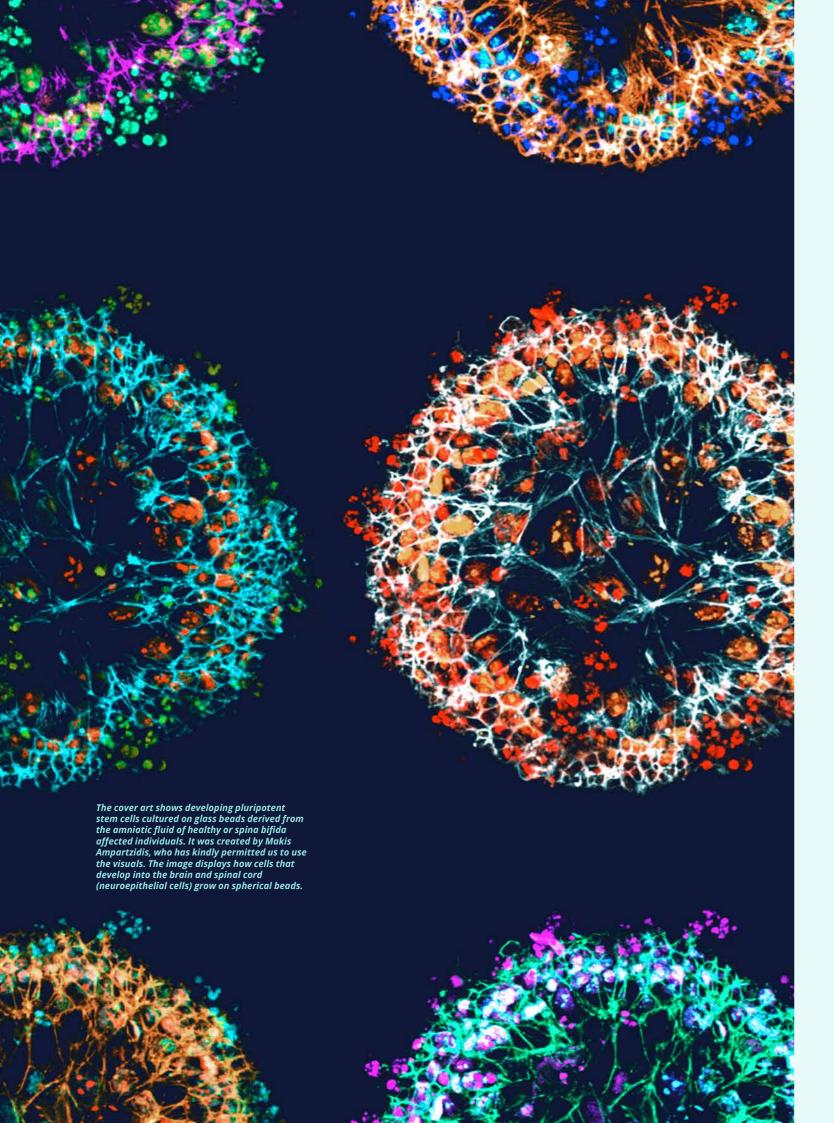
# **Annual Report**





#### With thanks to our funders and partners







University of Oslo\*





Research Council of Norway\*

REPUBLIC OF SLOVENIA MINISTRY OF HIGHER EDUCATION, SCIENCE AND INNOVATION

REPUBLIC OF SLOVENIA

Ministry of Higher Education Science and Innovation

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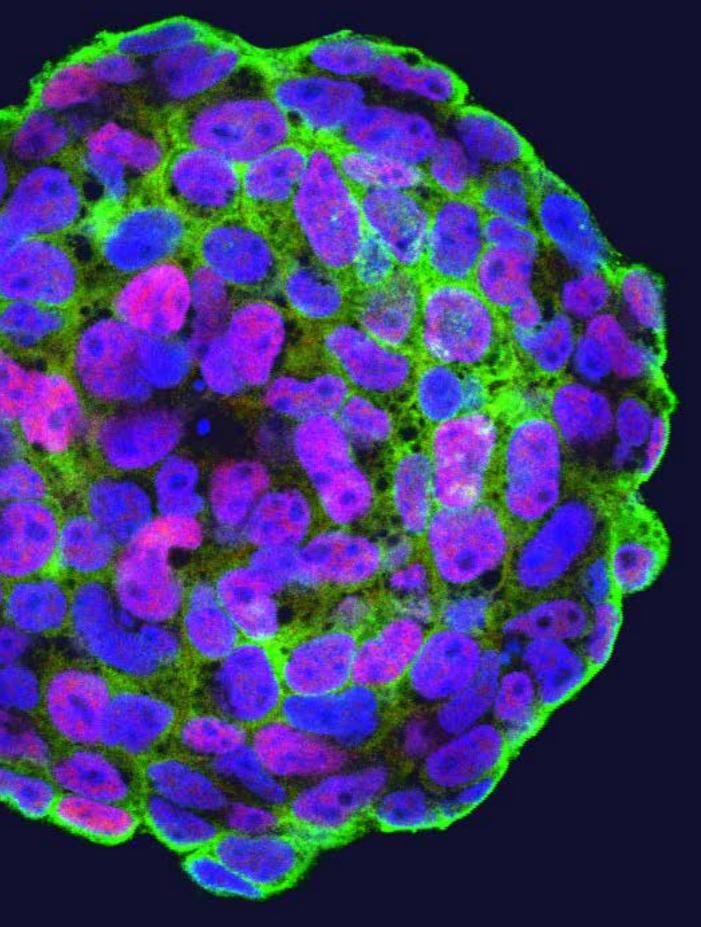
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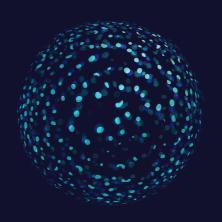
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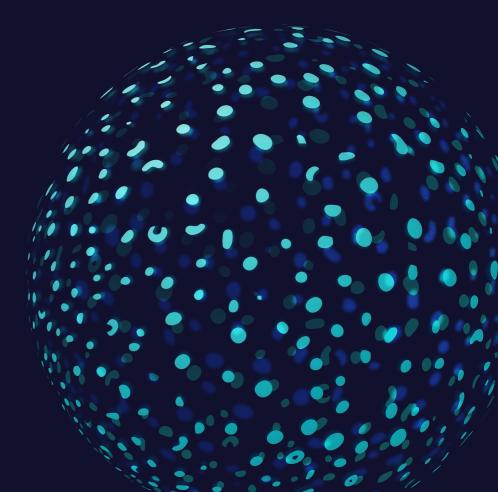
meet the community

abbreviations



# foreword





Helena Isla Magrané - Rosa de cèl·lules mare 2020

eatris foreword eatris foreword

# Joint Foreword from EATRIS Boards







Claudia Faria Chair of Board of National Directors



**Anton Ussi** *Operations & Finance Director* 



**Toni Andreu** *Scientific Director* 

#### Dear reader,

We are pleased to present the 2023 Annual Report, setting out the achievements and advancements made in the first decade of EATRIS' life, while presenting new, exciting initiatives set in place promising an even more productive future.

