IRCCS CRIBT	•	•	•	•	0
Fondazione IRCCS Fondazione Pascale	•	•	•	•	•

 Platform participation Platform participation new institutions in 2020 Name 	АТМР	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
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 Foundation Santa Lucia		•	•	•	•
RCCS Istituto Giannina Gaslini (IGG)	•	•	•	•	•
IRCCS Istituto Ortopedico Galeazzi	•	•			•
ISMETT	•	•			•
Istituti Fisioterapici Ospitalieri - Istituto Dermatologico "San Gallicano"					•
Istituti Fisioterapici Ospitalieri - Regina Elena Tumor research	•			•	
Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori" (IRST) - IRCCS	•	•		•	
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, LIH)	•	•			•
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		•			•
TNO		•	•		0
University Medical Center St Radboud (UMCN)	•	•	•		•
University Medical Center Utrecht (UMCU)		•	•		•
University Medical Centre Groningen (UMCG)		•	•		•
University of Technology Eindhoven (TU/e)	•				•
Wageningen Bioveterinary Research	•	•	•	•	•

 Platform participation Platform participation new institutions in 2020 Name	ATMP	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
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					
3B's Research Institute, University of Minho	•				
Association for Innovation and Biomedical Research on Light and Image (AIBILI)	•	•	•	•	•
Center for Neuroscience and Cell Biology; Coimbra University Hospital	•	•	•	•	•
Champalimaud Foundation	•	•	•	•	•
Coimbra Institute for Biomedical Imaging and Translational Research (CIBIT)	•	•	•	•	•
Institute for Bioengineering and Biosciences - Stem Cell Engineering Research Group (iBB - SCERG)	•	•	•	•	•
Institute of Biomedicine (IBIMED)		•			
Instituto de Biologia Experimental e Tecnológica (IBET)	•	•			•
Instituto de Investigação e Inovação em Saúde (i3S)	•	•	•	•	•
Instituto de Medicina Molecular João Lobo Antunes	•	•	•	•	•
Instituto Português de Oncologia do Porto Francisco Gentil (IPO-Porto)	•	•	•	•	•
Life and Health Sciences Research Institute / Clinical Academic Centre - Braga	•	•	•	•	•
NOVA Medical School, Unicersidade NOVA de Lisboa (NMS, NOVA)	•	•	•	•	•
SLOVENIA					
Maribor University	•	•			•
University of Ljubljana				•	
SPAIN					
August Pi i Sunyer Biomedical Research institute (IDIBAPS)		•	•		
Bellvitge Biomedical Research Institute (IDIBELL)	•	•	0	0	0
BioDonostia Health Research Institute	•	•	0	0	•
FIBICO, Foundation for Biomedical Research of Cordoba (IMIBIC)	•	•	•	•	0
Fundación Jiménez Díaz Institute for Medical Research (IIS-FJD)	•	•			•

INSTITUTE SPOTLIGHT

An Interview with Jesper Hedberg, Director of the Testa Center in Sweden





The Testa Center is an EATRIS institution based in Sweden. It is an initiative between the Swedish government and Cytiva. The Center aims to support the growth of life science industry and its manufacturing capabilities and bridge the gap from discovery to industrialisation. Director Jesper Hedberg tells us more.

TELL US ABOUT THE TESTA CENTER

We are an open access user facility, testbed and expertise provider for education, innovation and proof-of-concept experiments for production of biological products. We offer access to both equipment and expertise to go from lab bench scale to industrial scale of protein production processes.

HOW HAS THE TESTA CENTER BENEFITTED FROM BEING PART OF THE EATRIS COMMUNITY?

We firmly believe that companies and academic groups outside of Sweden can benefit from the offering of the Testa Center. We are always looking to increase the visibility of our offering to a larger European research and start-up community. Being part of the infrastructure of EATRIS has allowed us to showcase our facilities and services to the extensive EATRIS community in Europe.

HOW HAS TESTA CENTRE BENEFITED FROM BEING PART OF THE EATRIS INFRASTRUCTURE?

Being part of the EATRIS family has provided the opportunity for the Testa Center to connect with high quality research and engage with a remarkable calibre of investigators within the translational research field.

HOW DO YOU THINK SCIENTISTS BENEFIT FROM BEING PART OF EATRIS?

Scientists who are part of EATRIS can connect with other researchers and find synergies to accelerate the journey of an idea to benefit society, specifically the patient. Scientists benefit from access to cutting-edge science facilities, resources and services across an extensive European network.

TELL US ABOUT YOUR EATX EXPERIENCE

Working closely with the EATRIS National Coordinator of Sweden - Ulrika Bäckman - and Jake Fairnie and Piret Pajula from the EATRIS communications team based in Amsterdam, the Testa Center was featured as part of the newly launched EATx series. The format was a 30 minute session that allowed us to present live from the facility to the EATRIS community. It was a very smooth production, and the EATRIS team were very proactive in terms of helping with the logistics and follow up of the session. I would like to encourage anyone that was not able to attend the event to visit the EATRIS YouTube channel to watch it back, and get in contact if you think the Testa Center could help with your project.



Jesper Hedberg
Director of the Testa Center in Sweden





RESEARCH SERVICES FOR INDUSTRY

EATRIS built its operations through developing access to the EATRIS infrastructure for industry, hence fostering public-private partnerships. It resulted in successful project initiation for various companies. Our industry portfolio now includes multiple European and global Small and Medium-sized Enterprises (SMEs) and several long-term partnerships, including with big pharma.

In 2020, business development towards SMEs gained momentum by continued presence at industry partnering events. From March onwards, these events were held online, and were generally well attended by SMEs and pharma representatives compared to real-life events.

By the end of 2020, 24 companies had engaged with EATRIS, of which half of the requests were dedicated to COVID-19 research services making use of our COVID-19 Fast Response Service put in place in March which involved the dissemination of the COVID-related matchmaking requests directly to a selection of suitable institutes. The new procedure allowed us to accelerate the initiation of pandemic-related projects.

In parallel to offering services to industry, EATRIS has developed relationships with investment and proof of concept funds. This has allowed us to introduce a Czech institute with a patented asset to three different

investors. We will continue to provide introductions for EATRIS institutes to suitable funds.

In addition, we continued discussions with two pharma companies around long-term collaborations analogous to the GlaxoSmithKline (GSK) hub with the help of an industry consultant. Interest from other companies in the Hub model will be further explored in 2021.

The GSK hub has been extended for another three years to see the outcomes of a maturing portfolio which is a translational research collaboration given the range of projects (preclinical, clinical, multi- and single-site) and involvement of industry and academic partners. EATRIS continues to facilitate as a central point of contact for the Hub partners and provides legal and operational support.



In 2020, business development towards SMEs gained momentum by continued presence at industry partnering events. From March onwards, these events were held online, and were generally well attended by SMEs and pharma representatives compared to real-life events. Under the umbrella of EATRIS-Plus, we disseminated a survey focused on research infrastructure needs for SMEs via Biocat, the Catalonian biosciences cluster. This has increased the visibility of our services for industry towards around 500 life science companies.

To assist the national nodes in industry outreach, sharing business intelligence and best practices has been a part of our weekly national nodes teleconference.

Here are some of the partnering events we attended in 2020:

JANUARY

PHACILITATE LEADERS WORLD Miami,

21-24 January
9 partnering
meetings

FEBRUARY

15TH ANNUAL BIOMARKERS CONGRESS Manchester, 18-20 February 12 partnering

meetings

MARCH

BIO-EUROPE SPRING Digital event, 23-27 March

23-27 March20 partnering meetings

APRIL

COVID-19 VIRTUAL PARTNERING 4-6 April 17 meetings

JUNE

BIO DIGITAL 8-12 June 16 meetings

SEPTEMBER

SCANBALT DIGITAL FORUM (FOCUS ON COVID-19) Digital event,

4 September

BIOTECH ATELIER
(EUROPEAN
ANNUAL
BIOTECH
CONFERENCE
BULGARIA)
Digital event,
24-25 September

OCTOBER

BIO-EUROPE 26-29 October 22 company meetings

NOVEMBER

NEUROSCIENCE VIRTUAL PARTNERING 9-11 November 7 meetings

DECEMBER

7-10 December 10 meetings

RESEARCH SERVICES FOR ACADEMIA

2020 has seen a steady consolidation of our academic user group, through our support services towards Horizon 2020 and Innovative Medicines Initiative (IMI) funding applications. Following the structuring in 2018 of our offering into four main levels of support, 2020 focused on increasing further awareness about those levels of support among the academic community. In addition, possible collaborations with two EU funding support consultancy companies (ttopstart, Catalyze) were explored.



EATRIS performed 22 consortium-building requests, and joined 10 proposals as project partner. Among them, two new H2020 proposals with a focus on artificial intelligence (AI) were developed and submitted in June. The first, MultiAlm, is a unique coalition that focuses on deploying artificial intelligence (AI) for genomics and personalised medicine (PM) in the areas of comorbidity, multimorbidity and disease trajectories. The second proposal, EU-CIDDS-CAN, is about the establishment of a novel, international platform which brings together multiple diagnostic modalities and innovative analytical tools in order to ensure universal access to precision molecular diagnostics for the European childhood cancer population.

Among the H2020 proposals which received funding, EATRIS joined ERICA, a project that facilitates access to high quality cross-border healthcare and promotes and fosters cooperation on rare disease healthcare between member states.

Another project which received funding is the HealthyCloud project which will bring together data-intensive EU health research initiatives to design an implementation roadmap and strategic agenda for the development of a Health Research and Innovation Cloud FAIR data portal.

EATRIS participated as well in two IMI2-Call 23 proposal submissions. These were ERUDITE, which focuses on the shortening the path to rare disease diagnosis by using new-born genetic screening and digital technologies, and EPND, which aims to develop a platform for accelerating biomarker discovery and validation to support therapeutics development for neurodegenerative diseases and which was selected for second-stage application.

FUNDERS AND CHARITIES DEDICATED SERVICES

Through the EATRIS Translational Assessment, we proactively support in identifying potential gaps and bottlenecks which may hinder translational projects. In addition to the translational feasibility assessment, in collaboration with ZonMw (Dutch governing partner), we developed an early Health Technology Assessment (HTA) framework for translational projects. To date, we collaborated with three organisations: ZonMw, the foundation ReumaNederland and Prinses Beatrix Spierfonds.

In 2020, eight assessments were performed for the foundation ReumaNederland. Additional expert advice was given through the COVID-19 fast access track and special regulatory advice was accessed through the TRANSVAC-2 project (H2020 funded project offering high-quality technical vaccine R&D services, training and other resources to the research community).

In 2020, expert mentoring was developed in the context of the EJP Rare Diseases with support offered to 15 Principal Investigators developing their second-stage proposal for the EJP RD JTC2020 call around topics ranging from Translational feasibility to Regulatory compliance and Intellectual Property strategy.



Summary of activitiy

CORE ACTIVITIES	2017	2018	2019	2020
Consortium Building	14	20	13	22
Research Service	14	6	10	24
Translational Assessment/Expert advice	14	2	9	28
Hub Partnering	1	1	1	1
INCOME C&S OFFICE	2017	2018	2019	2020
Service Fees*	€ 114,838	€ 32, 417	€ 85,339	€ 57,530
Grants	€ 261,505	€ 309,768	€ 355,107	€885,042
INCOME INSTITUTIONS (BUDGET NEGOTIATED)	2017	2018	2019	2020
Industry Projects	€ 326,571	€ 5000	€ 818,500	€ 296,487
EATRIS Linked Third Party grants	-	€1,615,049	€ 7,713,536	€136,250
Users	5,500	3,000	6,500	6,978

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

USE CASE: EATRIS EJP RD EXPERT MENTORING SERVICE

Under the European Joint Programme on Rare Diseases (EJP RD) project, EATRIS developed an expert mentoring support programme for rare diseases researchers.

Panels of international multidisciplinary experts in translational research are assembled according to the needs of each project and guidance is provided to projects while at preparation stage or at a later stage during project execution. In 2020, EATRIS offered its mentoring programme to applicants of the EJP RD JTC2020 funding call. 15 projects that were selected for second-stage application were actively mentored with the involvement of 13 experts representing 90 hours of mentoring work and 400 hours of coordination work. The overall aim of the mentoring programme is to increase the impact and patient benefit of translational research projects in rare diseases.

WHAT IS THE AIM?

To increase the impact and patient benefit of translational research projects in rare diseases.

WHO IS IT FOR?

Any scientist working on (or planning to work on) a translational research project in rare diseases in the pre-proposal stage and after receiving funding.

WHO ARE THE MENTORS?

A panel of international experts working under full confidentiality.

WHAT DOES IT COST?

There are no costs - it is entirely free.



What do the scientists who have used our expert mentoring service have to say?



Davide Gabellini (Group Leader in the Division of Genetics and **Cell Biology in the San Raffaele** Scientific Institute, Italy):

"I benefited from the mentoring service during the preparation of the full proposal for the EJP RD Call

for Proposals 2020. I interacted with various professionals collaborating with EATRIS to discuss issues related to preclinical models; medical statistics; technology transfer, industrialisation and intellectual property; regulatory affairs. The support has been professional, timely, creative, flexible and accurate. Always ready to accommodate any request for the benefit of the project. All of this while maintaining a friendly and positive attitude. Thanks to the mentoring support, my application was funded! The mentoring professionals are well trained, honest, patient and meticulous. I believe they are an ideal choice for mentoring service provider."



Ilaria Meloni (Associate **Professor at the University of Siena Department of Medical Biotechnology, Italy):**

"The EATRIS mentoring service really helped me focus on essential points to outline in the project, and

how to improve analyses in order to make them stronger. I also appreciated the advice not to try to hide weaknesses but present them together with possible solutions. I will continue to use this expert mentoring service, and would recommend it to others."



Alessandro Prigione (Professor, **Group leader Stem cell** metabolism at the Henrich-**Heine University, Germany):**

"[EATRIS] set up a series of video calls to find ways to improve our proposal and to make the

translational impact more evident. They identified a series of experts who discussed our proposal and suggested how to improve - what were the weaknesses and the potential strengths that we should highlight. Thanks to these various inputs our proposal really was improved and more streamlined and with clear translational impact. I can strongly recommend EATRIS."

What do the mentors sav about this service?



Ramon Martí (Vall d'Hebron Research Institute, Spain):

"I think the mentoring program is good because of one reason specifically

- usually, I participate in these kinds of actions as an observer so there is no chance to interact with the investigators and there is no possibility to improve the application. In this case you read the proposal in order to find potential improvements and there is the possibility to communicate with the principal investigator. I think this way really improves the final version of the application."



Nathan Coussens (Director of Molecular **Pharmacology Laboratories at** Frederick National Laboratory, USA):

"EATRIS reached out to me about serving as a mentor for research proposals focused on therapeutic development for rare diseases. By this model, the mentor actually interacts with the applicants directly during the advanced stages of the proposal to provide strategic guidance before its submission and review. These are extensive multi-institutional and long-term discovery projects so early improvements to their design can ultimately have an enormous impact on the timeline and outcome. In my opinion, this mentoring program is an innovative, highly impactful and efficient way to increase the success rate of the Project Discovery teams to mitigate risks of the investors and to accelerate therapeutics for rare disease patients. In each of my experiences, the live discussions with the groups were critical, allowing us to openly discuss challenges and collaboratively identify solutions much more rapidly than a typical review process could possibly enable. I greatly appreciated the opportunity to assist these outstanding researchers and share my knowledge which might enhance the impact of their work to benefit rare disease patients."

EATRIS ANNUAL MEETING IN LISBON



The EATRIS annual meeting took place on 11 and 12 February 2020 and was hosted by the EATRIS-Portugal National Node at INFARMED in Lisbon. During two days, more than 180 EATRIS members exchanged best practices and further defined together the role that EATRIS plays in the development of Personalised Medicine. Through three plenary sessions and one collaborative session, EATRIS members discussed how to fully exploit the capacities of the Infrastructure to serve the needs of the patient community and how to develop technologies that will support the implementation of patient-targeted interventions.