In January 2023 we launched the Strategic Plan 2023-2026, along with EATRIS' new tagline "Science beyond barriers. Medicine beyond borders." Formed around six pillars this structures the ongoing development of our capacities and nurturing of broad communities to enhance the field of translational medicine.

We were delighted to welcome two new countries as full Members of the EATRIS infrastructure, Croatia and Latvia. By the end of 2023, all 14 National Nodes had developed Node Strategic Plans that were added to the EATRIS Long-Term Sustainability Plan. The synergy of the expertise and productivity of the National Nodes and Institutes is key to EATRIS' performance and this was further developed with a capacity-building programme including 10 professional workshops and a broad Staff Exchange Programme. Moreover, the Expert Centre Initiative commenced with the appointment of seven Expert Centres at selected Institutions to provide high value added services such as innovation management, technology assessment and regulatory support and road-mapping.

During the year, new crucial resources were launched to provide guidance and information to stakeholders: PERC, the "Patient Engagement Resource Centre", a platform created to provide training for researchers to enable and optimise meaningful patient engagement, and the Multi-omics Toolbox, a resource for researchers that provides validated resources related to multi-omics analysis. In addition, the EJP RD Innovation Management Toolbox (IMT), which the EATRIS team designed and co-developed, providing a library of resources for rare disease innovation..

In November, EATRIS celebrated its 10th anniversary of becoming a European Research International Consortium (ERIC), with over 200 attendees from a broad spectrum of stakeholders at a two-day celebration at the Museon-Omniversum in The Hague. At this event we reflected on and celebrated the achievements and developments of the past decade, and, more importantly, shared thoughts and plans for the future.

Everything EATRIS achieves is in concert with other parties – researchers, patients, healthcare providers, funders, charities, businesses, regulators, and the true measure of our success lies in the value we bring to all of these partners, which we gauge by seeking feedback and which is reflected in their willingness and enthusiasm to further cement our working relationships and foster new and innovative collaborations.

Reflecting our truly multi-sectoral approach, two very exciting long term collaboration agreements were inaugurated, with the European Organization for Nuclear Research (CERN), and with C-Path (Critical Path Institute). The long-term partnership with CERN offers unparalleled opportunities to develop innovative technologies arising from the experimental physics community in applications in health and life sciences, while working with C-Path offers great opportunities to address regulatory, technical and operational issues in drug development, leading to better patient outcomes.

As we grow and mature, we recognise that EATRIS' goals are shared goals, with patients, researchers, business, regulators, charities, healthcare providers, and we are committed to working more and more closely with them all to continue to advance Europe's innovation capacity. In so doing, we can realise our vision of a future with efficient translational research serving society with high impact precision medicine interventions.

EATRIS institutes across Europe have created a unique community of practice where science becomes a game changer for a better society. Dedicated members of the EATRIS family are tirelessly driven by a unique passion we all share: to alleviate human suffering, to bring novel solutions for the sick and to pave the way for a healthier future. At the end of the day, this is not about machines, test tubes, biopsies and molecular biology techniques. It is about the inspirational power of science as the transformative energy of human development and a community that has the ambition of passing the torch to the next generation for creating a healthier society.

Jelena Ilić-Dreven, Chair of Board of Governors Claudia Faria, Chair of Board of National Directors Anton Ussi, Operations & Finance Director Toni Andreu, Scientific Director

# highlights

#### Timeline of key moments in 2023



New EATRIS Strategic Plan Launches: "Science beyond barriers. Medicine beyond borders."

Science beyond barriers, Medicine beyond borders

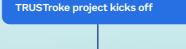


Impact Assessment of **Research Infrastructures** workshop publishes report



Patient Engagement Resource Centre (PERC) Launches







SIMPATHIC project kicks off



**EJP RD Innovation Management** Toolbox (IMT) recognised as an IRDiRC Resource



C-Path and EATRIS sign collaboration agreement aimed at fostering actionable scientific and educational cooperation



EATRIS joins forces with CERN to accelerate translational medicine and healthcare innovation for patient benefit



Ireland takes significant step towards collaboration with EATRIS



EATRIS celebrates a decade as the European infrastructure for translational medicine



























120 people from 26 countries

attend EATRIS patient

engagement webinar

Cell and gene therapies online course is launched



**EATRIS** appoints 7 **Expert Centres** 



EATRIS joins European health organisations to define **EHDS** opt-out clause



Latvia becomes a full member of EATRIS



**ESFRI Industry Cooperation** Report highlights EATRIS



**EATRIS** and the REMEDi4ALL consortium initiate new study to advance a potential treatment for multiple sulfatase deficiency (MSD)



"IT'S TIME WE TALK ABOUT



eatris Now live!



Multi-omics Toolbox (MOTBX) launches to empower multi-omics researchers

#### 2023 in numbers

144 **SCIENTIFIC PAPERS**  **PROPOSALS SUBMITTED** 

**WITH EATRIS AS PARTNER** 

**PROJECTS GRANTED WITH EATRIS INVOLVED** 

894 **TRANSLATIONAL** 

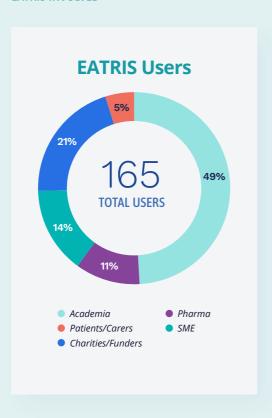
**SCIENTISTS** 

101 **EXPERT ADVICES AND MENTORING PERFORMED** 

165 SERVICE REQUESTS 151 **INSTITUTIONS OF WHICH OVER HALF ARE MEDICAL** 

PUBLIC-PRIVATE PARTNERSHIP HUB WITH A PHARMA COMPANY

**SERVICE REQUESTS** HANDLED WITH BIOTECH COMPANIES



#### **Overview of funding granted in 2023:**

€397,248

€55,875 €341,373 **RESEARCH SERVICES GRANTS** 

#### **EATRIS Online**



4,248,504

#### **Social Media**

2,513

**FOLLOWERS** 

I 519 POSTS





CONNECTIONS

I 517 POSTS

4,379

226

**FOLLOWERS | 516 POSTS** 



490 **SUBSCRIBERS** 68 VIDEOS

#### **Participation in EATRIS Events**

**EDUCATION &** TRAINING EVENTS

**†**1,050

**EATRIS PATIENT ENGAGEMENT WEBINAR** 

**†120** 

**EATRIS 10 YEAR ANNIVERSARY CELEBRATION IN THE HAGUE** 

**EATRIS-PLUS SUMMER SCHOOL PARTICIPANTS** 

**†**33

# infrastructure

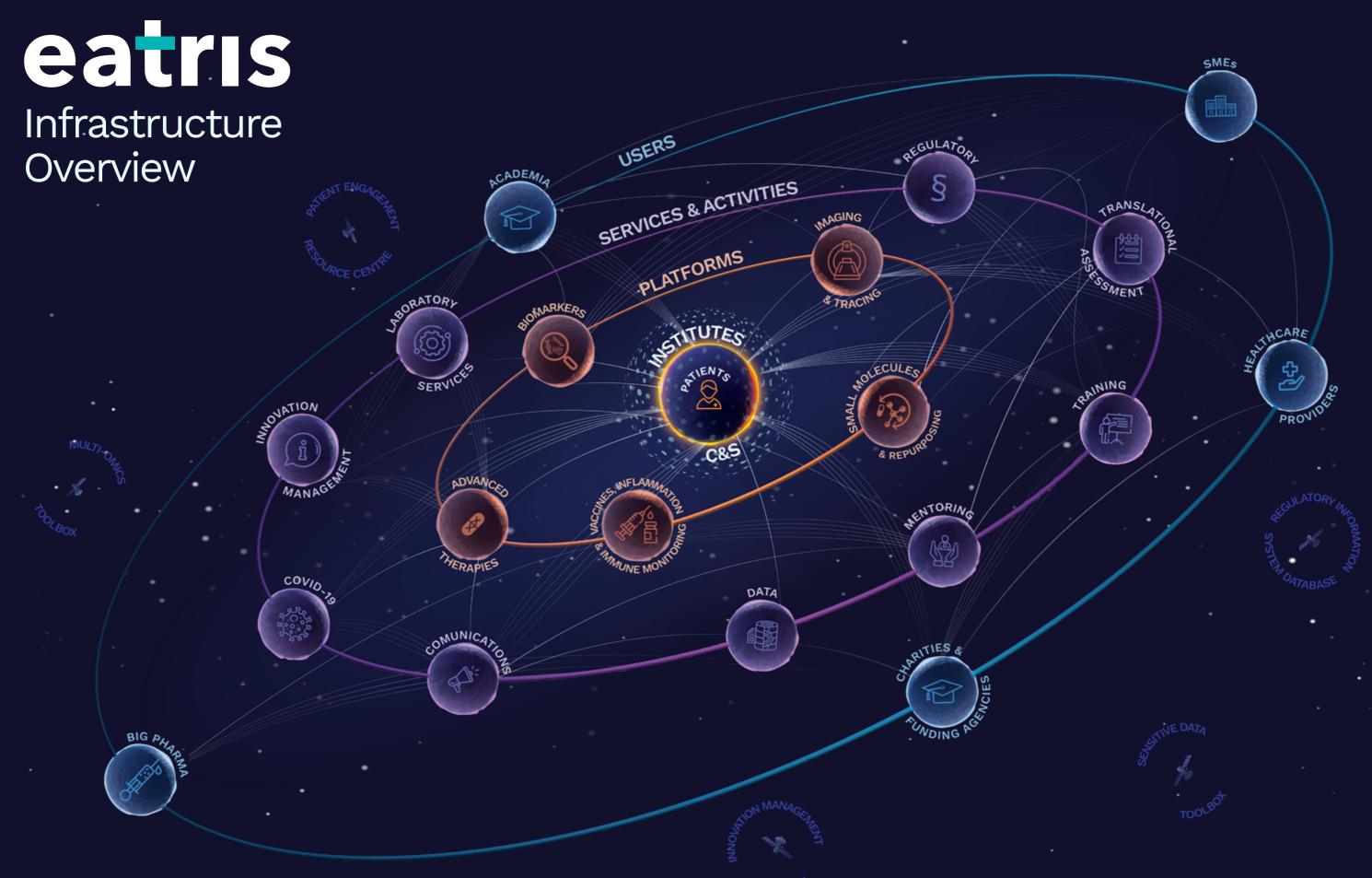
# Map of Participating Countries and Institutes

Participating countries: Bulgaria, Croatia, Czech Republic, Finland, France, Italy, Latvia, Luxembourg, the Netherlands, Norway, Portugal, Slovenia, Spain and Sweden.

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



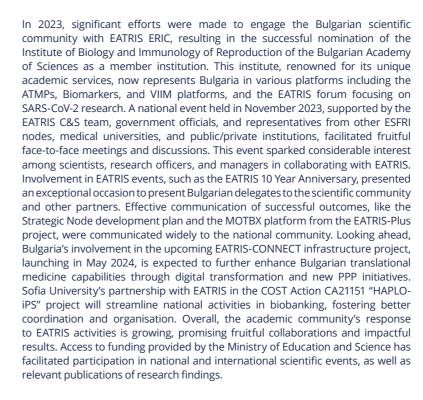
Member states of EATRIS



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# updates from member states







BOARD OF GOVERNORS REPRESENTATIVE Yanita Zherkova



NATIONAL DIRECTOR Rossitza Konakchieva



NATIONAL COORDINATOR Georgi Georgiev

In 2023, EATRIS Bulgaria was involved in the following successful funding proposal:

EATRIS-CONNECT

EATRIS Bulgaria took part in 8 education and training activities in 2023 involving 12 participants.

EATRIS Bulgaria is involved in the following ongoing projects:

EATRIS-Plus

#### **EATRIS Bulgaria consists of 3 institutes:**

- Institute of Biology and Immunology of Reproduction, Bulgarian Academy of Sciences (IBIR-BAS)
- National Center of Infectious and Parasitic Diseases (NCIPD)
- Sofia University

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**#EATRIS HR #EATRIS CZ** eatrıs eatris



In 2023, Croatia became a full member of EATRIS, A National Coordinator was appointed to lead our engagement with the infrastructure. UZSM organised a meeting with five other research institutions, resulting in six applications submitted for EATRIS platforms. Although a Horizon Europe proposal led by UZSM and EATRIS did not secure funding, it received an impressive score of 13.5. Looking forward, UZSM remains a key partner in the upcoming EATRIS-CONNECT project launching in 2024, promising further advancements in Croatia's translational research landscape.