The novelty of our 2020 Annual event was to include one collaboratory session: EATRIS Framework Café. Framework Café is a choral methodology that generates a multi perspective community discussion by which everyone will discuss different topics at different levels. It facilitates action-oriented, creative, and inspirational conversations that were divided over 3 rounds of 20 minutes.

The workshop focused on 3 topics that were identified as highly relevant by the EATRIS community before the meeting:

- 1. Multiomic technologies for Personalised Medicine
- 2. Predictive experimental models for Personalised Medicine
- 3. Unmet medical needs and novel therapeutic modalities

The session helped identify bottlenecks in each area and further refined the critical role that EATRIS could play to address key research challenges in the field of personalised medicine.

During the networking session 39 abstracts were presented in the form of a poster. A prize was awarded to Dr Jane Murray from Luxembourg Institute of Health for her poster titled "Transversal Translational Medicine Concept in Luxembourg: Parkinson's Disease as a Medical Use Case."







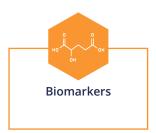




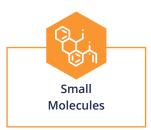


PRODUCT PLATFORM HIGHLIGHTS 2020











EATRIS product platforms have intensified their activities in 2020, not only due to the incorporation of new members that are reinforcing the capacities of our community, but also because novel projects have emerged through cross pollinating ideas and discussions which occurred during the EATRIS annual event in Lisbon and thanks to the strong engagement of the platform chairs.

In 2020 work started on developing new scientific agendas for the platforms energised with new goals and perspectives. Platform chairs are actively involved in a process of analysis and dialogue that will result in an updated platform model.

In addition, in 2020, the process of upgrading the IT platform and database was initiated, and it was completed in early 2021 with the final aim to create one integrated survey allowing institutions to navigate through each questionnaire seamlessly and to download reports which are interoperable and usable by the institutions themselves, facilitating the expansion of our service portfolio and research service activities.



ATMP

Chairs:

Maria Cristina Galli (ISS, Italy), Miguel Chillón Rodríguez (VHIR, Spain)

Platform Coordinator:

David Morrow (Senior Scientific Programme Manager, EATRIS C&S)

2020 saw the Advanced Therapy Medicinal Products (ATMP) platform grow in strength to over 46 institutions with the welcoming of the Testa Center and Laboratory Medicine at the Karolinska institute from Sweden, IBS Granada from Spain and the IRCCS Instituto Giannina Gaslini and IRST Institute from Italy.

The EATRIS flagship educational initiative - ADVANCE - was a highlight of the year as experts from across our Platform joined our group of experienced teachers to create the online educational program which was launched in November. Registrations for the course in the first few weeks would top 350 with great enthusiasm moving forward for participation to future workshops and webinars planned for 2021. The ADVANCE Webinar series also launched on 8 April with the opening lecture from the EATRIS ADVANCE Team, who set the scene for future events. Supporting our researchers in their project development was, as always, a priority.

2020 saw the Platform involved in the submission of two COST Actions. The first, which was co-developed by EATRIS, started from a survey to find EATRIS researchers who worked in the field of cord blood iPSC. This project

coordinated by IDIBELL, titled the "Generation of Human IPSCs from Haplo-selected Cord blood samples", involved nine EATRIS ATMP Institutions. The second, coordinated by the University of Eastern Finland titled "Next Generation restorative for stroke recovery" also involved seven EATRIS ATMP Institutions. The EATRIS Platform continued its involvement with the HESI CT-TRACS global network, focusing on the tracking, circulation, and safety of cell therapies with EATRIS presenting a joint HESI/ NIHLBI webinar on cell tracking in September.

Work began on the development of four industry collaborative projects which will be disseminated to our Platform in early 2021. Promoting the expertise and technologies of the Platform was again paramount with EATRIS presenting at the Phacilitate Advanced Therapies Week in Miami in January, followed by two presentations at the Advanced Therapies and Regenerative Medicine Congress showcasing EATRIS capacities in regenerative medicine and cell tracking, and at the Tissue Cure Finland conference in September.

Our partnership with the European Medicines Agency (EMA) on ATMPs continued with their ownership of the Regulatory section for ADVANCE and a working group on identifying training needs in ATMPs. In preparation for Horizon Europe calls, work began with several EATRIS ATMP sites on developing a project on next generation advanced therapies that will be central to the strategic agenda of the ATMP platform for the next two years.

Small Molecules

Chairs:

Mario Salmona and Alfredo Budillon (IRCCS Pascale, Napels, Italy)

Platform Coordinator:

Martin de Kort (Senior Scientific Program Manager at EATRIS)

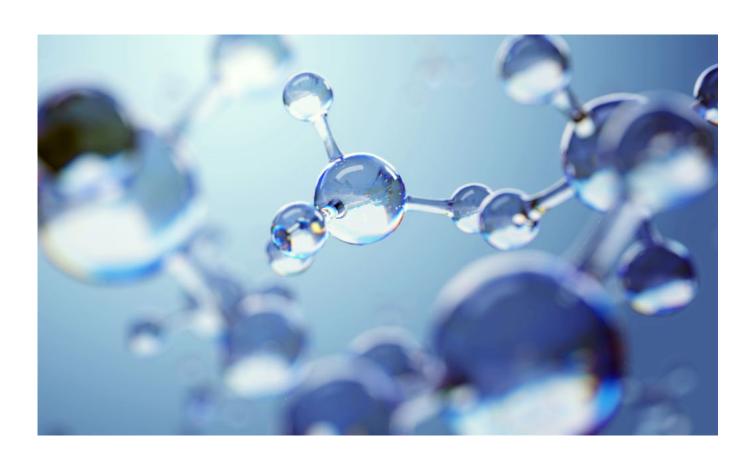
In 2020 the scientific agenda of the platform was further developed with the EATRIS community. Of note, the last face to face gathering at the annual meeting held in Lisbon, before the COVID-19 restrictions came into effect, brought a lively session on predictive experimental models for personalised medicine, chaired by Alfredo Budillon (IRCCS Pascale, Naples) and Inmaculada Ibáñez de Cáceres (IdiPAZ, Madrid, Spain). This session discussed challenges and possible solutions in four areas:

- 1. The use of human induced pluripotent stem cells;
- 2. Screening in 3D tissue cultures (organoids, tumours on a chip);
- 3. In vivo immune monitoring of fresh peripheral blood mononuclear cells
- 4. CRISPR edited models.

Within the same scope, EATRIS took part in the scientific committee of the conference "Towards replacement of animals of scientific purpose" to shape the program, hosted

by the European Commission and ultimately to be held virtually in early 2021, with keynote contributions from the Mario Negri Institute for Pharmacological Research (Milan, Italy).

This year the agenda saw drug repurposing, chemosensitivity screening and artificial intelligence as additional emerging themes to be further matured in the context of ongoing initiatives, such as the recently launched MICHA webserver (developed under the EOSC-life project) for the annotation and reporting of chemosensitivity assays by FAIRifying drug sensitivity screening data. Several requests in the COVID-19 task force (e.g. support of mode of action studies to the Exscalate4Cov consortium) and mentoring support for rare disease repurposing (European Joint Programme on Rare Diseases) was provided by institutions in the platform. This year also marked the launch of the iNext discovery project, which held its virtual kick off meeting on 28 May. EATRIS will continue to serve the community with joint services complementing structural biology capacity in collaboration with other biomedical research infrastructures. New institutions that were welcomed by the platform in 2020 are the IRCCS Istituto Giannina Gaslini (IGG) and Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori IRST from Italy.





Vaccine, Inflammation and Immune Monitoring

Chairs:

Jan Langermans (BPRC, The Netherlands) and Lucia Gabriele (ISS, Italy)

Platform Coordinator:

David Morrow (Senior Scientific Programme Manager at EATRIS)

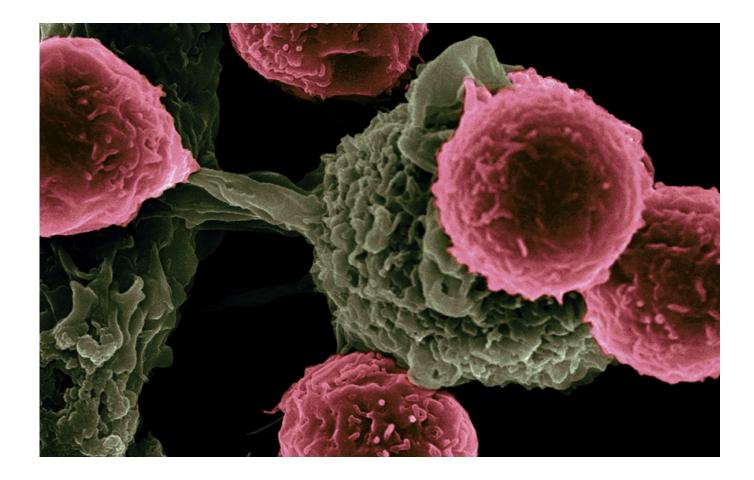
The Vaccine, Inflammation and Immune Monitoring (VIIM) platform welcomed the National Centre of Infectious and Parasitic Diseases from Bulgaria, the Testa Center from Sweden, and the IIS Aragon from Spain in 2020 with the platform now consisting of over 23 leading institutions in vaccine development. Following the previous year's work by the Chairs to reshape the platform in order to give better focus to our research service offering, the new VIIM platform aimed to develop and provide innovative technologies for the investigation characterisation and monitoring of the immune and inflammatory network and responses.

The new EATRIS VIIM platform was launched at the Board of National Directors meeting in April with a view that its new direction would better meet the needs of biotechnology companies, pharmaceutical industry, the academic research community, and manufacturing industry. To support the platform's new scientific focus, an EATRIS authored article titled "Developing harmonized immune platforms: a must-have

for realizing personalized therapies in solid tumors" was published in Cell and Gene Therapy Insights* in October 2020. Through our ongoing participation in the TRANSVAC-2 Project, EATRIS regulatory experts provided support for an innovative EC funded project on a novel vaccine candidate for SARS-CoV-2.

Furthermore, discussions with the EC, EATRIS and TRANSVAC coordinators, EVI, helped secure additional funding for COVID-19 vaccine related projects through TRANSVAC-2, some of which went towards EATRIS institutions. The TRANSVAC-Design study project funded by H2020 also started in June involving EATRIS and multiple EATRIS sites as partners. The strength of the EATRIS VIIM platform was critical in 2020 to establish the EATRIS COVID-19 Research Forum which served as a resource of expertise and available technologies that could be readily accessed for COVID-19 vaccine development projects.

^{*}Morrow, D., Langermans, J., Ussi, A., Andreu, A.L., & Gabriele, L. (2020). Developing harmonized immune platforms: a must-have for realizing personalized therapies in solid tumors. Cell & Gene Therapy Insights. 6(9), 1231-1235. DOI: 10.18609/cgti.2020.139



Biomarkers

Chairs:

Alain van Gool (Radboudumc, The Netherlands), Andreas Scherer (FIMM, Finland), Laura García Bermejo (IRYCIS, Spain) **Platform Coordinator:**

Emanuela Oldoni (Scientific Programme Manager at EATRIS)

In 2020 EATRIS strengthened its position as a key Research Infrastructure enabling personalised medicine development. This was achieved with EATRIS participation in relevant projects, such as PERMIT, EATRIS-Plus and B1MG launched in early 2020.

In the summer, as part of the response to COVID-19 pandemic, Emanuela Oldoni, the Biomarkers chairs, BBMRI and ECRIN co-authored a paper in the Clinical Infectious Diseases journal about the common strategic objectives to improve the research process and tackle challenges related to diagnostic tests and biomarker development for COVID-19.

A second area of focus for the platform in 2020 was towards biomarkers commercialisation efforts. If the biomarker discovery is a substantial investment from research institutions, the route to industrial development and to

commercialisation is not part of the skills and expertise easily available in academia, even when having a Technology Transfer Office. For tackling this challenge the BiC-BRIDGE project, in which EATRIS is full partner since autumn, developed a Biomarker Commercialisation Guide. This publicly available tool offers hints on, for example, commercialisation aspects, intellectual property rights, business models and legal viewpoints for different phases of biomarker discovery and development.

The EATRIS Biomarker platform welcomed ten new institutions in 2020, namely the Netherlands Organisation for Applied Scientific Research (TNO), Maribor University (Slovenia), Institut Hospital del Mar d'Investigacions Mèdiques (IMIM), Insituto de Investigación Biosanitaria (IBS-Granada), Institute for Health Research Aragón (IIS-Aragón), Institut de Recerca Biomèdica de Lleida (IRB-Lleida), Instituto de investigación sanitaria Valdecilla (IDIVAL) in Spain, the Swedish National Infrastructure for Biological Mass Spectrometry (Sweden) and IRCCS Istituto Giannina Gaslini and Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori in Italy. This brings the number of biomarker institutions to seventy-two.

Imaging & Tracing

Chair:

Albert Windhorst (AmsterdamUMC/VUmc, Amsterdam, The Netherlands)

Platform Coordinator:

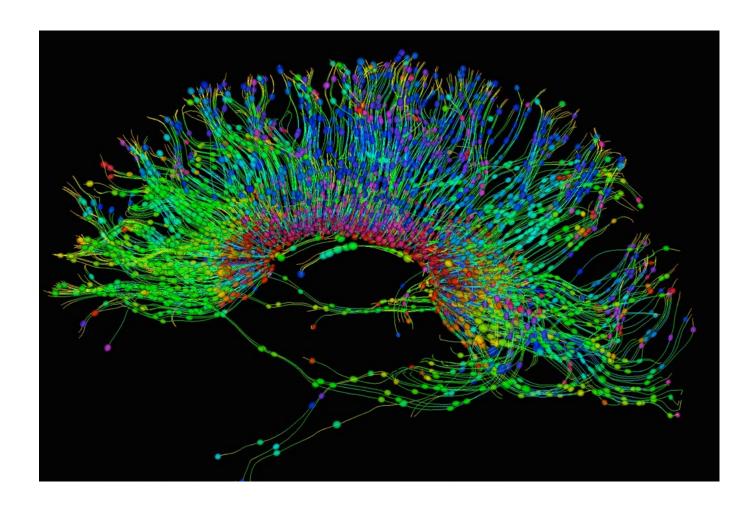
Martin de Kort (Senior Scientific Program Manager at EATRIS)

2020 marked the start of new engagement with the translational imaging community and the continuation of key initiatives. Notably, the H2020-funded ARCAID and RECOGNISED projects kicked off in January, involving clinical imaging of rheumatoid arthritis and imaging of neurodegenerative pathways in the brain and retina of type-2 diabetic patients, respectively. During the annual conference of the European Society of Molecular Imaging (ESMI) in August, EATRIS participated in a session of the 15th European Molecular Imaging Meeting (EMIM 2020) that was dedicated to creating awareness of the European Infrastructures.

A similar engagement followed with the HYBRID international training network on 10 September, dedicated to the development of novel methods for anatomical, functional and hybrid imaging in personalised medicine. Ties with the physics community were further extended through

CERN (CH) where EATRIS institutions from Spain (The Medical Research Institute of the Hospital La Fe) and Italy (IRCCS San Raffaele Hospital, HSR, Milan) brought clinical oncology expertise into the CAFEIN project, reflecting radiomics/AI. In November, EATRIS and GlaxoSmithKline (GSK) announced the extension of the translational molecular imaging Hub for a further three years, continuing to work on a maturing project portfolio with the partner institutions in Sweden (Uppsala) and the Netherlands (Amsterdam, Groningen and Nijmegen). This unique collaboration now has 12 active collaborative projects with more than 20 legal agreements executed under the Hub framework, ranging from preclinical to clinical projects, as well as co-funded PhD positions.

The Imaging platform welcomed new institutions from the Netherlands (Netherlands Organisation for Applied Scientific Research, TNO), Spain (Institute for Health Research Aragón, IIS-Aragón); Institut de Recerca Biomèdica de Lleida, IRB-Lleida), Instituto de Investigación Sanitaria Valdecilla (IDIVAL) and Italy (IRCCS Istituto Giannina Gaslini), complementing the current members to develop an active, post-pandemic, scientific agenda.