**BOARD OF GOVERNORS** REPRESENTATIVE Jelena Ilić-Dreven



**NATIONAL DIRECTOR** Fran Borovečki



NATIONAL COORDINATOR Lozika Mašić

**EATRIS Croatia was involved in the following** successful funding proposal in 2023:

EATRIS-CONNECT

EATRIS Croatia took part in 4 education and training activities in 2023 involving 13 participants.

**EATRIS Croatia is involved in the** following ongoing projects:

• EATRIS-Plus

20

Croatia became a full member of EATRIS in 2023 and is coordinated by the University of Zagreb School of Medicine (UZSM).



#### Czech Republic

In 2023, EATRIS-CZ continued to provide services to users both within the Czech Republic and internationally. We advanced a phase I clinical trial for 68Ga-desferioxamine in collaboration with Innsbruck Medical University, using it as a tracer for imaging bacterial infections. Our ongoing clinical trials saw increased recruitment, and we contributed to mapping the Czech multiome by providing biological materials, data, and data management support for EATRIS institutions within the H2020 project EATRIS-Plus. Additionally, we completed metabolomic profiling of 1,000 individuals and plasma proteome profiling of approximately 400 individuals. The Research Infrastructure (RI) developed and implemented proprietary software, LabScheduler, for monitoring RI use and booking instrumentation, and continued developing tools for (pre)clinical data stewardship, now available to users as open access. Significant efforts were made to secure our IT systems, resulting in ISO 27001 certification for the management of GDPR-sensitive data. Our IT team also contributed to the preparation of EOSC-CZ activities, particularly in multiomic and sensitive data management. This year we also initiated a comprehensive breath biomarker validation clinical study, "Study of Early Cancer Biomarkers in Breath Condensate in a Population of Individuals With High-Risk of Lung Cancer Undergoing LDCT Screening," aiming to enrol 3,000 individuals.



**BOARD OF GOVERNORS** REPRESENTATIVE Judita Klosakova



**NATIONAL** DIRECTOR Marian Hajdúch



**NATIONAL COORDINATOR** Katerina Sromova

**EATRIS Czech Republic was involved in the** following successful funding proposal in 2023:

EATRIS-CONNECT

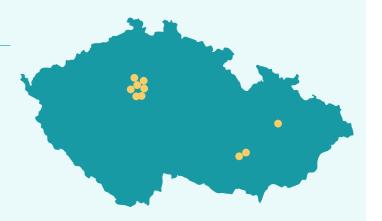
**EATRIS Czech Republic took part in 14 education** and training activities in 2023 involving 38 participants.

**EATRIS Czech Republic is also involved in the** following ongoing projects:

- EATRIS-Plus
- EOSC-Life
- TRANSVAC2
- canSERV
- EOSC4Cancer
- **EATRIS Czech Republic consists of 11 institutes:**
- Central European Institute of Technologies (CEITEC)
- Charles University

- Institute of Chemical Technologies Prague
- Institute of Experimental Medicine AS CR
- Institute of Macromolecular Chemistry Prague (IMC ASCR)
- Institute of microbiology of the AS CR, v.v.i

- Institute of Organic Chemistry and Biochemistry, Czech Academy of Sciences
- Masaryk University
- Nuclear Physics Institute of the ASCR/UJF, v. v. i.
- Palacky University Institute of Molecular and Translational Medicine (IMTM)
- St. Anne's University Hospital Brno



#EATRIS FI eatris #EATRIS FR



Activities concentrating on high-quality ATMP materials including vectors and cell materials, precise immunological methods, accurate PET imaging services with novel ligands, GMP manufacturing and preclinical GLP safety and efficacy studies have been in the focus of EATRIS-Finland in 2023.

Examples of successful translational work of EATRIS-Finland partners include recent approval by FDA of adenovirus-based bladder cancer gene therapy (Adstiladrin, developed and manufactured in National Virus Vector Laboratory and its spin-off company FinVector Oy), technology transfer for local manufacturing for clinical cell therapy phase 1/2 trial by Finnish Red Cross Blood Service, several validated new PET tracers developed and tested in Turku PET Center (e.g. discovery of 68Ga-DOTA-Siglec-9 for imaging inflammation and participation to a multicenter clinical trial of diagnostic prostate cancer tracer 18F-rhPSMA-7.3), recent establishment of Rokote Laboratories Finland Oy for the development intranasal COVID-19 next generation adenoviral vaccine and tissue transplant products for bone defects developed by Regea.

Thus, EATRIS-Finland has an excellent international standing and track record in its service areas offered to Finnish and international customers via the EATRIS-ERIC and EATRIS-Finland infrastructure network.



BOARD OF GOVERNORS REPRESENTATIVE Sirpa Nuotio



NATIONAL DIRECTOR Seppo Ylä-Herttuala



NATIONAL COORDINATOR Petri Mäkinen

EATRIS Finland was involved in the following successful funding proposal in 2023:

EATRIS-CONNECT

EATRIS Finland took part in 8 education and training activities in 2023 involving 13 participants.

EATRIS Finland was involved in the following ongoing projects:

- EATRIS-Plus
- ISIDORe
- EOSC-Life
- REMEDi4ALL
- iRISE

#### **EATRIS in Finland consists of 6 institutes:**

- 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)





In 2023, NeurATRIS' activities focused mainly on strengthening training and teaching in the field of translational neuroscience, supporting academic research through calls for projects that promote new collaborations between NeurATRIS members and the scientific community involved in neurodegenerative and neurodevelopmental diseases, and making our platforms and cutting-edge skills available to new academic and industrial partners. Our actions enabled 48 students to attend international conferences, workshops and specialised programmes, 4 Masters students and 2 PhD students to finance their internship or fourth year PhD in our laboratories. We also spearheaded the development of novel methodological approaches, including machine learning tools for predicting clinical scores from short voice recordings and pioneering nonhuman primate models of synucleinopathies, addressing critical challenges in neurodegenerative and developmental diseases. NeurATRIS remained actively engaged in major national and European programmes, contributing to the advancement of neuroscience research and maintaining our scientific productivity with 118 publications. In summary, NeurATRIS continued to drive impactful research, nurture talent, and foster collaborations, positioning itself at the forefront of translational neuroscience in 2023.



BOARD OF GOVERNORS REPRESENTATIVE Catherine Le Chalony



NATIONAL DIRECTOR Philippe Hantraye



NATIONAL COORDINATOR Emilie Hangen

EATRIS France was involved in the following successful funding proposal in 2023:

EATRIS-CONNECT

EATRIS France took part in 18 education and training activities in 2023 involving 73 participants.