COLLABORATION SPOTLIGHT

GlaxoSmithKline Imaging Hub Collaboration Extension



Molecular Imaging Innovation Hub supporting drug development



New translational imaging tools for immune inflammation



Unique industryacademia (public-private) collaboration



Flexibility: supporting many different collaboration types



Single point of contact to facilitate project initiation



3 years into collaboration 3 years extended



12 active projects (3 preclinical, 2 clinical, 1 co-funded PhD, 2 scouting, 4 public co-funded applications)



15 molecular (tracer) targets under exploration



8 organisations/ legal entities involved



Over 20 legal agreements established

The Translational Molecular Imaging Hub is a novel international public-private partnership between EATRIS, GlaxoSmithKline (GSK) and the following five EATRIS member institutions: 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.



The Hub delivers a clinical and scientific expert network for the development and application of innovative imaging methods for inflammatory diseases. Applying imaging in information-rich, small cohort studies can provide a high, immediate impact to enhance the productivity of research and development: developing our understanding of disease in the patient; enriching clinical trial cohorts; measuring therapeutic response.

Now at the end of the initial collaboration period, EATRIS-ERIC, EATRIS member institutions and GSK have expressed their commitment to continue their partnership for a minimum of three more years. Already, the Imaging Hub has built a mature project portfolio consisting of three preclinical projects and two clinical projects, which hold great translational potential. Partners are also involved in a joint PhD programme supported by the Marie Skłodowska-Curie programme of Horizon 2020.

A GROWING PROJECT PORTFOLIO SUPPORTED BY A FLEXIBLE LEGAL FRAMEWORK

The flexibility of the Innovation Hub legal framework allows it to support several project types with pre-set terms (e.g. Intellectual Property, publication), with EATRIS-ERIC acting as the Hub Secretariat and portfolio manager, playing a key role in administering the Hub's operations. Over 20 legal agreements have been prepared to date (including multilateral Confidentiality Disclosure Agreements, Material Transfer Agreements, third party licensing, project agreements, external consortium agreements) and proposals can be individually tailored to support the collaboration. The Hub framework has demonstrated that it is possible to realise complex agreements involving multiple academic and industry parties, that would

otherwise be challenging to achieve in the absence of such a supporting legal structure.

UNLOCKING THE INNOVATION POTENTIAL OF RESEARCH **INFRASTRUCTURES**

Multi-stakeholder collaboration, such as academia-industry partnerships, is one of the cornerstones of successful translational research, and therefore a priority for EATRIS' mission. Working together with a company increases the chances of translating research findings into patient benefit, and several of the Hub's projects have received follow-on funding based on promising results.

The five EATRIS institutions involved in the Hub benefit from gaining access to expertise and resources of a global top 10 pharma company, providing a unique setting for patient-centric, academically driven research complementing industry's own strengths. A public-private collaboration brings new networking opportunities and provides access to translational resources that are frequently (still) very rarely accessible to academic researchers.

From the operational perspective, a clear legal and governance structure added much value to the successful start by all partners. A single point of contact offered by EATRIS ERIC provides capacity for overall coordination, legal and operational support, as well as an independent negotiator when needed. Anton Ussi, EATRIS Operations & Finance Director said: "The Innovation Hub is a fantastic example of how a European research infrastructure can fulfil its role as enabler of research and accelerator of innovation. We are now looking at setting up more Innovation Hubs in Europe and globally, so we can continue translating research findings into benefit for patients.



EATRIS RESPONSE TO THE COVID-19 PANDEMIC

From the very start of the pandemic the EATRIS community, composed of university medical centres and research facilities, placed themselves and their expertise at the forefront of the COVID-19 fight. The immediate question for the EATRIS C&S Team was simple: how can we support them?

Our first task was closely monitoring the efforts undertaken by EATRIS members and to create a non-exhaustive list of activities that they were involved in, and additional targeted services they could provide for COVID-19 research projects. Following an initial request in March, EATRIS sites began populating this list of COVID-19 resources and activities on a daily basis, which the C&S team made available on the EATRIS website to internal and external researchers. As the list grew, these institutions were placed in a COVID-19 Research Group where any service requests, consortium building requests or enquiries for specific expertise related to COVID-19, could be directed, or matched specifically within this group. We waived the EATRIS fee for research services and simply connected both parties together within 48 hours. This rapid response COVID-19 research group was further developed into the EATRIS COVID-19 Research Forum in May, which consisted of a shared online platform where all resources and activities were displayed, in addition to relevant news and resources of interest to COVID-19 researchers. This included funding calls, publications and open research service requests which members could apply to if they had the right expertise and capacity to do so. By the end of 2020, the COVID-19 Research Forum consisted of over 90 members across 43 EATRIS institutions.

As direct result of the EATRIS COVID-19 Research Forum Group, by the end of 2020, 25 projects were directed specifically to this group and potential partners were identified, linking clients to our institutions. These projects included regulatory expertise to help establish a GMP facility in Latvia or developing the IMPD for a novel virus like particle vaccine candidate for SARS-CoV-2. Expertise on developing and providing access to SARS-CoV-2 virus was also requested. A technology validation project which led to the set-up of a revolutionary molecular assay platform that delivers a throughput of 100,000 RT-LAMP results for COVID-19 per day per machine was facilitated in one of our Spanish institutions. Access to samples, clinical trial sites, in addition to an array of services for the vaccine developer or mode of

action studies for repurposed drugs, have all been examples of project types matched successfully within the EATRIS COVID-19 Research forum.

The COVID-19 Research Forum Group has also proved very beneficial to consortium building for COVID-19 related projects. During 2020, applications for calls such as EUREKA, JPND and the upcoming Horizon Europe programme have sought partners from within this group by coordinators from within and outside of the EATRIS network.

The establishment of the EATRIS COVID-19 Research Forum Group in 2020 represented a strong example of how our network of institutions can pool their resources together to create an efficient array of must have services for novel vaccine and therapy development. Moreover, these services and experts could be accessed and matched within days of the request through a streamlined facilitation process. We move forward into the coming years with strong commitment to further improving this initiative with the single aim of supporting our COVID-19 researchers to the best of our abilities.



The EATRIS COVID-19 Response has been coordinated by David Morrow, Senior Scientific Programme Manager at EATRIS

ART IN A PANDEMIC



NATURARTE BY ANGELA ARAUJO

Angela Araujo recently received her PhD and is working on breast-cancer research at the Biodonostia Health Research Institute in Spain. "Art has helped me to take my mind to beautiful places during my blue/stressful moments and realise how science and art are not that different: both depend on creativity and can be gorgeous. Naturarte is a sunset made of 'pieces of science'. The entire collage is made from small cuts from Nature covers. It represents the hope for new and better days during the pandemic, when science can save us all from COVID-19, and that we appreciate it like a beautiful piece of art."



MITOCHONDRIAL INHERITANCE BY LYNNE MENNIE

"I am a clinical genomics project manager currently based in Scotland. During the pandemic I have been creating artwork exploring mitochondrial inheritance."



SKETCHES BY FILIPE ZIMMER DEZORDI

Filipe Dezordi is a PhD student at the Fundação Oswaldo Cruz-Instituto Aggeu Magalhães, Recife, Brazil, who works with bioinformatics applied to mosquito and viral genomics.

"In Brazil we were in social isolation for a sustained period of time. My art has worked as an escape from reality, a moment for me and myself."



COVID IKEBANA BY ANITA KAVLIE

Anita Kavlie is the EATRIS National coordinator for Norway and our Innovation Manager.

"In this Japanese Ikebana, the Corona virus (Red protea) is getting embedded and soon disappearing by vaccination (flower made of Japanese paper cut into petals and stapled together)."

FEATURED PUBLICATIONS FROM OUR NODES



Publication from our Swedish node

INTEGRATION OF MOLECULAR PROFILES IN A LONGITUDINAL WELLNESS PROFILING COHORT

Longitudinal monitoring of wellness using multiomics: Compelling multi-omic wellness study shows low intra- and high inter-individual differences and uniqueness of each person's profile.

KEY MESSAGES:

This study from researchers at KTH Royal Institute of Technology in Sweden analyses blood omic profiles, namely genomics, transcriptomics, proteomics, metabolomics and fecal microbiota, of a longitudinal wellness cohort with 100 healthy individuals. The results show that each individual has a unique and stable plasma protein profile throughout the study period and that many individuals also show distinct profiles with regards to the other omics datasets, supporting the concept that comprehensive omics profiling in a longitudinal manner is a path forward for personalised medicine.

SUMMARY:

Approaching a new era of personalised medicine, there has recently been a growing trend of omics projects with the premise of utilising high-throughput analyses to achieve personalised healthcare. In this direction, personal omics profiles, composed of the genomics, transcriptomics, proteomics, metabolomics, and fecal microbiota, could be defined and used to monitor drug interventions. In this study researchers performed a comprehensive and deep phenotyping, analysing the global molecular omics profiles of a healthy cohort composed of hundred individuals and investigating the longitudinal stability and interconnections of such profiles. The analyses are based on molecular profiles in blood complemented with gut microbiota profiles to allow multi-omics data

integration and comparison with clinical data. The results show that each person has a unique protein and antibody signature, often stable over time in the absence of acute diseases. In addition, the proteomic analysis confirmed the highly individual specificity of longitudinal circulating protein profiles. Remarkable are the data that underline the importance of taking into account the metabolism differences between the sexes for implementing personalised approaches.

Overall, these findings support an individual-based definition of health and show the importance of developing personalised approaches and monitoring individual trajectory perspective for disease prevention and treatment selection.

This study lays a reference point for the EATRIS-Plus project with regards to the multi-omic toolbox development. Indeed, the toolbox will be tested with a real-setting demonstrator, an already established cohort of 1,000 healthy individuals and the dataset from Tebani et al. analysis could be used for validation purposes.

CITATION:

Tebani et al. (2020). Nature Communications 11, 4487. DOI: 10.1038/s41467-020-18148-7

HUMAN-IPSC-DERIVED CARDIAC STROMAL CELLS ENHANCE MATURATION IN 3D CARDIAC MICROTISSUES AND REVEAL NON-CARDIOMYOCYTE CONTRIBUTIONS TO HEART DISEASE

Demonstration of multicellular 3D cardiac microtissues utility in modelling heart diseases using hiPSC technology. Tri-cellular combinations of human iPSC-derived cardiomyocytes, cardiac fibroblasts and cardiac endothelial cells enhance maturation in easily constructed, scaffold-free, 3D microtissues.

KEY MESSAGES:

In this translational study, a joint effort between Dutch, Italian and Spanish researchers led by Leiden University, a three-dimensional microtissue model for cardiac diseases has been developed using hiPSC technology. This is a simple and versatile platform that will facilitate industry and academic engagement in high-throughput molecular screening.

SUMMARY:

Cell culture methods have been used by researchers for more than 100 years. In particular, twodimensional monolayer cultures were the gold standard in determining the in vitro efficacy and safety of drug candidates. In the last few years, however, there has been a push to develop increasingly complex in vitro models that can more accurately recapitulate the physiologic in vivo features and potentially allow personalised approaches, such as three-dimensional (3D) cell culture. Indeed, these new technologies try to mimic the cells microenvironment and maintain tissue homeostasis. In this study Giacomelli et al. described a 3D microtissue (MT) system composed of the three major cell types of the heart cardiomyocytes, cardiac fibroblasts and cardiac endothelial cells derived entirely from hiPSCs. The results showed that this

model is low-cost, robust and highly reproducible, all features that will allow its further implementation. In addition, researchers used hiPSC derived from a

patient affected by an arrhythmogenic cardiomyopathy, a rare genetic disorder, for developing a disease model MT and they compared it with the control. Such comparison demonstrates the utility of the system in modelling heart diseases, even not autonomous to cardiomyocytes. Moreover, departing from patient-specific lines this 3D system grants personalised approaches and brings the promise of personalised medicine, i.e. that each patient's treatment can be optimally tailored to their disease, to a step further. Taken together, these findings show that hiPSC-derived MT represents a precious platform that not only can be used for studying cardiac diseases, but also is valuable for drug target identification and drug response prediction.

CITATION:

Giacomelli et al. (2020). Cell Stem Cell 26, 862–879. DOI: 10.1016/j.stem.2020.05.004

ULTRASENSITIVE AND ROBUST POINT-OF-CARE IMMUNOASSAY FOR THE DETECTION OF PLASMODIUM FALCIPARUM MALARIA

A more accurate rapid diagnostic test to detect malaria: a collaborative study between DBT-Translational Health Science and Technology Institute (DBT-THSTI) and University of Turku

KEY MESSAGES:

In this collaborative study, Finnish and Indian researchers have developed a highly sensitive and robust point-of-care test that can detect P. falciparum infection, that is responsible for malaria. The test was validated by running samples containing different strains of the parasite from different geographical areas. The results indicate that the test can be used to detect infection in populations from different regions and those affected by different strains of the parasite.

SUMMARY:

Malaria is a life-threatening disease and although it is preventable and curable, the estimated number of malaria deaths stood at 409,000 in 2019. There are ongoing efforts to eliminate malaria from large parts of the world, and accurate and rapid diagnosis of low-density infections is a critical component of elimination programs. In fact, current point-of-care tests are not sufficiently sensitive to detect P. falciparum in asymptomatic individuals. In order to improve the malaria parasite detection, the teams of the two institutions have developed and validated a highly-sensitive and robust method using luminescent upconverting nano-phosphor (UCNP) reporter particles. UCNP allows the development of an ultrasensitive rapid diagnostic test, able to detect even at low levels of 0.2-2 parasites/µL, depending on the strain. This is a 50- to 250-fold improvement over conventional rapid diagnostic tests in use currently.

The test is stable even at 40 °C for at least 5 months thus making it quite suitable for the tropical regions, most affected by this parasite. Further, it requires only 5 μ L of whole blood and the reading can be done in a location different from the sampling one. These features suggest that UCNP-immunoassay could be suitable for detection of low parasitemia asymptomatic patients in elimination or eradication settings.

This study stands as an example of cross-sectional activities between EATRIS platforms, for example the Vaccine and Biomarkers platforms, and how they have complementary capacities covering different aspects of the translational pipeline.

CITATION:

Salminen et al. (2020). Analytical Chemistry 92 (24), 15766-15772.

DOI: 10.1021/acs.analchem.0c02748

Publication from our Luxembourg node

A PATIENT-BASED MODEL OF RNA MIS-SPLICING UNCOVERS TREATMENT TARGETS IN PARKINSON'S DISEASE

KEY MESSAGES:

In this highly multidisciplinary, multi-site collaboration, a specific pathogenic mutation caused by a splicing defect was studied in Parkinson's disease (PD) patients using brain organoids. Functional studies were key to validate (drug treatment) predictions and underscore the role of splicing mutations in pathogenesis. It is a prime example of how a powerful in vitro predictive model can spur the development of new treatment options for patients with unmet medical need, using a mechanism-based strategy across groups that share certain molecular signatures.

SUMMARY:

PD is increasingly recognised as a heterogeneous neurodegenerative disorder. Using a patient-based in vitro model of PARK7-linked PD, a U1-dependent splicing defect was identified that causes a drastic reduction in DJ-1 protein and, consequently, mitochondrial dysfunction. Targeting defective exon skipping with genetically engineered U1-snRNA recovered DJ-1 protein expression in neuronal precursor cells and differentiated neurons. After prioritisation of candidate drugs, a combinatorial treatment with the small molecule compounds rectifier of aberrant splicing (RECTAS) and phenylbutyric acid was identified and validated. DJ-1 protein and mitochondrial dysfunction was restored in patient-derived fibroblasts as well as dopaminergic neuronal cell loss in mutant midbrain organoids.

Analysing a large number of exomes revealed that U1 splice-site mutations were enriched in sporadic PD patients. Therefore, the study suggests an alternative strategy to restore cellular abnormalities in in vitro models of PD and provides a proof of concept for neuroprotection based on precision medicine strategies in PD.