EATRIS France is involved in the following ongoing projects:

- EATRIS-Plus
- RITIFI
- iNEXT-DISCOVERY
- TRANSVAC2
- ISIDORe
- TRANSVAC-DS
- **EATRIS in France consists of 5 institutes:**
- 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)



**#EATRIS IT #EATRIS LV** eatrıs eatris



Throughout 2023, our primary focus was on education and training initiatives, organising and participating in numerous meetings, workshops, and courses. Notably, we sustained dialogue with ECRIN and BBMRI National Node coordinators to finalise collaborative activities for the year. We prioritised Education & Training to spotlight the impactful contributions of the three Infrastructures. Hosting two workshops titled "Tools offered by BBMRI, EATRIS and ECRIN to support the construction and development of European projects" in May and December, we disseminated insights via Zenodo. These events aimed to showcase the RI activities, enhancing support for biomedical research in Europe. Additionally, we actively engaged in multiple national and international events organised by EATRIS. This included participation in events such as Industria e tto network: il ruolo dei brevetti e dell'informazione brevettuale in Napoli, the ADVANCE course in Ljubljana, EATRIS National Nodes' meetings, the National Coordinator workshop on impact assessment, and the EATRIS webinar on regulatory knowledge.



**BOARD OF GOVERNORS** REPRESENTATIVE Francesca Capone



**NATIONAL DIRECTOR** Franca Moretti

EATRIS Italy was involved in the following successful funding proposals in 2023:

- EATRIS-CONNECT
- ERDERA

EATRIS Italy took part in 19 education and training activities in 2023 involving 107 participants.

#### EATRIS Italy was involved in the following ongoing projects:

- EATRIS-Plus
- EOSC-Life
- BY-COVID
- EDITSCD
- EIP RD
- ERICA
- EUCAIM

- EU-PEARL ISIDORe
- canSERV
- REMEDi4ALL RECOGNISED
- SIMPATHIC
- TRUSTroke

#### **EATRIS in Italy consists of 25 institutes:**

- Centro di Riferimento Oncologico di Aviano (CRO Aviano)
- Centro Medicina Rigenerativa (CMR)
- CNCCS IRBM Science Park
- Fondazione IRCCS CRIBT
- Fondazione IRCCS Fondazione Pascale

- Fondazione IRCCS Giovanni Paolo II
- Fondazione IRCCS Istituto Nazionale dei Tumori (INT-Milan)
- Fondazione IRCCS Ospedale Pediatrico Bambino Gesù
- Fondazione IRCCS SDN per la Ricerca e l'Alta
- Formazione in Diagnostica Nucleare
- IDI-Fondazione IRCCS Luigi Maria Monti
- IRCCS Foundation Santa Lucia IRCCS Istituto Giannina Gaslini (IGG)
- IRCCS Istituto Ortopedico Galeazzi

- 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)
- Fondazione Policlinico Universitario A. Gemelli IRCCS
- IRCCS Istituto Giannina Gaslini (IGG)
- University Milano-Bicocca (UNIMIB)





In 2023, Latvia became a full member of EATRIS, demonstrating our commitment to advancing translational research in Europe. This significant achievement was largely attributed to the consistent and effective communication efforts of Rīga Stradiņš University (RSU) with the Ministry of Education and Science. Throughout the year, Latvia engaged in several noteworthy activities to foster collaboration and strengthen its position within the EATRIS infrastructure. A key highlight was the hosting of an online Grant Writing Workshop in January 2023, where Latvia provided participants with essential skills for securing research funding. Additionally, fruitful scientific cooperation meetings were held with Centrālā Laboratorija, the Latvian Network of Patient Organisations, and the Biocatalyst Foundation, exploring potential areas of collaboration within the EATRIS-Plus framework. Efforts were also made to formalise collaboration through the development of draft Memoranda of Understanding (MoUs) between RSU and key stakeholders. Notably, RSU organised the Latvian node event for patient engagement in June 2023 as part of the EATRIS-Plus project, highlighting our dedication to involving patients in translational research.



**BOARD OF GOVERNORS** REPRESENTATIVE Uldis Berkis



**NATIONAL** DIRECTOR Liene Nikitina-Zake



**NATIONAL COORDINATOR** Zaiga Nora-Krukle

**EATRIS** Latvia was involved in the following ongoing project

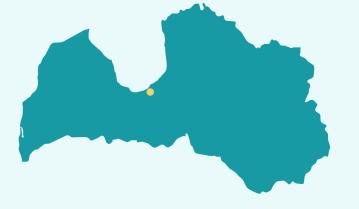
EATRIS-CONNECT

EATRIS Latvia took part in 9 education and training activities in 2023 involving 19 participants.

**EATRIS Latvia was involved in the following** successful funding proposal in 2023:

EATRIS-Plus

Latvia became a full member of EATRIS in 2023 and is coordinated by Riga Stradins University (RSU).



#EATRIS LU eatris #EATRIS NL



In 2023, the Luxembourg node was steadfast in its commitment to advancing ongoing projects with a focus on patient-centricity and aligning with cutting-edge biomedical research. Leveraging transformative technologies like big data, artificial intelligence, and machine learning, our research aimed for academic excellence. A key initiative, Clinnova, was launched to establish a 'Centre of Excellence in Digital Health and Personalised Healthcare'. Concurrently, we prioritised activities fostering patient and public Involvement, in line with EATRIS priorities. The EATRIS-Plus project bore fruit, amplifying our contributions to numerous publications and fortifying our node's growth and sustainability. The 2023 EATRIS Stakeholder Meeting was a resounding success, showcasing our Translational Medicine Operations Hub (TMOH) developments to our national stakeholders. In summary, our efforts in 2023 underscore our dedication to advancing biomedical research through patient welfare and collaborative innovation, ensuring Luxembourg remains at the forefront of transformative healthcare solutions in Europe.



BOARD OF GOVERNORS REPRESENTATIVE Jean-Claude Milmeister



NATIONAL DIRECTOR Frank Glod



NATIONAL COORDINATOR Catherline Nannan

EATRIS Luxembourg is involved in the following ongoing project:

• EATRIS-Plus

EATRIS Luxembourg was involved in the following successful funding proposal in 2023:

EATRIS-CONNECT

EATRIS Luxembourg took part in 12 education and training activities in 2023 involving 46 participants.