CITATION:

Boussaad et al. (2020). Science Translational Medicine. DOI: 10.1126/scitranslmed.aau3960

Publication from our Portuguese node

PATIENT-DERIVED OVARIAN CANCER EXPLANTS: PRESERVED VIABILITY AND HISTOPATHOLOGICAL FEATURES IN LONG-TERM AGITATION-BASED CULTURES

KEY MESSAGES:

This work from Lisbon describes the first long-term patient-derived ex vivo model for Ovarian carcinoma (OvC) in which the tumour microenvironment (TME) features are conserved. It can be used to explore and evaluate the efficiency of new compounds or drug combinations.

SUMMARY:

Efficacy of chemotherapy treatment is limited for OvC patients due to the development of drug resistance, in which interactions of tumour cells with the TME play a key role. This study describes the development of a long-term OvC patient-derived explant (OvC-PDE) culture strategy in which architecture and cell type heterogeneity of the original tumour is retained. Samples from 25 patients with distinct OvC types and one with a benign tumour, were cultured for 30 days in agitation-based culture systems with 100% success rate. OvC-PDE cultures retained the original tumour architecture and main cellular components: epithelial cells, fibroblasts and immune cells. Epithelial cells kept their original levels of proliferation and apoptosis. Moreover, the major extracellular components, such as collagen-I and -IV, were retained in explants. OvC-PDE cultures were exposed to standard-of-care chemotherapeutics agents for 2 weeks, testing the ability of the platform for drug assays employing cyclic drug exposure regimens. Such OvC-PDE dynamic culture in which tumour architecture and cell type

heterogeneity are preserved for the different OvC types, replicating features of the original tumour, paves the way to study long-term drug exposure for drug efficacy and resistance studies with a higher prediction accuracy.

CITATION:

Abreu et al. (2020). Scientific Reports 10, 19462. DOI: 10.1038/s41598-020-76291-z

A COMBINED ANXA2-NDRG1-STAT1 GENE SIGNATURE PREDICTS RESPONSE TO CHEMORADIOTHERAPY IN CERVICAL CANCER

KEY MESSAGES:

In this interdisciplinary study, a three-gene expression signature was identified that is able to predict neoadjuvant chemoradiotherapy (CRT) treatment outcome, in patients with locally advanced cervical cancer (LACC). Results obtained have been patented and awarded with the Best Practice in Personalised Medicine Recognition at ICPerMed Conference 2020, indicative of the potential to impact clinical practice in cervical cancer management.

SUMMARY:

A better understanding of LACC is mandatory for further improving the rates of disease control, since a significant proportion of patients still fail to respond or undergo relapse after concurrent CRT, and survival for these patients has generally remained poor. To identify specific markers of CRT response, pretreatment biopsies from LACC patients were compared with pathological complete response (sensitive) with those from patients showing macroscopic residual tumour (resistant) after neoadjuvant CRT, using a proteomic approach integrated with gene expression profiling. The study of the underpinning mechanisms of chemoradiation response was carried out through in vitro models of cervical cancer.

Annexin A2 (ANXA2), N-myc downstream regulated gene 1 (NDRG1) and signal transducer and activator

of transcription 1 (STAT1) were identified as biomarkers of LACC patients' responsiveness to CRT. The dataset collected through qPCR on these genes was used as training dataset to implement a Random Forest algorithm able to predict the response of new patients to this treatment. Mechanistic investigations demonstrated the key role of the identified genes in the balance between death and survival of tumour cells.

These results define a predictive gene signature that can help in cervical cancer patient stratification, thus providing a useful tool towards more personalised treatment modalities.

In the near future the development of a RNA-based array is planned, that in turn will be validated in multicenter clinical trials. Ultimately, patient phenotyping for prediction of treatment outcome would enable allocation to personalised treatment procedures, with significant benefits to both patients and healthcare system.

CITATION:

Buttarelli et al. (2020). Journal of Experimental & Clinical Cancer Research 38, 279 (2019). DOI: 10.1186/s13046-019-1268-y

Publication from our Norwegian node COMBINATORIAL CAR DESIGN IMPROVES TARGET RESTRICTION

KEY MESSAGES:

This study from researchers at the Oslo University Hospital, describes an alternative CD19 CAR which becomes selective through IGK 285 combination to avoid B-cell aplasia. This next generation CD19 CAR can improve selectivity, which should result in an increased safety of this therapeutic approach. Innovative approaches to CAR-T design contributes to the optimisation of this effective therapy for B cell leukemia and lymphoma where current treatments fail and their development represents a strategic scientific priority for the EATRIS ATMP Platform in 2021.

SUMMARY:

Over the past few years CAR T cells targeting the B lymphocyte antigen CD19 have led to remarkable clinical results in B cell leukemia and lymphoma. However, this therapeutic approach can eliminate all B lineage cells, leading to increased susceptibility to severe infections. As malignant B cells will express either immunoglobulin (lg) light chain κ or λ , researchers at the University hospital in Oslo have designed a next-generation CAR targeting lg κ , IGK CAR. This construct demonstrated high target specificity but displayed reduced efficacy in the presence of serum lgG. Since CD19 CAR is insensitive to serum lgG, they designed various combinatorial CAR constructs in order to maintain the CD19 CAR T cell efficacy, but with IGK CAR target selectivity.

The Kz-19BB design, combining CD19 CAR containing a 4-1BB costimulatory domain with an IGK CAR containing a CD3zeta stimulatory domain, maintained the target specificity of IgK CAR and was resistant to the presence of soluble IgG. Their results demonstrated that a combinatorial CAR approach can improve target selectivity and efficacy.

CITATION:

Köksal et al. (2020). Journal of Biological Chemistry. DOI: 10.1074/jbc.RA120.016234

Publication from our Spanish node

DEVELOPMENT OF SEVERITY AND MORTALITY PREDICTION MODELS FOR COVID-19 PATIENTS AT EMERGENCY DEPARTMENT INCLUDING THE CHEST X-RAY

KEY MESSAGES:

Researchers at La Fe Health Research Institute have developed and internally validated severity and mortality prediction models that could be useful as triage tools for COVID-19 patients.

SUMMARY:

The COVID-19 pandemic is posing a large challenge for health systems, forcing a balance to be found between resource management and safe decisionmaking with a lower than needed scientific evidence. Uncertainties make necessary the development of specific disease models in order to identify patients by prognosis and severity, requiring hospital or even intensive care. Thoracic imaging has served as a diagnostic tool in emergency department (ED) as it may reveal suggestive COVID-19 patterns of lung involvement. However, studies on the utility of the chest X-ray (CXR) for predicting health outcomes are limited and the prognostic studies have mainly been based on chest CT. Considering the higher use of CXR, its larger availability and safer use to control the spread of the virus when compared with CT, this study aimed to develop two multivariable prediction models for severity and mortality estimations in COVID-19 taking into consideration the radiological, demographic, clinical and laboratory variables registered on the emergency evaluation. These researchers who are part of the EATRIS COVID-19 Research Forum, have developed and

internally validated severity and mortality prediction models as potential triage tools for COVID-19 patients at the ED.

CITATION:

Batllés et al. (2020). Research Square. DOI: 10.21203/rs.3.rs-88282/v1



EATRIS QUALITY INITIATIVE

The EATRIS Quality Initiative (EQI) is an umbrella term for EATRIS activities addressing reproducibility, standards and reference materials. The EQI aims to involve EATRIS member facilities in international consortia addressing data quality and reproducibility in translational medicine. EATRIS, with its 110+ member-facilities, is well-suited to help tackle some of the challenges in translational medical research, for example by organising or participating in multi-site benchmarking studies.

Projects from 2019 were continued throughout 2020 and may see fruition during the years to come. While the progress appears small, they all involve massive technical, analytical and managerial efforts by many participants around the globe, and thus may require time during preparation, execution and reporting.

Development of best-practice process in somatic mutation detection by NGS: this is a long-standing, ongoing project which receives persistent support by several members of the EATRIS community. In particular, the Biomarker platform is involved in the FDA-driven community effort SEQC2 (Sequencing Quality Control Phase II) 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.

Hundreds of scientists worldwide are contributing to the SEQC2 project to address sensitivity and quality of somatic mutation detection with NGS technologies and bioinformatics. EATRIS contributes with five sites that provide sequencing data, and seven bioinformatics teams. Besides workshop participations and poster presentations (e.g. at the AACR 2020), the biggest achievement thus far has been the acceptance of a manuscript to Nature Biotechnology. During 2020, several analyses were taken to the level of manuscript preparation and submission, and the team hope to get them published in 2021.

High-throughput screening ring test under the Translation Together (TT) initiative, and five 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. Following the completion of a pilot phase in 2018 with four sites, the study now comprises twelve research sites in total, and the data

generation process is near-finalised. During 2020, the results were analysed and additional experiments were initiated.

Two EATRIS sites have engaged with a private-public consortium led by the Foundation of National Institute of Health (FNIH) with the goal to establish sensitivity thresholds and clinical applicability of ctDNA reference material. In 2019, the scope of the study was developed. The Institute for Molecular Medicine Finland (FIMM) at the University of Helsinki was one of the first study participants to sign the contract in 2020. All members are awaiting the sample shipment in 2021.





Dr Andreas Scherer Chair of the EATRIS Quality Initiative and Co-chair Biomarker Platform





PARTNERSHIPS AND LONG-TERM INITIATIVES

Engaging with key global stakeholders to collectively address high risk of failure in medicines development is essential to the mission of EATRIS. Successful translational research requires cross-sectoral collaboration among diverse stakeholders, namely academia, industry, funders, hospitals, regulators and patient organisations. In 2020, EATRIS continued to build closer ties with BBMRI and ECRIN. 2020 also saw the solidification of our partnership with the patient community through the European Patients Academy for Therapeutic Innovation (EUPATI), a foundation that provides education and training to increase the capacity and capability of patients and patient representatives to understand and meaningfully contribute to medicines research and development.

WORKING CLOSER WITH OTHER RESEARCH **INFRASTRUCTURES**

EU-AMRI: THE ALLIANCE OF MEDICAL RESEARCH INFRASTRUCTURES (BBMRI, EATRIS, ECRIN) GROWS STEADILY

In 2019, the collaboration solidified through the signature of a long-term collaboration agreement that lays the ground for facilitating user access to pan-European medical research infrastructures and supporting the development of tools, joint services and common approaches on quality, standards and advocacy.

In 2020, alliance members joined forces to offer a COVID-19 fast response service, a coordinated and accelerated procedure for researchers to access the academic facilities, services and resources of the three medical research infrastructures. Given the need for a better coordinated response across national research policies and for the involvement of research infrastructures, the Alliance also took an active part in science policy debates, organised by ESFRI, OECD and the Personalized Medicine Coalition, and issued two publications. The first was a policy statement that gave five recommendations to accelerate COVID-19 research, including the need for increased use of research

infrastructures. The second was a peer reviewed paper published in Clinical Infectious Diseases* that provided detailed scientific insights into necessary standards and coordination.

The alliance also continued to further build its advocacy presence and set up a joint Policy and Advocacy Working Group which supported outreach efforts in preparation of Horizon Europe.

EATRIS JOINS THE ERIC FORUM SECRETARIAT AND **EXECUTIVE BOARD**

The ERIC Forum brings together all European Research Infrastructure Consortia (ERICs). The ERIC Forum aims to provide information, best practices and potential solutions

*Oldoni, E., van Gool, A., García Bermejo, L., Scherer, A., Mayrhofer, M., & Florindi, F. et al. (2020). Biomarker Research and Development for Coronavirus Disease 2019 (COVID-19): European Medical Research Infrastructures Call for Global Coordination. Clinical Infectious Diseases. doi: 10.1093/cid/ciaa1250

to challenges which ERICs can face in the preparation phase or throughout the implementation of the ERIC Regulation. The ERIC Forum is also a consultation body for EU policies related to Research Infrastructures.

In 2020, Anton Ussi, EATRIS Operations and Finance Director, became the first elected Vice-Chair of the ERIC Forum. Chairs are responsible for the strategic planning of the Forum and coordinate external relations with the European Commission (EC), the European Strategy Forum on Research Infrastructures (ESFRI), and other strategic stakeholders.

Working under the experienced guidance of the Chair, John Womersley, the ERIC Forum can lay claim to numerous achievements, and have steadily built a strong reputation as a reliable interlocutor in the ERA. As an active member of the ERIC Forum governance bodies, EATRIS actively

contributed to the Forum's coordinated response to the advancing of Mission agendas and took the lead on behalf of the Secretariat to support the EC with the revision of the ERIC Practical Guidelines.

Anton Ussi has been re-elected Vice Chair of the Forum early 2021. Through his leadership, EATRIS will continue the excellent work already undertaken to improve the Forum's visibility, among others within the very important communities around ESFRI, EOSC, the Missions, the relevant EC units and research funders, and to reinforce the Forum's long-term sustainability. Talent, capacity and infrastructure of ERIC Forum members play an important role in cementing Europe's global leadership in science and innovation and should continue to be exploited optimally by research communities.

STRENGTHENING EATRIS ROLE IN THE GLOBAL RESEARCH ENVIRONMENT

SHAPING THE FUTURE OF PERSONALISED MEDICINE

Following the kickoff of the EATRIS-Plus project early 2020, the leadership of EATRIS in the field of personalised medicine continued to strengthen. EATRIS was invited to speak at several international conferences on precision medicine, such as the Nordic Precision Medicine Forum and the PEMED conference (Germany), to present efforts carried out by the infrastructure to support personalised medicine research. Toni Andreu, EATRIS Scientific Director, was also invited to a panel organised by the Personalised Medicine Coalition to discuss the impact of the COVID-19 pandemic on the progress of the personalised medicine, as well as to join expert working groups of the IC2PerMed project, supporting the integration of China in the International Consortium for Personalised Medicine.

EATRIS also launched a multi-stakeholder group on omics technologies, looking at strengthening synergies between several European and global initiatives in the field, and accelerating the use of such technologies in the field of personalised medicine research.

TRANSLATION TOGETHER, A GLOBAL INITIATIVE TO ADVANCE TRANSLATIONAL INNOVATION

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

In 2020, the Translation Together partners continued to engage in collaborative actions and initiatives to:

- 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.

Under the leadership of NIH-NCATS, an awareness video on Translational Research and the Translation Together initiative we developed in 2020 and launched in early 2021. In 2020, the initiative expanded with the addition of the Oswaldo Cruz Foundation in Brazil. The Oswaldo Cruz Foundation (Fiocruz), founded in 1900, is the largest public health-related R&D institution in Latin America. Fiocruz's mission is to produce, disseminate and share knowledge and technologies aimed at strengthening and consolidating the Brazilian Unified Health System and contributing to promoting health and quality of life of the population. The Center for Technological Development in Health (CDTS) is a Fiocruz unit focused on translational science and has full synergy with the Translation Together initiative.

face-to-face. Instead, the annual meeting was in the form of a two-week digital event that allowed partners across six time-zones to meet and share the burden of unconventional timeslots. The annual event was used to review progress and discuss the COVID-19 responsiveness of each organisation separately and towards combined actions put in place, such as the contribution of the partners to the open data COVID-

19 portal developed by NIH-NCATS, lessons learnt and develop a call for actions for future infectious diseases preparedness which will be the topic of a manuscript under preparation.

Visit the website: translationtogether.org

FOSTERING MULTI-STAKEHOLDER **ENGAGEMENT**

ADVOCATING FOR PATIENT ENGAGEMENT IN TRANSLATIONAL RESEARCH

In 2019, EATRIS entered a three-year collaboration agreement with the European Patients' Forum ensuring stronger patient involvement throughout the research process and demonstrating both parties' interest in advancing patient engagement in the translational research process and in implementing joint actions, particularly in the fields of advocacy and training.

In 2020, EATRIS continued to deepen its ties with the patient community by entering a bilateral collaboration with EUPATI, the European Patients' Academy on Therapeutic Innovation. This development has demonstrated both organisations' commitment to provide education and training opportunities in translational research for patient advocates and strengthen academic researchers' capacities to effectively engage with patients in their research. EATRIS is currently supporting the improvement of the EUPATI toolbox, by providing additional scientific content and has welcomed patient experts to its online courses on translational medicine.

Furthermore, EATRIS supported the Patient Focused Medicine Development (PFMD) initiative by joining its working group on patient engagement in early phases of research. As a working group member, EATRIS hub and EATRIS members directly contributed to the co-creation of a how-to guide for patient engagement in the early discovery and preclinical phases, which provide a full set of instructions on how to involve patients across the research, development, and delivery of medicines.

EATRIS MAINTAINS CLOSE DIALOGUE WITH REGULATORY AUTHORITIES

EATRIS continued to contribute to advancing regulatory science and the shaping of the European Medicines Agency (EMA) Strategy by answering on behalf of the EATRIS community the EMA's summer public consultation on its

Network Strategy to 2025. EATRIS further developed relationships with EMA services involved in regulatory approvals of ATMPs, providing the EMA with a summary of common regulatory issues faced by academics in the field.

In addition, the EMA supported EATRIS and the ADVANCE consortium in delivering an online learning course to train the next generation of advanced therapy medicinal products (ATMPs) specialists. To provide learners with the best possible learning materials directly from the source, EMA developed the Regulatory learning unit for the online curriculum, as well as agreed to deliver a webinar on regulatory affairs in 2021.

SUPPORTING EU RESEARCH POLICY DEVELOPMENTS

The preparatory phase of Horizon Europe provided opportunities for EATRIS and close partners to support policy-making process. One of the main novelties of the Horizon Europe research programme will be the "Missions". EU missions are commitments to solve some of the greatest challenges facing our world like fighting cancer, adapting to climate change, protecting our oceans, living in greener cities and ensuring soil health and food. EATRIS along with three other European Research Infrastructures (BBMRI, ECRIN, ELIXIR) published a comprehensive overview of the relevant expertise and services all research infrastructures are in a position to offer to support the implementation of the Cancer Mission Board's 13 recommendations.

Through the EU-AMRI Alliance, EATRIS joined forces with BBMRI and ECRIN to raise the voice of medical research infrastructures in public consultations of the European Commission on the future of the European Research Area, Horizon Europe or European Data Spaces.

PATIENT ENGAGEMENT

Interview with Maria Dutarte from EUPATI





The European Patients' Academy on Therapeutic Innovation (EUPATI) was launched as a flagship project of the Innovative Medicines Initiative (IMI). It aimed to trigger a major rethink in the way patients and the public understand the medicines development process and their own involvement within. Maria Dutarte, Executive Director of **EUPATI**, tells us more.



WHAT IS EUPATI AND WHAT DOES IT OFFER?

EUPATI is a multi-stakeholder public-private partnership, established as a non-profit Foundation. We were launched in 2012 as a project of the Innovative Medicines Initiative (IMI). Since the start our main goal has been to provide training for patients and patient representatives on the end to end process of medicines research and development. We believe that trained patient experts are the core resource for patient involvement in medicines R&D, regulatory deliberations, and other patient engagement initiatives. EUPATI is committed to changing the face of patient engagement through patient education.

COLLABORATIONS BETWEEN PATIENT ORGANISATIONS AND ACADEMIC RESEARCH ORGANISATIONS REMAIN SCARCE IN EUROPE, WHY DO YOU THINK THAT IS?

I personally think that there are a lot of misconceptions among academic researchers about involving patients in research. Researchers might, for example, think that it is a complex and costly process, and are not aware of the benefits for research outputs. Today we have documented evidence that involvement of patients in research increases the impact of research and enhances the acceptance of scientific research by patients and citizens.

EUPATI AND EATRIS ENTERED A COLLABORATION AGREEMENT IN THE SPRING 2020, WHAT DO YOU SEE AS THE ADDED VALUE OF THIS COLLABORATION?

Our collaboration has provided patients with increased knowledge about the area of translational medicine and strengthened their engagement in research. I am confident that our collaboration will expand further and we will together build bridges between patients and academia.

PATIENT ENGAGEMENT REMAINS A CHALLENGE, PARTICULARLY IN EARLY-STAGE RESEARCH. WHAT WOULD BE YOUR TOP RECOMMENDATIONS TO RESEARCHERS TO ADDRESS THIS ISSUE?

My recommendation would be to start looking into those challenges together with other actors in the field, and to join the discussion. There are today many good tools available for guidance. We at EUPATI have also launched trainings for institutions that wish to start implementing patient engagement in practice. I would also encourage participating at the European-wide Patient Engagement Open Forum event that addresses these key questions.

WHAT ARE YOUR HOPES FOR THE FUTURE WITH EUPATI?

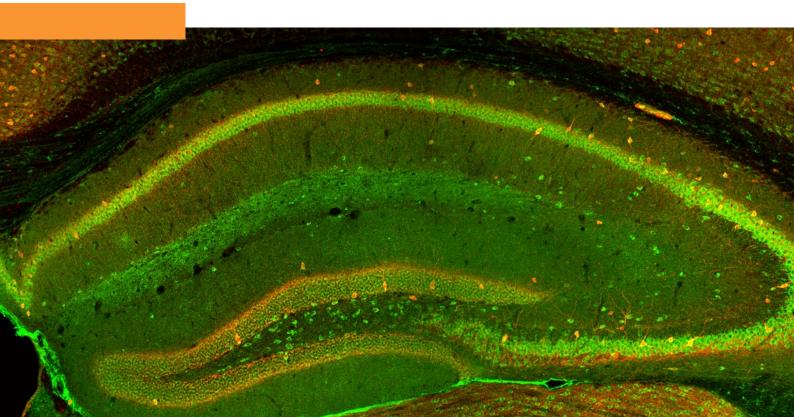
We hope to provide training for an increased number of expert patients through our newly launched EUPATI Open Classroom and thereby empower patients to become key actors in medicines research and development.



Maria Dutarte **EUPATI Executive Director**

INDUSTRY PARTNER SPOTLIGHT

Interiew with Matthew Cleveland, Senior Director within the GSK Imaging Department



Dr Matthew Cleveland is Director of Translational Bioimaging UK at GlaxoSmithKline (GSK) in Stevenage, **UK. His role supports GSK projects** across all diseases in utilising imaging to answer specific questions of biodistribution, target engagement and pharmacodynamic responses in a translational setting. He works across a broad network of internal and external partners. We asked Matthew a few questions about his work.

WHEN DID YOU FIRST HEAR ABOUT EATRIS?

Mats Bergstrom an external consultant and expert of PET imaging previously worked with members of EATRIS on an earlier collaboration and highly recommended them and their academic centres. After some initial introductions and discussion, the benefits soon became clear to us of working with EATRIS and we developed the current Imaging Hub model.

CAN YOU TELL US ABOUT THE IMAGING HUB COLLABORATION. AND WHAT YOUR ROLE WAS IN THE **COLLABORATION?**

The aim of the Imaging Hub is to develop novel imaging endpoints using molecular and functional imaging for informative Ph1b studies through pre-clinical and clinical studies in world leading centres across Europe. These studies aim to deliver disease agnostic imaging tools that can be validated pre-competitively and as broadly as possible in indications such as IBD, RA, liver disease, asthma/COPD, neuroinflammation and oncology. The use of imaging should provide molecular understanding of the underlying disease pathophysiology, such as inflammation, fibrosis, epithelial barrier integrity and function, and cell populations involved (T-cells, macrophages, NK cells, neutrophils). The first molecular tracers are entering the clinic this year with the aim to validate these disease agnostic translational imaging tools for a broad panel of indications.

The Hub Steering Committee agreed to extend the initial period by another 3-years, resulting in renewal of the collaboration agreement in July 2020.

My role on the steering committee is to bring new ideas from GSK to the hub partners from specific projects to new disease areas. I also help oversee ongoing projects from both scientific and an operational perspective and continually look for synergies between GSK and the hub partners to maximise the mutual benefits between industry and academia.

WHY DO YOU THINK THE IMAGING HUB COLLABORATION IS AN IMPORTANT PROJECT?

The imaging hub complements our internal imaging expertise to support Ph1-3 clinical trials. One major benefit of the alliance structure is the flexibility of the framework which spans a broad range of project formats from bespoke imaging probe development to investigator-led clinical trials. The one common factor is that EATRIS are central to the coordination as a single point of contact, successfully delivering complex agreements involving multiple external partners. The access to world leading imaging centres across Europe enables us to seek experts in many different areas of imaging and allows the addition of extra hub members should the need arise.

HOW DO YOU THINK COLLABORATION WITH EATRIS CAN **BE BENEFICIAL TO COMPANIES SUCH AS GLAXOSMITHKLINE?**

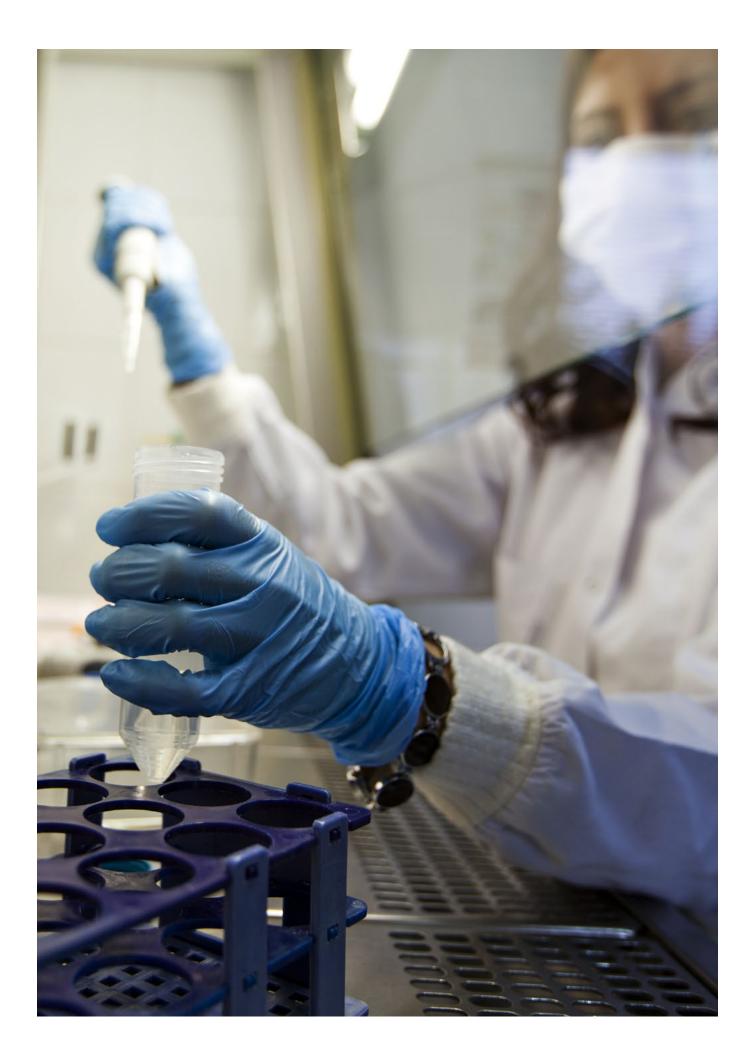
The public-private partnership brings the best of both to the academic researcher and industrial partner. The hub partners have opportunities to interact with GSK whilst we can partner with world leading imaging experts across multiple centres in a flexible, shared and focussed manner. It also ensures we are at the forefront of expertise and technology as exemplified by the clinical optical imaging at University Medical Center Groningen, that some of our partners are likely to have whole body PET in the future and further development of zirconium labelling methods at AUMC. Ultimately this results in more advanced novel imaging methodologies for our early clinical studies resulting in faster and better medicines for patients.

WHAT DO YOU VALUE IN EATRIS AS A PARTNER?

EATRIS have been fantastic to work with on all aspects of the Imaging Hub. They have supported the organisational and legal logistics of the public-private partnership and maintain its operational fluidity. Their knowledge of hub partners and other academic institutes across Europe is extensive and they can find the right centre and often person to help with a new area or project. I know we can rely on EATRIS to deliver which builds trust across the hub.



Matthew Cleveland Senior Director GSK Imaging Department



UPDATE ON EC FUNDED PROJECTS WITH EATRIS INVOLVEMENT

ADVANCE

EDUCATING THE NEXT GENERATION OF ATMP PROFESSIONALS



Next Generation of Advanced Therapies' Specialists

Funding Programme: Erasmus-Plus

Total Budget: 371,927 EUR **Budget EATRIS: 84,366 EUR**

Coordinator: EATRIS

Website: eatris.eu/projects/advance

Starting - end date: November 1st 2019 - April 30th 2022

EATRIS role: Coordinating Partner

PROJECT UPDATE

ADVANCE is an educational project that kicked off in November 2019 coordinated by EATRIS and funded by Erasmus Plus. Its aim is to train early-career biomedical scientists in the field of Advanced Medicine Therapy Products (ATMPs) development.

In early April 2020 ADVANCE project was publicly kicked off with the webinar series. Between April and June five webinars were held including an introduction to the ADVANCE Programme, ATMPs regulatory, clinical and manufacturing aspects, as well as two sessions on career coaching topics. All webinars in the series are posted on our YouTube channel and can be watched on demand at any time.

Through summer and early autumn twelve experts across academia and industry, including the European Medicines Agency, were invited to contribute to the online course that was launched successfully on 1 December. In the first two weeks over three hundred participants had registered from twenty five different countries around the world.

Due to the pandemic the face-to-face workshop was to be held online and was postponed until May 2021. The workshop will be a continuation of the online course curriculum and will give thirty participants a chance to take a deeper dive to the exciting world of ATMPs.

Beyond 1 Million Genomes (B1MG)

A NETWORK OF GENETIC AND CLINICAL DATA ACROSS EUROPE



Funding Programme: H2020 Total Budget: 4,000,000 EUR Budget EATRIS: 76,378.13 EUR

Coordinator: ELIXIR Website: b1mg-project.eu

Starting - end date: June 2020 - May 2023 EATRIS role: WP1- Stakeholders engagement

PROJECT UPDATE

B1MG project aims to make it easier to share human health data around Europe. It will support the European Union's 1+ Million Genomes Initiative, which aims to provide access to at least one million sequenced genomes in the EU by 2022. The B1MG project will support this initiative by creating the infrastructure, the legal guidance and the best practices to enable this access. It will make it possible for scientists and clinicians to study the genotypic and phenotypic data from over one million people. This data will be linked, so the genetic data from one individual can be matched with their phenotypic data.

EATRIS has a key role in WP1, that aims to implement a way to drive stakeholder involvement. For this purpose, EATRIS, supported by WP6, developed the stakeholder coordination portal to efficiently deliver timely analysis of challenges, opportunities and solutions resulting from external stakeholders to the operational WPs. The portal allows the creation of a vibrant community, organised and focused, that can collaborate in an effective and advantageous way for improving the project outcomes.

BiC-BRIDGE

BIOMARKER COMMERCIALISATION IVD APPLICABLE BIOMARKER RESEARCH AND INNOVATION IMPLEMENTATION DEVELOPMENT GUIDE



Funding Programme: European Regional Development

Fund- the Interreg Baltic Sea Region programme

Total Budget: 760,000 EUR **Budget EATRIS:** 31,125 EUR

Coordinator: Ideklinikken, Aalborg University Hospital

Website: biomarker.nu

Starting - end date: October 2020 - June 2021

EATRIS role: partner in WP4 - support further the uptake of

the BiC-tool through targeted dissemination

PROJECT UPDATE

The main challenge of biomarker commercialisation is that while there is research identifying links between some biological signatures with diseases or response to the treatment, less than 2% will convert into clinical applicable diagnostic tests. The discovery part is a substantial investment, but the route to industrial development and to commercialisation is not part of the skills and expertise easily available in research institutions, even when having a Technology Transfer Office to support commercialisation of an invention.