#### **EATRIS in Luxembourg consists of 3 institutes:**

- Integrated Biobank of Luxembourg (IBBL, LIH)
- Luxembourg Institute of Health
- Luxembourg Center of System Biomedicine



#### The Netherlands

In 2023, Health-RI and FAST (Centre for Future Affordable and Sustainable Therapy development) together made progress towards creating an integrated national infrastructure for health research and innovation under EATRIS-NL. Health-RI, in partnership with ELIXIR-NL and BBMRI-NL and supported by NFU, continued to oversee EARTIS-NL operations. Highlights for 2023 include:

- Securing €47M funding until 2028, marking the completion of early milestones and ensuring financial stability.
- Conducting interviews with the five EATRIS platform Chairs to identify active institutes, contacts, and priority topics.
- Participation in establishing the Dutch Health Data Access Body for the European Health Data Space (EHDS), alongside the development of an integrated national health data architecture.
- Forging multi-year collaboration agreements with all Dutch medical centers, fostering deeper engagement with the scientific communities involved in EATRIS.
- Contribution to the EATRIS-CONNECT project proposal, aiming to integrate services offered by other Research Infrastructures.
- Prominent presentation of EATRIS at the Health-RI national conference.
   With EATRIS, FAST initiated a network infrastructure of communities focusing on rare diseases, drug repurposing, and infectious diseases to support therapy development, fostering innovative collaborative models. These communities will be connected to the EATRIS network and platforms. ZonMw's active involvement in REMEDi4ALL with various Dutch parties further underscores efforts towards unlocking the potential of drug repurposing.



BOARD OF GOVERNORS REPRESENTATIVE Saco de Visser



NATIONAL DIRECTOR Gerrit Meijer



NATIONAL COORDINATOR Lifang Liu

#### EATRIS Netherlands was involved in the following successful funding proposals in 2023:

- EATRIS-CONNECT
- ERDERA

EATRIS Netherlands took part in 24 education and training activities in 2023 involving 217 participants.

#### EATRIS Netherlands is involved in the following ongoing projects:

- EATRIS-Plus
- EOSC-Life
- EU-PEARL
- BY-COVID
- EOSC4Cancer
- REMEDi4ALL
- EJP RD

- ERICA
- EUCAIM
- iNEXT-DISCOVERY
- iRISE
  - ISIDORe
  - TRANSVAC2
  - TRANSVAC-DS

#### **EATRIS** in the Netherlands consists of 14 institutes:

- Amsterdam UMC Academic Medical Centre (AMC)
- Amsterdam UMC VU Medical Center (Vumc)

- Biomedical Primate Research Centre (BPRC)
- Erasmus University Medical Centre
- Intravad
- Leiden University Medical Centre (LUMC)
- Maastricht University Medical Center (MUMC)
- Netherlands Cancer Institute
- TNO
- 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



**#EATRIS NO #EATRIS PT** eatrıs eatris



In 2023, EATRIS-Norway reaffirmed its commitment as a member until at least 2025. Two national ATMP capacity mapping events were held to explore the formation of a Nordic ATMP Hub. Notable gatherings included a Nordic EATRIS strategy meeting in Oslo and the inaugural Nordic ATMP meeting in Uppsala. Utilising the node reward from 2022. Norwegian scientists' participation was supported in these events. Collaborative efforts were evident through two national events organised together with BBMRI, ECRIN, and ELIXIR. Our national coordinator engaged in various outreach activities, presenting at international events such as the Mohn Research Center of Regenerative Medicine and the NCMM annual retreat. EATRIS Norway actively participated in numerous events including EATRIS BoND meetings, the 10-year anniversary conference, and Nordic Life Science days. Oslo University Hospital and Universities of Oslo and Bergen joined consortia like the European Rare Disease Partnership and two COST actions, RealiseD and EATRIS-CONNECT. Further leveraging EATRIS resources, our involvement extended to the European Joint Program on Rare Diseases, providing mentoring for scientists who passed the first stage of the JTC2023 call. EATRIS Norway remains committed to fostering collaboration, advancing research, and enhancing expertise in the Nordics.



**BOARD OF GOVERNORS** REPRESENTATIVE Marianne Grønsleth



**NATIONAL DIRECTOR** Janna Saarela



NATIONAL COORDINATOR Anita Kavlie

**EATRIS Norway was involved in the following** successful funding proposals in 2023:

- EATRIS-CONNECT
- ERDERA

EATRIS Norway took part in 13 education and training activities in 2023 involving 29 participants.

**EATRIS Norway is involved in the** following ongoing projects:

- EATRIS-Plus
- BY-COVID
- EIP RD
- EOSC4Cancer
- ISIDORe
- canSERV

#### **EATRIS in Norway consists of 4 institutes:**

- 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





In 2023, the EATRIS Portuguese Node, led by Infarmed, remained steadfast in its commitment to advancing the main goals of EATRIS. Our national institutions reaped significant benefits from EATRIS participation, fostering collaborations, consortia involvement, and successful grant applications, while leveraging and providing services through the network. Emphasising training and education to align with EATRIS's mission, we organised the third edition of the EATRIS-Plus Summer School in Lisbon in collaboration with the University of Ljubljana and EATRIS C&S. The event attracted a diverse audience from 12 countries, including participants from Kenya, Nigeria, and Somalia. With a focus on personalised medicine, the programme covered various topics such as multimodal biomarkers, digital health, and ethical considerations, fostering fruitful discussions, knowledge sharing, and networking. Additionally, EATRIS-PT held its annual meeting at Infarmed, bringing together all national node institutions to share achievements, discuss future plans, and enhance synergies and collaborations. Notably, institutions secured funding from national and European projects, resulting in high-impact publications. Furthermore, three Portuguese node institutions were recognised as EATRIS Expert Centers, providing support in areas including health technology assessment and innovation management.



**BOARD OF GOVERNORS** REPRESENTATIVE Rui Santos Ivo



**BOARD OF GOVERNORS** REPRESENTATIVE Carlos Alves



**NATIONAL DIRECTOR** Claudia Faria



NATIONAL COORDINATOR Helena Baião

#### **EATRIS Portugal was involved in the following** successful funding proposal in 2023:

EATRIS-CONNECT

**EATRIS Portugal took part in 17 education** and training activities in 2023 involving 84 participants.

#### **EATRIS Portugal is involved in the** following ongoing projects:

- EATRIS-Plus
- iNEXT-DISCOVERY
- ISIDORe
- TRANSVAC2
- canSERV
- TRANSVAC-DS

#### **EATRIS in Portugal consists of 16 institutes:**

- 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 Investigacao e Inovacao em Saude (i3S)
- Instituto de Medicina Molecular Ioão Lobo Antunes (IMM)
- Instituto Pedro Nunes (IPN)
- 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)
- University of Beira Interior, Health Sciences Research Center (CICS-UBI)
- VectorB2B