BiC-BRIDGE is based on the main outputs and results from the initial BiC – Biomarker Commercialisation project. Thanks to the regular project, the BiC consortium managed to tackle specific challenges from the biomarker development and commercialisation field. BiC-BRIDGE serves not only to improve the outputs delivered in the original project but also to develop a whole new set of activities aiming at increasing the scope of the tools and broadening the target groups, as well as increasing usability, sustainability and impact, through:

- Commercialisation and regulatory guidance in advanced stages of development
- Practical conversation of the Biomarker Commercialisation Guide
- Educational Training Toolbox
- Increased visibility and awareness

CORBEL

COORDINATED RESEARCH INFRASTRUCTURES BUILDING ENDURING LIFE-SCIENCE SERVICES



Funding programme: H2020 (Research Infrastructures)

Total budget: 14,837,800 EUR Budget EATRIS: 745,900 EUR Coordinator: EMBL/ ELIXIR (UK) Website: corbel-project.eu

Starting - end date: September 2015 - May 2020 **EATRIS role:** Leader WP8 - Accelerating Innovation

EATRIS participating institutions: Stichting Lygature (NL), Rizzoli Institute (IT), Netherlands Cancer Institute (NL)

PROJECT UPDATE

The CORBEL programme, which integrates 13 LS RIs, was extended until May 2020 and EATRIS contributed through delivery of a sustainability plan for the Innovation Help Desk (which continues through EATRIS) and through maintenance of the guideline documents and agreement templates from the project, which are available via the CORBEL website and the Life Sciences RI web site. Products from CORBEL are also being fed into other EU projects as part of mutual cooperation.

The two day workshop on best practices in public-private biomedical research collaboration, including a comprehensive use case exercise for teamwork, was held for a second time, in Lisbon in February 2020.

EATRIS-Plus

FLAGSHIP PROJECT IN PERSONALISED MEDICINE



Funding Programme: H2020 (Research Infrastructures)

Total Budget: 4,999,023.25 EUR Budget EATRIS: 724,637.50 EUR

Coordinator: EATRIS

Website: eatris.eu/projects/eatris-plus

Starting - end date: January 1, 2020 - December 2023

EATRIS role: Coordinating Partner

PROJECT UPDATE

EATRIS-Plus is a H2020-funded personalised medicine flagship project that kicked off in January 2020. The main scientific objective is to delivering a multi-omic toolbox to support cross-omic analysis and data integration in clinical samples. To that end and the biological sample shipments for the transcriptomic, proteomic and metabolomic data generation started in December 2020.

EATRIS-Plus is a comprehensive sustainability project that involves strategic stakeholder engagement, with the aim to increase EATRIS industry and international collaborations, as well as provide training opportunities to the EATRIS research community and beyond. To support these goals the planning started for the first EATRIS-Plus Summer School in Personalised Medicine, and the Public Private Partnerships Best Practices workshop.

Stakeholder engagement highlights were certainly the kick-off of the Patient Advisory Committee led by EPF and EATG, as well as the launch of the new EATx webinar series. Not less noteworthy were also the publishing of the Communications Plan, Project Partners Communications Toolkit, and the launch of the Quarterly Newsletter. Capacity-building activities were represented by the organisation of the National Coordinators workshop held in October 2020 focussing on translational assessment, as well as the launch of the Node Handbook in the end of the year.

International collaboration was strengthened by forming an Education and Training working group within the Translation Together (TT) initiative, as well as welcoming the Oswaldo Cruz Foundation from Brazil as a new member of TT.

EJP RD

EUROPEAN JOINT PROGRAMME ON RARE DISEASES



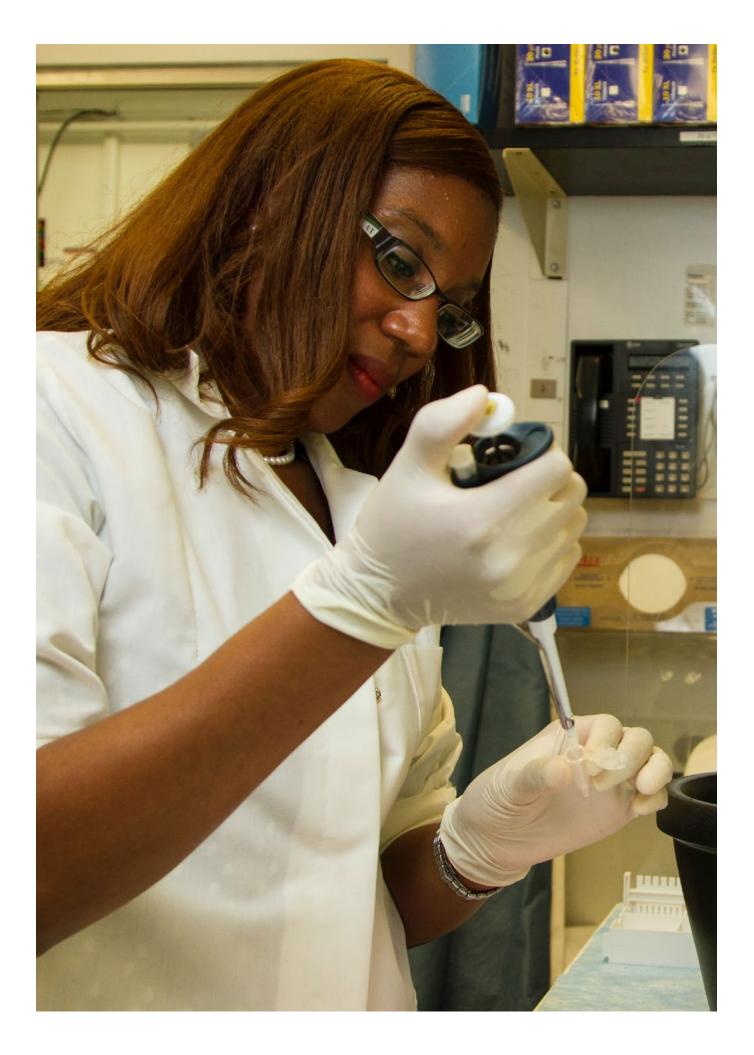
Funding Programme: H2020 Total Budget: 55,073,831 EUR Budget EATRIS: 376,678 EUR Coordinator: INSERM (FR) Website: ejprarediseases.org

Starting - end date: January 2019 - December 2023 EATRIS role: Co-leader of Pillar IV "Accelerating Translation"; Co-leader of WP19 "Facilitate partnerships and accelerate translation" and WP3 "Sustainability" EATRIS participating

institutions: VHIR (ES), University of Oslo (NO)

PROJECT UPDATE

The European Joint Programme for Rare Diseases (EJP RD) entered its second year begin 2020. Despite the COVID crisis, Pillar 4 (Translational research and clinical innovation) led by EATRIS and Necker Hospital made excellent progress. Notable achievements for EATRIS included a wildly successful industrial/translational mentoring pilot that saw 15 multi-national rare disease projects in development receive multi-disciplinary mentoring support in advance of study start. In a 5-week period these teams received feedback from regulatory, drug development, biomarker validation, biostatistics, innovation and IPR and other experts in order to ensure robust study design to maximise their chances of success and future translation to the patient. Almost 500 hours person-hours were dedicated to organising and delivering mentoring from 3 continents to leading European teams. A standout performance by our linked third parties VHIR (Spain – led by Agustín Arasanz) and UiO (Norway - led by Anita Kavlie) was a critical success factor. All investigators requested that the mentoring continue if their projects are funded. Elsewhere in EJP RD, EATRIS co-leads the Sustainability WP together with our Spanish governing partners, ISCIII. Good progress was made in inventorising EJP RD's high value outputs, an important step for the overall planning for life after the programme ends in 2023.



ENRIITC

A PAN-EUROPEAN NETWORK OF INDUSTRIAL LIAISON AND CONTACT OFFICERS (ILOS AND ICOS) TO ENABLE **INDUSTRY TO BECOME A FULL PARTNER OF RESEARCH INFRASTRUCTURES WHETHER IT IS AS A USER, A** SUPPLIER, OR A CO-CREATOR.



Funding programme: H2020 (Research Infrastructures)

Total budget: 1,499,823 EUR Budget EATRIS: 185,312 EUR

Coordinator: European Spallation Source ERIC (ESS)

Website: enriitc.eu

Starting - end date: January 2020 - December 2022 **EATRIS role:** Leader of WP5 Communications

PROJECT UPDATE

ENRIITC aims to establish a sustainable European network of Industrial Liaison and Contact Officers (ILOs and ICOs) which enables mutual learning, mapping of collaboration potential between RIs and industry, development and refining of strategies and best practices to foster these collaborations, raising awareness among industry for collaboration opportunities at research infrastructures, and demonstrating impact.

Early in the ENRIITC project a website was launched, social media set up and a visual identity established. The communications work package continued to update these media and also provided communications support to a precedent-setting online networking meeting including a unique virtual evening entertainment programme. 125 participants from 21 countries took part. A series of online meetings for networking around specific topics of interest was instituted under the title #ENRIITCyourCoffee. This was attended weekly up to 40 participants and helped to expand the ENRIITC network.

EATRIS staff also participated in an industry mapping survey yielding an extensive report, in preparation of a step by step best practice guide for organising brokerage events and in making plans for a series of training webinars and interactive meetings.

EOSC-LIFE

AN OPEN COLLABORATIVE DIGITAL SPACE FOR LIFE **SCIENCE**



Funding Programme: H2020 (Research Infrastructures)

Total Budget: 26,145,996.25 EUR **Budget EATRIS:** 494,271.25 EUR

Coordinator: ELIXIR Website: eosc-life.eu

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 UPDATE

EOSC-Life is the project regrouping the 13 LS RIs in Europe into the European Open Science Cloud (EOSC). EATRIS contributes to the project as main partner and through five linked third parties. In 2020, EATRIS through the E&T WP produced an online EOSC-Life workshop on "Transferring face-to-face courses to remote delivery" on July 7 and under the WP3 we contributed to the launch of the EOSC-life open calls through the preparation of the communication materials.

We kept supporting EATRIS LTPs for the development of MICHA, a webserver to facilitate the annotation of chemosensitive assay and its extension towards the annotation of antiviral assays.

ERIC-FORUM

BRINGING EUROPEAN RESEARCH INFRASTRUCTURE CONSORTIA TOGETHER



Funding programme: H2020 (Research Infrastructures)

Total budget: 1,495,281 EUR **Budget EATRIS: 77.916 EUR** Coordinator: BBMRI-ERIC Website: eric-forum.eu

Starting - end date: January 2019 - December 2022 EATRIS role: Leader of WP3 "Operations, Administration,

Finance, Human Resources of ERICs".

PROJECT UPDATE

In 2020, EATRIS continued to take a leading position in the Forum. Anton Ussi, EATRIS Operations and Finance Director, was elected Vice-Chair of the ERIC Forum (see interview page 79). As a result, EATRIS joined the ERIC Forum Secretariat alongside BBMRI-ERIC and European Spallation Source. Furthermore, EATRIS through its role as Work Package 3 ("Operations, Administration, Finance, Human Resources of ERICs") leader supported the European Commission with the revision of the ERIC Practical guidelines and coordinated a consultation of the ERICs on areas of improvements and best practices examples.

EATRIS also conducted bilateral interviews of 9 infrastructures preparing for the ERIC legal status to better understand their needs and challenges and ensure the ERIC Forum can provide them adequate support.

iNEXT-Discovery

INFRASTRUCTURE FOR TRANSNATIONAL ACCESS IN STRUCTURAL BIOLOGY AND TRANSLATIONAL RESEARCH



Funding programme: H2020 (Research Infrastructures)

Total budget: 9,987,757 EUR **Budget EATRIS: 19.375 EUR**

Coordinator: Dutch Cancer Institute (NKI) - Antoni van

Leeuwenhoek Hospital Amsterdam

Website: inext-eu.org

Starting - end date: February 1, 2020 - January 2024 **EATRIS role:** Partner (outreach and valorisation)

PROJECT UPDATE

The iNEXT-Discovery project has completed its first year of operations bringing together structural biology facilities of various life science infrastructures in medicinal chemistry, translational medicine, biological imaging, and food research, to facilitate the use of structural biology resources and expertise across Europe, scientific disciplines and research sectors.

The joint activities undertaken by the 26 participants from 14 countries are coordinated by the Dutch Cancer Institute (NKI) with transnational accessible research services being developed in synergy with INSTRUCT ERIC and with relevance to translational research. An industry access portal is in place and proposals are reviewed by expert panels.

The consortium held its virtual kick off meeting on May 28. EATRIS will create awareness of the relevant aspects of translational medicine among the structural biology community highlighting the (early) development of novel therapeutics and diagnostics, drug development tools, engaging with SMEs, aspects of innovation management and regulatory aspects.

PERMIT

METHODOLOGICAL STANDARDS FOR PERSONALISED MEDICINE



Funding programme: H2020 Total budget: 2,000,000 EUR Budget EATRIS: 161,250 EUR Coordinator: ECRIN-ERIC Website: permit-eu.org

Starting - end date: January 2020 – December 2021 **EATRIS participating institutions:** University of

Bergen (NO)

EATRIS role: Partner in WP2 and leader of WP5 on "Translational development of patient-stratification

processes"

PROJECT UPDATE

PERMIT will develop recommendations for robust and reproducible personalised medicine (PM) research. The objective of PERMIT is to establish recommendations ensuring the robustness of personalised medicine trials, which also requires validation of the stratification methods. EATRIS-ERIC participates as leader of WP5 due to its expertise in translational research, in collaboration with the University of Bergen, a member of the EATRIS community.

During its first year, the PERMIT project carried out a scoping review of scientific publications and grey literature (following a defined protocol) to map the existing methodologies in the different stages of the PM research pipeline, and identify existing gaps and opportunities for recommendations.

Throughout the second and final year, a series of working sessions and workshops will take place. The working sessions will gather consortium members and external experts from diverse fields (academic investigators, regulators, HTA representatives, Industry representatives, and more) to address the specific questions identified in the scoping reviews and gap analysis. The workshops will follow, and will be focused on presenting and discussing a draft of the recommendations with field experts and consortium members.

RECOGNISED

RETINAL AND COGNITIVE DYSFUNCTION IN TYPE 2
DIABETES: UNRAVELLING THE COMMON PATHWAYS AND
IDENTIFICATION OF PATIENTS AT RISK OF DEMENTIA



Funding programme: H2020 Total budget: 5,998,273 EUR Budget EATRIS: 104,000 EUR Coordinator: VHIR (ES)

Website: eatris.eu/projects/recognised-retinal-and-

cognitive-dysfunction-in-type-2-diabetes

Starting - end date: January 2020 – December 2023 **EATRIS role:** Lead Beneficiary WP8 (Dissemination and

Exploitation)

PROJECT UPDATE

The RECOGNISED project aims to unravel the (common) biological mechanisms underlying structural and functional alterations in the eye (the retina) and in the brain, in people with type 2 diabetes and (at risk of) developing cognitive impairment and dementia. In the the first year this ambitious project focused on starting the clinical activities embarking on a cross sectional study to recruit patients eligible to participate in a longitudinal study (3 year follow-up during the project) to generate a multitude of clinical (biomarker) data. The activities of the 11 clinical partners are harmonised through the efforts of EATRIS partner AIBILI (Coimbra, Portugal) and the main coordinating institution VHIR (Barcelona, Spain).

The project is translational as complementary to the clinical activities, basic research efforts involving animal models of diabetes and neurodegeneration are pursued by an exchange of tissues of the retina and brain among the various specialists in the consortium. The search of its 21 project partners for specific biomarkers and cell types linking common mechanisms in type-2 diabetes and (the onset of) cognitive decline can lead to results that can be exploited during or after the project.

EATRIS facilitates this process in close collaboration with GENESIS Biomed (Barcelona, Spain), responsible for exploitation management, and both take part in the Dissemination and Exploitation Board, that met twice since the project kicks off on 28 January in Barcelona. On 3 December, an innovation Management workshop was attended by 35 consortium members informing the consortium members on the steps involved in this process and creating awareness on the types of potentially exploitable results.

RI-VIS

INCREASING THE VISIBILITY OF THE EUROPEAN RESEARCH INFRASTRUCTURES



Funding programme: H2020 (Research Infrastructures)

Total budget: 1,500,000 EUR **Budget EATRIS:** 24,625 EUR **Coordinator:** INSTRUCT-ERIC

Website: ri-vis.eu/network/rivis/home

Starting - end date: February 2019 – July 2022 **EATRIS role:** Participant in all work packages

PROJECT UPDATE

RI-VIS aims to increase the visibility of European RIs to new communities in Europe and beyond. The face-to-face activities foreseen by the project (e.g. Showcase event in Cape Town, South Africa) were very much affected by the pandemic and all events planned for 2020 have been postponed to 2021. EATRIS continued to participate in exchange of experiences in the field of communication and to utilize the communications toolbox for research infrastructures developed by the project early 2020.