**#EATRIS SI #EATRIS ES** eatrıs eatris



In 2023, EATRIS-Slovenia was involved in the events held under the EATRIS-Plus project. EATRIS SI was co-organiser of the EATRIS-Plus Summer School in Personalised Medicine held in Portugal. With the Slovenian Pharmaceutical Society, we co-organised a symposium on "Crossing the Boundaries of Medicinal Chemistry" in Liubliana. We carried out three doctoral student exchanges and prepared a strategic plan for the EATRIS node until 2030. EATRIS SI continued with training activities in the field of ATMPs by obtaining the NOO ULTRA project. Within this framework, EATRIS SI co-organised a live workshop and recorded content for online courses. EATRIS SI was further involved intensively on the REMEDi4ALL project including preparing an interactive workshop entitled "In silico tools in drug development." EATRIS SI was also involved in the SIMPATHIC project and in the application preparation for the EATRIS-CONNECT project. We presented EATRIS at several events, including at the 2023 ADVANCE Summer School, the 2023 Advanced Therapies Congress in London, the World Congress of Basic and Clinical Pharmacology in Glasgow, and the Kemomind Science Conference in Zagreb. In 2023, University of Ljubljana, Faculty of Pharmacy (UL FFA; an EATRIS institute) joined the EATRIS VIIM platform. Finally, EATRIS was mentioned in two scientific publications from UL FFA, reflecting our commitment to advancing scientific knowledge. In summary, 2023 marked significant achievements for EATRIS Slovenia, showcasing our dedication to advancing translational research and fostering excellence in personalised medicine.



**BOARD OF GOVERNORS** REPRESENTATIVE Albin Kralj



NATIONAL **DIRECTOR** Irena Mlinarič-Raščan



**NATIONAL** COORDINATOR Dunja Urbančič

Slovenia was a recipient of the Node Reward 2023.

EATRIS Slovenia was involved in the following successful funding proposal in 2023:

EATRIS-CONNECT

EATRIS Slovenia took part in 13 education and training activities in 2023 involving 80 participants.

EATRIS Slovenia is involved in the following ongoing projects:

- EATRIS-Plus
- REMEDi4ALL
- SIMPATHIC

#### **EATRIS in Slovenia consists of 3 institutes:**

- Maribor University
- University of Ljubljana
- · University Medical Center Ljubljana, Department of Nuclear Medicine





The Spanish node plays a pivotal role in EATRIS, leveraging its Health Research Institutes (HRIs) and research quality. In 2023, efforts intensified to integrate Spanish HRIs into EATRIS, with five new additions. The node's strategic plan prioritises public health, precision medicine, digital transformation, patient engagement, and collaboration with other research infrastructures. Leading initiatives like TRUSTroke, EUCAIM and SYMPATHIC underscore Spain's research leadership. Moreover, the Spain Node contribution to the MOTBX build and validation, long-COVID workshop and COST Action application are noteworthy. Collaborations with European Research Infrastructures are actively pursued through formal meetings and annual events, bolstering connections. Participation in EU-AMRI and collaborations with BBMRI and ECRIN underscore Spain's commitment to engaging with other research infrastructures. Education and training initiatives thrived in 2023, with Vall d'Hebron hosting programmes and workshops. Remarkably, Spain also developed a "Patient Engagement Pilot Initiative" as part of the EATRIS-Plus project, involving 25 out of 32 HRIs, delivering an patient engagement strategy to be implemented in the HRIs, also contributing to the PERC launched by EATRIS. In summary, EATRIS Spain's engagement in EATRIS not only underscores its leadership in translational medicine research but also demonstrates its unwavering commitment to fostering collaboration and innovation in Europe.



**BOARD OF GOVERNORS** REPRESENTATIVE Daniel Ruiz



**NATIONAL** DIRECTOR Laura Garcia Bermejo



**NATIONAL** COORDINATOR David Velasco Gail

Spain was a recipient of the Node Reward 2023.

**EATRIS Spain was involved in the following** successful funding proposals in 2023:

EATRIS-CONNECT

FRDFRA

EATRIS Spain took part in 24 education and training activities in 2023 involving 236 participants.

#### **EATRIS Spain is involved in the** following ongoing projects:

- EATRIS-Plus
- ISIDORe
- EUCAIM canSERV
- EOSC-Life EU-PEARL RECOGNISED
- REMEDi4ALL
- TRUSTroke
  - EIP RD

EOSC4Cancer

SIMPATHIC

#### **EATRIS in Spain consists of 32 institutes:**

- August Pi i Sunyer Biomedical Research Institute (IDIBAPS)
- Bellvitge Biomedical Research Institute (IDIBELL)
- BioDonostia Health Research Institute • FIBICO, Foundation for Biomedical
- Research of Cordoba (IMIBIC)
- Fundacion Instituto de Investigacion

- Sanitaria de Navarra (IdiSNA)
- Fundacion Jimenez Diaz Institute for Medical Research (IIS-FJD) Galicia Sur Health Research Institute (IISGS)
- Germans Trias i Pujol Foundation (IGTP)
- Health Research Institute Biocruces Bizkaia
- Health Research Institute of the Balearic Islands (IdISBa)
- Health Research Institute of the Puerta de Hierro Majadahonda-Segovia de Arana (IDIPHISA)
- Health Research Institute of Santiago de Compostela (IDIS)
- Health Research Institute of Asturias (ISPA)
- Hospital Clinico San Carlos (IdISSC)
- Hospital de la Santa Creu i San Pau (IR-HSCSP)
- Hospital La Fe (IIS-La Fe)
- Hospital La Paz Institute for Health Research (IdiPAZ)
- Institute of Biomedical Research of A Coruña (INIBIC)
- Insitute of Biomedicine of Seville (IBIS) • Institut de Recerca Biomèdica de Lleida
- Fundació Dr. Pifarré (IRBLLEIDA) • INSTITUT HOSPITAL DEL MAR D'INVESTIGACIONS MÈDIQUES (IMIM)
- Instituto de Investigación Biosanitaria (IBS GRANADA)
- Instituto de Investigación Marqués de Valdecilla (IDIVAL)
- Instituto de Investigación Sanitaria Aragón (IISAragon)
- Instituto Ramón y Cajal (IRYCIS)
- Malaga Health Research Institute
- Research Institute Hospital Universitario 12 de Octubre (i+12 institute)
- University Hospital La Princesa (IIS-IP)
- Biomedical Research Institute of Murcia (IMIB)
- Vall d'Hebron Research Institute (VHIR)
- Valencian Community Foundation for the Management of the Health and Biomedical Research Institute of Alicante (ISABIAL)



**#EATRIS SE** eatrıs eatris



In 2023, Uppsala University and the Swedish node hosted the international EATRIS ERIC meeting, welcoming delegates from 14 member countries. Sweden had the opportunity to showcase its organisation, goals, and future strategies. At the subsequent EATRIS ERIC Board Meeting, the Swedish node received the prestigious EATRIS Node Reward Framework Award. Collaborating with EATRIS nodes in Finland and Norway, we organised a Nordic meeting aimed at mapping research infrastructures and expertise in ATMPs across the region. Representatives from healthcare, pre-clinical sectors, and national initiatives convened in Uppsala, initiating a comprehensive survey to map relevant research infrastructures, expertise, and needs in the Nordic countries.