Preparatory work was also performed ahead of series of virtual events supporting RI collaborations foreseen for 2021 and focusing on several world regions such as Africa, South America and Asia.

RITRAIN

TAILORED TRAINING FOR MANAGERS IN RESEARCH INFRASTRUCTURES



Funding programme: H2020 (Research Infrastructures)

Total budget: 1,900,000 EUR **Budget EATRIS:** 35,000 EUR **Coordinator:** BBMRI-ERIC

Website: ritrain.eu

Starting - end date: September 2015- March 2020 EATRIS role: Partner WP2 "Definition of competencies" and

WP5 "Continued professional development

PROJECT UPDATE

2020 saw the closing of the RI-TRAIN project, the Research Infrastructure Training Programme, aimed at improving and professionalising the training of managerial and leadership staff in research infrastructures. EATRIS' participation in the project led to EATRIS receiving the Certificate of Excellence in Research Infrastructure Leadership in 2019 and to the organisation of two staff visits at its headquarters in Amsterdam for sharing best practices on RI business planning and governance models.

The project led to the creation and development of the Executive Master in Management of Research Infrastructures, which Florence Bietrix, EATRIS Head of Operations, successfully completed in 2020. The project has successfully paved the way to closer interactions among RI from various disciplines, which, since the end of the RI-TRAIN project, have continued to exchange best practices and support cross-RI training programmes, notably through the RI-VIS project.

TRANSVAC-2

EUROPEAN INFRASTRUCTURE FOR VACCINE DEVELOPMENT



Funding programme: H2020 (Research Infrastructures)

Total budget: 14,556,732.34 EUR **Budget EATRIS:** 185,375 EUR

Coordinator: European Vaccine Initiative (EVI)

Website: 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 – Participant – Training: responsible for the development of

two regulatory workshops.

PROJECT UPDATE

2020 marked the fourth year of the TRANSVAC-2 project, where EATRIS's main tasks would include the organisation and hosting in Amsterdam of a two day regulatory training programme. This programme, led by regulatory experts from across the EATRIS network, would consist of lectures and interactive sessions on the different aspects of regulatory knowledge required for vaccine development. The COVID-19 pandemic would ultimately see this initiative postponed to a virtual event in June 2021.

Similarly, an additional regulatory workshop to be organised with EVI was also cancelled with the funding made available for regulatory support projects. TRANSVAC coordinators, EVI, and EATRIS held a meeting with the EC in May to help secure an additional ten million euros for a TNA call specifically directed towards COVID-19 projects. This initiative saw COVID-19 funded projects carried out by EATRIS institutions BPRC, iBET and LUMC some of which are still currently ongoing. USC in Spain was one of the successful applicants to this TNA call receiving funding to help further develop their own SARS-CoV-2 vaccine candidate.

For the same COVID-19 TNA call in April, EATRIS provided regulatory support to a previously EC funded project Prevent-nCOV. This project coordinated by the University of Copenhagen, received regulatory guidance to develop their IMPD and advance their SARS-CoV-2 vaccine candidate towards first in man clinical trials. This project was completed in December 2020.

TRANSVAC-DS

DESIGN STUDY FOR AN EUROPEAN VACCINE INFRASTRUCTURE



Funding Programme: H2020 (Development and long-term sustainability of new pan-European research infrastructures)

Total Budget: 1,879,216 EUR **Budget EATRIS:** 39,375 EUR

Coordinator: European Vaccine Initiative (EVI)

Website: transvac.org/transvac-ds

Starting - end date: June 2020 - May 2022

EATRIS role: WP3 - Feasibility and option analysis – governance, finance and business models: contribution in developing financing plans and long-term sustainability, support in the integration and coordination of the operations with existing biomedical research infrastructures.

PROJECT UPDATE

In 2020 the TRANSVAC-DS project, with EATRIS as one of the 25 partners, was successfully approved for EU funding. TRANSVAC-DS aims to build on the success and lessons learned from TRANSVAC and during the two-year project duration will look to further explore and prepare the establishment of a sustainable European vaccine infrastructure. The main objective and output of TRANSVAC-DS is the preparation of a conceptual design report that will describe in detail the maturity of the vaccine infrastructure concept.

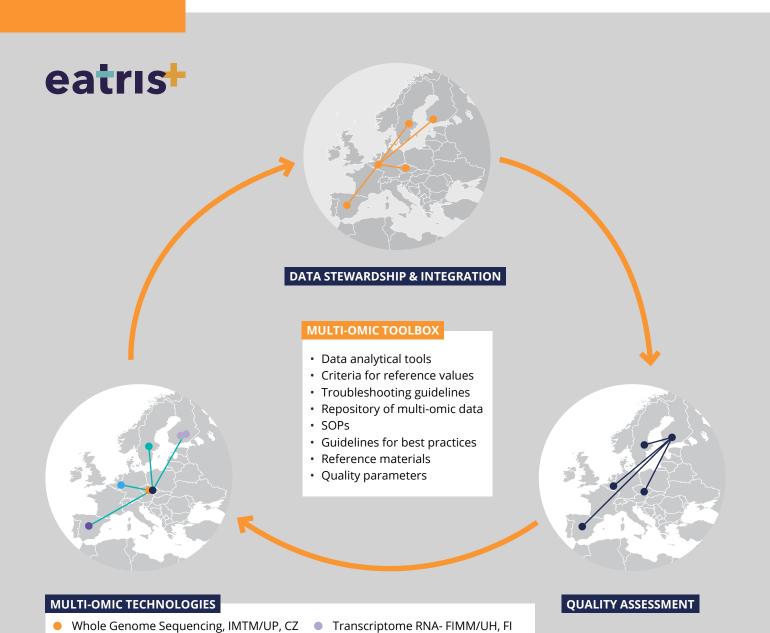
This will be the basis for the establishment of a permanent and sustainable vaccine infrastructure with the aim to be a direct relevance to and benefit for Europe and further afield. The first months of the project saw EATRIS begin its contribution to this design study by assessing gaps and needs and performing a context analysis of the research infrastructure landscape in vaccine development. This was carried out by individual surveys with other biomedical research infrastructures in the EU that currently offer different services to the vaccine developer.

Epigenetic modifications DNA- UU, SE

Metabolomic analysis- RUMC, NL

Proteomic analysis- IMTM/UP, CZ

SPOTLIGHT ON EATRIS-PLUS



MicroRNA sequencing-FIMM/UH, FI

MicroRNA qRT-PCR, IRYCIS, ES

EATRIS-Plus is a H2020-funded project that kicked off in January 2020. The project is one of EATRIS's key flagship initiatives in Personalised Medicine (PM) and includes the participation of 20 partners and all 13 nodes of the infrastructure. With a budget of nearly 5 million euros, EATRIS-Plus will play a defining role in EATRIS' long-term sustainability and will guarantee EATRIS's leadership position in translational research on a global scale.

ULTIMATE MISSION: ALWAYS PATIENTS

PM research seeks to identify interventions that can be targeted to individual patients based on their predicted response. This has substantial value for patients, as it can reduce trial-and-error treatments, enable better choices for determining which medications would be most effective, which in turn can help to manage rising healthcare costs. EATRIS-Plus will work towards improving the understanding, data-sharing, and clinical needs of how gene, protein, mRNA and metabolite analysis will directly impact PM solutions.

In addition we have formed a Patient Advisory Committee who will be providing us with input from the patient perspective, and will help us make our scientific messages clearly understandable to the wider public, as well as support us in delivering patient engagement related training to our research community.

KEY SCIENTIFIC OUTPUT - THE MULTIOMIC TOOLBOX

The role of multi-omic technologies in the advancement of PM cannot be more vital. Efficient advancement of PM depends on the availability of validated patient-targeted biomarkers. However, as our capacity to identify genetic variants associated with complex diseases increases, these do not fully recapitulate the resulting disease phenotypes, and a more precise understanding of the molecular profiles are needed.

Hence the consortium's ambition is to deliver a multi-omic toolbox to support cross-omic analysis and data integration in clinical samples. The multi-omic toolbox will include standard operating procedures (SOPs), guidelines for best practices, reference materials, quality parameters, analysis tools, criteria for establishing reference values, and will provide access to a repository of multi-omic data and will be

made available to the research community. The omic tools will be developed and tested with a real-world setting healthy demonstrator cohort in the Czech Republic, upon whom genomic sequencing has been already performed. The human biological samples from this cohort will be analysed by laboratories across Europe and transcriptomic, proteomic and metabolomic data will be produced.

Despite the global pandemic the sample shipments started in December 2020. The transcriptomic analysis will be conducted by SERMAS in Spain (MicroRNA qt-PCR) and FIMM in Finland (RNA and miRNA sequencing). Epigenetic modifications will be done by Uppsala University in Sweden, the proteomic analysis in the Czech Republic, and the metabolomic data will be generated by Radboudumc in the Netherlands.

LONG-TERM SUSTAINABILITY AND EDUCATIONAL **EFFORTS**

EATRIS-Plus is a comprehensive sustainability project that involves strategic stakeholder engagement, with the aim to increase EATRIS industry and international collaborations, as well as provide training opportunities to the EATRIS research community and beyond. To this end in 2020 the planning started on the first iteration of the EATRIS-Plus Summer School in Personalised Medicine taking place in June 2021 and led by partner INFARMED.

In addition, the Public Private Partnerships Best Practices workshop, led by partners University of Ljubljana and Biocat saw its organisation committee formed, and the event is planned to take place in September 2021.

The long-term sustainability of EATRIS will be supported by increased efforts in node capacity-building and one such capacity building workshop was held for the National Coordinators focussing on translational assessment in October 2020.

In May we published our project's communications plan and our collaboration with patient organisations was fruitful. Led by the European Patients Forum, we started the Patient Advisory Committee (PAC) and EATRIS became a sustaining partner of EUPATI. The collaboration with the latter has centred around our experts reviewing the EUPATI Toolbox materials, as well as EUPATI fellows attending our 5-day Translational Medicine workshop. A noteworthy progress in our outreach activities was the start of new webinar series called EATx, to showcase the EATRIS community from institutes to experts; partners to projects.

As 2020 was dominated by travel restrictions we formed the Education and Training working group with the Translation Together initiative members to explore virtual exchange possibilities.



The ERIC Forum brings together all European Research Infrastructure Consortia (ERICs). The ERIC Forum aims to provide information, best practices and potential solutions to challenges which ERICs can face in the preparation phase or throughout the implementation of the ERIC Regulation. The ERIC Forum is also a consultation body for EU policies related to Research Infrastructures. In 2020, Anton Ussi, EATRIS Operations and Finance Director, was elected Vice-Chair of the Forum.

PLEASE CAN YOU EXPLAIN WHAT AN ERIC IS?

A European Research Infrastructure Consortium (ERIC) is a specific legal form to facilitate the establishment and operation of research infrastructures with European interest. Among others, it provides a legal capacity recognised in all EU Member States, a faster process than creating an international organisation, and exemptions from VAT and excise duty. The European Commission granted EATRIS the ERIC legal status in November 2013, the first ERIC to be constituted in the life sciences domain.

WHY WERE YOU INTERESTED IN BECOMING VICE-CHAIR OF THE FORUM?

I was very excited to have the opportunity to work closely with the ERIC community at such a critical moment in the EU. Closer cooperation allows us to jointly overcome the challenges and share the opportunities to serve the European Research Area better. The wealth of experience and expertise residing within the individual Members of the ERIC Forum is an invaluable source of knowledge; I personally feel that exchange of best practices both internally and with our key stakeholders should remain the priority of the Forum, and hope to contribute to that goal in my role.

WHAT IS YOUR ROLE AS VICE-CHAIR OF THE ERIC FORUM?

The Chairs are responsible for the strategic planning of the Forum, and coordinate external relations with the European Commission, the European Strategy Forum on Research Infrastructures (ESFRI), and other strategic stakeholders. We are supported in our work by three other members of the Executive Board, each representing a specific scientific cluster: Franciska de Jong (Executive Director, CLARIN ERIC) for the social sciences cluster, Wolfgang Fecke (Director General, EU-OPENSCREEN) for the life sciences cluster, and Juan Miguel González Aranda (Chief Technical Officer, LifeWatch ERIC) for the environment cluster.

WHICH 2020 ACHIEVEMENT OF THE ERIC FORUM ARE YOU THE PROUDEST OF?

In September 2020, the ERIC Forum published an important policy brief on "Funding models for access to ERIC

multinational / transnational services". This action typically reflects how far we will go together as a community: how we can comprehensively capture shared challenges and opportunities across multiple disciplines and research infrastructures, and become a strong policy voice advocating for change in national and European funding policies. The brief was presented to funders and policy makers in September 2020 and recommendations were officially released during the Research and Innovation Days organised by the European Commission later that month.

YOU HAVE BEEN RE-ELECTED FOR A SECOND TERM IN 2021. IN YOUR OPINION, WHAT WILL BE HIGH ON THE AGENDA OF THE ERIC FORUM?

In 2021 the ERIC Forum will be at a crossroad for its sustainability planning. Looking at the agenda for next year and beyond, I believe we will need to focus on ensuring solid sustainability planning for the Forum, as the project funding will end in 2022. Moreover, we must continue the excellent work already undertaken to improve our visibility, among others within the very important communities around ESFRI, EOSC, the Missions, the relevant EC units and research funders. We have a lot of talent, capacity and infrastructure that, when exploited optimally, can cement Europe's place as a global leader in science, and improve our standing in innovation.



Anton Ussi
EATRIS Operations & Finance Director

October 2020 saw the arrival of the new EATRIS Head of Communications, Jake Fairnie, and Junior Communications Manager, Piret Pajula. Jake and Piret began building on the great work of Spyros Goudelis and his predecessors, and have exciting plans for the future of EATRIS communications.

Within their first few months, an internal audit was conducted on EATRIS communications platforms and activities that led to a number of changes across our digital estate. This included several website updates, setting up a social media implementation schedule, overhauling the visuals of the monthly email update and standardising externally facing materials, amongst other items. They also set up and disseminated a communications survey to the EATRIS community to integrate stakeholder feedback into future designs and activities.

Throughout 2020, EATRIS supported the communications of all of the projects we are involved in. Most notably, as part of the flagship EATRIS-Plus project the EATx online series was launched that showcases EATRIS to the world ("from institutes to experts, partners to projects") and embedded regular EATRIS-Plus content in our social media implementation schedule. For the ENRIITC project we designed, activated and promoted the #ENRIITCyourCoffee series, and continued to guide the communications on the project. On the BiC-BRIDGE Biomarker Commercialisation Project, we produced, edited, published and disseminated the "BiC Biomarker Commercialisation Project" video.

In addition to communicating about our projects, work began on setting up a new *EATRIS Communications Strategy* that takes a digital-first, multi-channel approach. The following priorities were identified: empowering our constituents (namely EATRIS nodes, institutes and scientists), simplifying our messaging, nurturing our existing community, growing our audience, adopting an implementation schedule and content policy, and co-designing our communications activities based on data and community input. The strategy has been set up as a live document that will evolve over time, and will be closely monitored with periodical analytics conducted across all platforms by the communications team.

The aforementioned communications survey, and subsequent follow-up interviews, indicated that the EATRIS website is an area needing considerable attention. Plans for conducting a series of focus groups with representatives from all of our stakeholder groups have begun. This will

allow us to identify what is needed before proceeding with a redesign.

The new communications team is very much looking forward to showcasing the brilliance of our infrastructure, enhancing the voice of EATRIS and ramping up the visibility of the organisation. Please reach out to Jake and Piret if you have any feedback, comments or ideas about how we can improve the way we present ourselves to the world... and don't forget to like and follow us on Twitter, LinkedIn, Facebook and YouTube.



Dr Jake Fairnie Head of Communications at EATRIS



Piret Pajula Junior Communications Manager at EATRIS

EDUCATION AND TRAINING

In 2020, EATRIS trained over 1,200 students, researchers, medical doctors, supporting staff and other stakeholders of translational research through webinars, e-learning, workshops and courses. The training offers support to our community in reaching our mission to support researchers in translating biomedical discoveries into patient benefit.

TransMed Academy, the e-learning platform powered by EATRIS

Launched in September 2019 and now counting over 270 users, EATRIS' very own e-learning platform offers biomedical researchers a better understanding of translational research and medicines' development. TRANSMED Academy provides open access to online courses and webinars on hot topics in translational medicine.

E-LEARNING - THE LANDSCAPE OF TRANSLATIONAL

Especially for the next generation of translational scientists (PhDs, Postdocs and MDs), we have developed an online course touching upon key aspects of translational research and medicines development. Participants will learn more about target validation, predictive models, biomarkers, clinical trials, intellectual property (IP) and European regulations through a variety of learning activities including reading assignments, videos, quizzes, interactive modules and mindmaps. Learning progress of each participant is monitored and upon successful completion of all modules and the final test, a certificate can be obtained. This course requires a time investment of approximately ten hours.

EATRIS WEBINARS

The webinar series on quality and reproducibility concluded with a webinar dedicated to issues related to clinical development in February 2020. The series highlighted best practices and discussed solutions for the identified bottlenecks. Two webinars dedicated to translational neuroscience were organised with NeurATRIS: "Innovating therapies for glial cells related



diseases" and "The role of microglia in health and disease". As glial cells were found to play major role in CNS development and interact with neurons, an exciting novel way to tackle nervous system diseases is to better understand their role. All webinars are also accessible on the EATRIS YouTube channel.

TMex winter school on translational medicine

On 26-30 October 2020, twenty-eight early-career scientists came together for the "Translational Medicine Explained" (TMex) winter school, kindly supported by VHIR and La Caixa Foundation. The course was held for the fifth time and for the first time entirely online. The winter 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. The course covered a variety of activities, including a drug discovery game, students' short presentations, group work and lectures. Experts in the field from academia and industry addressed essential elements of the translational pipeline such as assay guidance, target validation, target product profiles, clinical trials, patient-driven research and personalised medicine.

Several innovation sessions took place, covering the business canvas model, critical success factors in the translational pathway and regulatory aspects of drug development. The wide range of activity type and extensive use of interactive tools transformed the challenge of a full virtual five day course into a great opportunity to build a community of geographically and professionally highly diverse young translational scientists. The next edition will take place online on 8-12 November 2021.





A huge thanks to Rebecca and Lauranne for organising and conducting such an incredible course! It has been a truly wonderful and fun learning experience, and you made it work so fantastically in an online format. Thank you for all your hard work and the immense creative energy you put into this to make this a great success.

Rakenduvadhana Srinivasan (PhD student at University of Helsinki, Finland)

I really enjoyed my time on this course. The learning materials were well organised and well written. Most importantly, thank you for inviting all those lecturers that give me a new perspective about science and what "translation" means in science. Thanks Rebecca and Lauranne.

Giovanni Di Pinto (PhD student at Biodonostia HRI, Spain)

Thanks very much for spending the whole week with us. If this was a face-to face conference, we would be somewhat of a family! Lots of insight into different facets of the research.

Juan Espinosa-Pereiro (PhD student at VHIR, Spain)

ADVANCE

ADVANCE is an educational project that kicked off in November 2019 coordinated by EATRIS and funded by Erasmus Plus. Its aim is to train earlycareer biomedical scientists in the field of Advanced Medicine Therapy Products (ATMPs) development. It brings together six partners from academia, biotech industry and e-learning development, and will wrap up after 30 months in Spring 2022. In early April 2020 we publicly kicked off the ADVANCE project with our webinar programme and launched the online course in

December 2020. It is open to all and free of charge to anyone interested in the ATMPs development topic. The course consists of seven hours of interactive lectures and nearly 20 hours of independent assignments. It is self-paced, and participants can move through the course as their schedule allows. The course garnered a great deal of interest within the first couple of weeks from launch and had 360 registrants from 25 countries who had signed up to take the online course.



STUDENT SPOTLIGHT

Interiew with Juan Espinosa Pereiro, MD



Hello, I am Juan Espinosa Pereiro, MD. I am an Infectious Diseases Specialist currently working in Vall d'Hebron University Hospital, in Barcelona. I am also a PhD student at Vall d'Hebron Research Institute (VHIR), Universitat Autónoma de Barcelona.

HOW DID YOU FIND OUT ABOUT THE TMEX COURSE?

The course was offered to the PhD students from my institution. I also heard about it at some conversations in the EU Pacient Centric Clinical Trial Platforms (EU-PEARL) project, where EATRIS is also a partner.

PLEASE COULD YOU GIVE A GENERAL DESCRIPTION OF THE COURSE?

This is a subjective description, of course. The TMex course is a practical rollout through the Research and Development process, encompassing all the overlapping spheres of research, from bench to bedside, keeping in mind the final beneficiaries of any new therapy and the repercussion that the therapy and the research process in itself can have on society.

TELL US ABOUT YOUR EXPERIENCE DOING THE COURSE.

Although this year the course was online due to the coronavirus pandemic, and the intensive schedule was sometimes hard to follow in full focus, the wide scope of the themes addressed, the experience and knowledge of the instructors, and the fellow trainees from all over the world made it a unique (perhaps even rare) experience for learning, knowing people, and even have some material for intros.

WHAT WERE YOUR BIGGEST HIGHLIGHTS AND LEARNING **MOMENTS FROM THE COURSE?**

I am familiar with all the clinical stages of the research. In this area, the increasingly central role of patients and community advocates stands out as a must for any project. I think that this is something that in academia we are not very used to and even, in some aspects, we are somewhat reluctant to think about, as we are used to patients seeking our help. Happily, this vision of the patient-doctor relationship is changing quite fast in the daily practice and in academia research. Besides that, the biggest lesson for me was the importance of a good communication system, including social media and the use of a lay person language; we are used to explain things to patients in the clinic, but in research the academic bigotry often despises plain language.

HAVE YOU APPLIED ANY OF YOUR LEARNINGS FROM THE COURSE SINCE COMPLETING IT (EITHER WITHIN OR OUTSIDE OF ACADEMIA)?

Well, COVID-19 hasn't let us do much research since the course, but I have adopted some of the patient-centric ideas in protocols and other research documents. I have also stressed the need for improving the intertalk of our group with the community.

WOULD YOU RECOMMEND THE COURSE TO OTHERS? IF YES, WHY?

Yes. The course helps to set some basic concepts clear, to learn about some areas of the research and development process one is less used to, and to know that the PhD's problems are alike everywhere.

DID THE COURSE CHANGE THE WAY YOU ENVISIONED YOUR CAREER? IF YES, HOW SO?

Not in the main objectives: my vocation is that of a bedside clinician. But the course strengthened how I would like to become one who is able to answer those questions arising from the complex relationship with the patients with a rigorous and inclusive method.



Juan Espinosa, MD Vall d'Hebron University Hospital

The amounts stated below concerning the figures 2020 and 2019 have been derived from the audited financial statements 2019 and 2020 of EATRIS ERIC.

FIGURE 1 - IMPROVEMENT IN INCOME AND OPERATING RESULT

	Annual report 2020	Approved budget 2020	Annual report 2019
			€
Contributions income	1,664,608	1,555,000	1,727,651
Subsidy income	885,044	745,672	355,107
Total income	2,549,652	2,300,672	2,082,758
Salaries and wages	1,157,179	1,137,129	913,304
Recharge to EU projects	-546,704	-546,704	-202,088
Sub total staff	580,452	654,000	448,264
Personnel expenses	1,190,927	1,244,425	1,159,480
Depreciation	6,318	-	5,539
Other expenses	352,403	313,322	533,020
Other expenses "project costs EU"	742,376	742,376	299.914
Total expenses	2,292,024	2,300,123	1,997,953
Total operating result	257,628	549	84,805

In order to be able to properly compare the comparative figures with the budget, a reclassification has taken place with regard to the budget for EU projects.

The budget 2020 for EU projects is the salaries charged to projects plus the recharge for overhead costs to EU projects.

The total budget for 2020 concerning the EU projects is:

	2020 €
Subsidy income	745,672
Recharge to EU projects	546,704-
Other expenses "project costs EU"	742,376
Total budget EU projects according to the BoG reporting	550,000

FIGURE 2 – ANALYSIS OF THE BALANCE SHEET

Below we have included an analysis on the balance sheet as per 31 December 2020 versus 31 December 2019:

	2020	2019	Analysis
Activa	€′000	€′000	
Tangible fixed assets	17	17	The book value of the tangible fixed assets increased as a result of investments during 2020, plus regular depreciation.
Current receivables	372	583	
Cash at banks	2,014	1,380	Cash at banks increased mainly due to an increase current liabilities.
	2,402	1,980	
	2020	2019	Analysis
Equity & Liabilities	€′000	€′000	
Reserves	687	430	The reserve increased with a net of €257K, equal to the positive result of the financial year.
Current liabilities	1,715	1,551	The increase is caused by subsidy advance payments.
	2,402	1,980	



Anne-Charlotte
Fauvel
Head of EU Affairs



Anton UssiOperations & Finance
Director



Antonio (Toni)
Andreu
Scientific Director



Ben LydallFinance & Sustainability
Specialist



Camilla Santinelli Grants Administrator



Chris Tieken
Business
Development
Manager



David MorrowSenior Scientific
Programme Manager
ATMP and VIIM



Edwin van de Ketterij Clinical Project Director



Eliis Keidong EU Project Manager



Emanuela Oldoni Scientific Programme Manager Biomarker Platform



Florence Bietrix Head of Operations



Frank de Man Governance & Finance



Giovanni Migliaccio Regulatory Advisor

MEET THE C&S TEAM



Jake FairnieHead of
Communications



Lalageh Masihi Financial Controller



Laura BiziouOffice Assistant



Lauranne Duquenne Education & Training Manager



Laure Boudaud IT & Platforms Coordinator



Lisa Marie Williams Head of Administration



Martin de Kort Senior Scientific Programme Manager I&T and SM platforms



Nigel Wagstaff Advisor Innovation Support



Piret PajulaJunior Communications
Manager



Rebecca LudwigSenior Education and
Training Manager



Rosan Vegter
Training Manager**



Spyros Goudelis Communications Manager*



Tamara Carapina Senior Legal Counsel

COUNTRY	Board of Governors	Board of National Directors	National Coordinator
BULGARIA			
	Yanita Zherkova	Rossitza Konakchieva	
	Milena Glavcheva	Rumen Pankov	
CZECH REPUBLIC			
	Marta Vandrovcová	Marian Hajdúch	Miroslav Hutnan**
	Marian Hajdúch		
FINLAND			
	Sirpa Nuotio	Seppo Ylä-Herttuala	
	Riina Vuorento		
RANCE			
	Eric Guittet	Philippe Hantraye	Lauranne Duquenne***
	Simone Mergui	Simone Mergui	Emilie Hangen
ITALY			
	Maria Ferrantini	Franca Moretti	
	Francesca Capone	Francesca Capone	
LATVIA		r	
	Uldis Berkis	Liene Nikitina-Zake	
	Oldis Belliis	Uldis Berkis	
		Zaiga Nora-Krukle	
LUXEMBOURG		Zaiga Nora Ni aide	
LOXLINIBOOKG	Jean-Claude Milmeister	Frank Glod	Iris Egner
	Jean-Claude Militierster	FI di IK Gioù	IIIS Egilei
THE NETHERLANDS			
THE NETHERLANDS	Martintia Daldort	Cowit Mailor	
	Martijntje Bakker*	Gerrit Meijer	
	Saco de Visser	Jan-Willem Boiten	
NORWAY			
	Marianne Gronsleth	Janna Saarela	Anita Kavlie
PORTUGAL			
	Rui Santos Ivo	Claudia Maria Coelho de Faria (Chair)	Dinah Duarte
	Helena Baião	ue i and (Chail)	Helena Baião
SLOVENIA	חפופווט שטוטט		пенена ВанаО
SLOVENIA	Alle in IZee Ii	James Milianai' - D	Ž: !-!'
	Albin Kralj	Irena Mlinaric-Rascan	Žiga Jakopin
	Irena Mlinaric-Rascan		
SPAIN			
	Gonzalo Arévalo Nieto	Joan Comella	Marta Marin
	Cristobal Belda	Fatima Nunez	
SWEDEN			
	Maria Nilsson	Pontus Aspenström	Ulrika Bäckman
	Håkan Billig (Chair)		

LIST OF ABBREVIATIONS

- AI Artificial Intelligence

> **ATMP Advanced Therapy Medicinal Products**

BBMRI-ERIC Biobanking and BioMolecular Resources Research Infrastructure

BMS RI Biological and Medical Research Infrastructures

BoG Board of Governors BoND Board of National Directors

BPRC Biomedical Primate Research Centre

C-COMEND Competency-based course on Translational Research and Medicines

Development

CAR-T Cell Chimere Antigen Receptor Cell

CDRD Centre for Drug Research and Development

CEST/MRI Chemical Exchange Saturation Test - Magnetic Resonance Imaging

— CORBEL Coordinated Research Infrastructures Building Enduring Life-Science Services

E&T **Education and Training**

EANM European Association of Nuclear Medicine

EARL EANM Research Ltd.

EATRIS -C&S EATRIS Coordination and Support Office

EATRIS European Infrastructure for Translational Medicine

EC **European Commission**

ECRIN European Clinical Research Infrastructure Network

EFPIA European Federation of Pharmaceutical Industries and Associations

EIC European Innovation Council EMA European Medicines Agency

EMMRI Executive Masters in Management of Research Infrastructures

EPF European Patients' Forum

EPTRI European Paediatric Translational Research Infrastructure

EOI **EATRIS Quality Initiative ERA** European Research Area

European Research Infrastructure Consortium **ERIC**

ESFRI The European Strategic Forum for Research Infrastructures

European Society for Medical Oncology FSMO

FU European Union

EU-AMRI Alliance of Medical Research Infrastructures

EUPATI European Patients' Academy on Therapeutic Innovation **EURIPRED** European Infrastructure for Poverty-Related Diseases

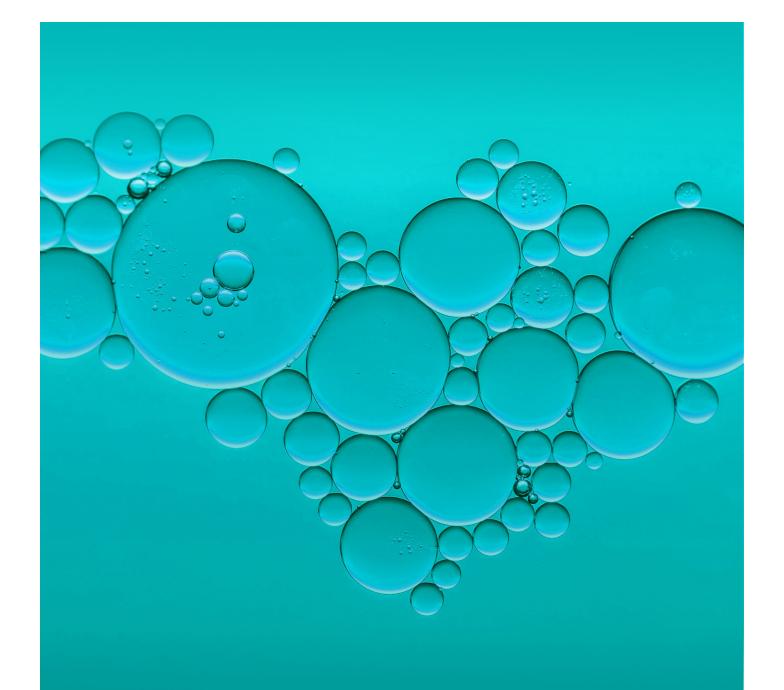
EVI European Vaccine Initiative

G -**GDPR** General Data Protection Regulation

GSK GlaxoSmithKline HE Horizon Europe

> Health and Environment Sciences Institute **HFSI**

HTA Health Technology Assessment HTS High Throughput Screening



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