Another highlight was our participation in the NLS days in Copenhagen, facilitating over 30 face-to-face meetings with small companies and research infrastructures. Furthermore, during EATRIS' 10 year anniversary conference and BoND meeting in The Hague in November, our National Coordinator was honored with the EATRIS Longevity Award for her dedication to fostering contacts between academia and industry in biotechnology and life sciences. This commitment remains a priority in our upcoming endeavors.



**BOARD OF GOVERNORS** REPRESENTATIVE Annika Jenmalm Jensen



**BOARD OF GOVERNORS** REPRESENTATIVE Katrin Brandt



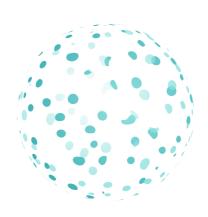
**NATIONAL DIRECTOR** Pontus Aspenström



**COORDINATOR** Ulrika Bäckman



COMMUNICATIONS **OFFICER** Mikael Törnblom-Duthu



Sweden was a recipient of the Node Reward 2023. • Lund University

**EATRIS Sweden was involved in the following** successful funding proposal in 2023:

EATRIS-CONNECT

**EATRIS Sweden took part in 11 education** and training activities in 2023 involving 30 participants.

**EATRIS Sweden is involved in the** following ongoing projects:

- EATRIS-Plus
- BY-COVID
- canSERV
- REMEDi4ALL

**EATRIS** in Sweden consists of the following institutes:

- Chalmers University of Technology
- Karolinska Institute
- KTH Royal Institute of Technology
- Linköping University

- Örebro University
- Protein Production Sweden, University of Gothenburg
- Stockholm University
- Umeå University
- University of Gothenburg
- Uppsala University and Uppsala University Hospital
- Swedish National Infrastructure for **Biological Mass Spectrometry**
- Testa Center
- Uppsala Clinical Research Center (UCR)



#### Memberships and Governance

In 2023, EATRIS celebrated a significant milestone with Croatia and Latvia transitioning from observer status to full membership, consequently expanding the infrastructure to 14 full member states.

As a result of the efforts carried out by the University of Zagreb School of Medicine (UZSM) over the past two years as part of the EATRIS-Plus project, Croatia formally became a member of EATRIS in early 2023, with the support of the Croatian Ministry of Science and Education. The EATRIS Board of Governors approved Croatia's membership request in February 2023, and the decision was ratified by the European Commission in March 2023. Following the full membership in EATRIS, UZSM appointed a National Coordinator and organised a stakeholder meeting with representatives from six of the most significant research institutions in Croatia to discuss the application for EATRIS platforms and future plans.

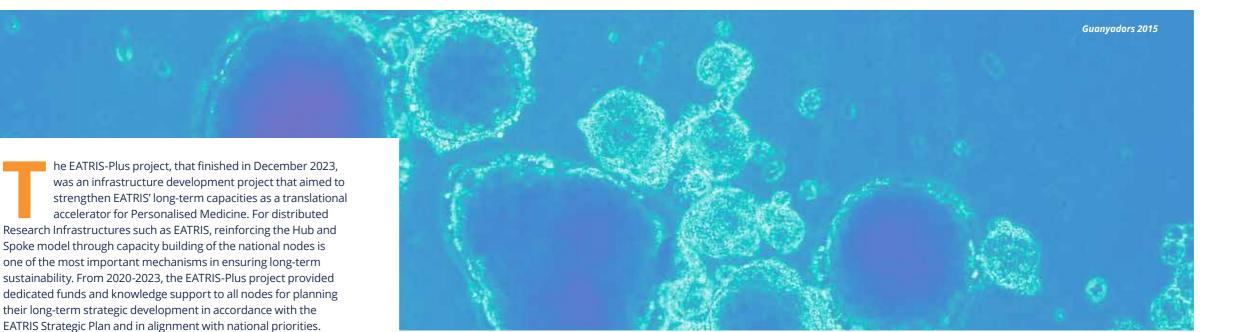
Similarly, Latvia became a full member of EATRIS in 2023, supported through the EATRIS-Plus project. Riga Stradins University (RSU), serving as the node coordinating institution, spearheaded Latvia's accession process. Following approval by the EATRIS Board of Governors in August 2023 and subsequent ratification by the European Commission, RSU appointed a National Coordinator and convened a national stakeholder meeting to discuss the application for EATRIS platforms and future plans.

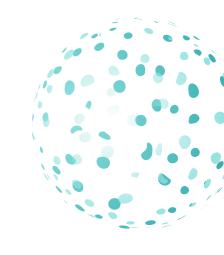
Additionally, as a partner of the EATRIS-Plus project, RSU raised awareness of translational medicine and the EATRIS-Plus project results in Latvia, with a particular focus on promoting patient engagement in research. Looking ahead to 2024, both UZSM and RSU will continue coordinating the application process for all institutions to access EATRIS technology platforms.

In parallel with expanding its membership base, EATRIS continues to forge strategic partnerships with leading academic institutions across Europe. Dialogues are continuing in Germany, Belgium, Ireland, and Greece. To streamline these efforts, EATRIS has established several Memoranda of Understanding with national academic institutions, laying the groundwork for future cooperation. Through these initiatives, EATRIS remains dedicated to advancing translational research and fostering a vibrant ecosystem of collaboration within the European research community.

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#### Node Capacity Building





## Reinforcing EATRIS' identity though community engagement

An ambitious capacity-building programme for all 14 national nodes was launched at the start of the project. 10 workshops took place with over 150 participations with topics ranging from translational assessment to patient engagement; from building communities to impact assessment. Two of these workshops took place in 2023. The first one was in May, to coincide with the EATRIS Spring Board Meetings, that brought together all of the EATRIS National Directors and Coordinators. The topics explored were community resource development and impact assessment, with a focus on the identification and communication of national success stories. The second workshop ran over two days in October and took a deep dive into impact assessment in theory and practice. The Node Coordinators prioritised and developed their own impact pathways and expressed

interest to form a Node Impact Assessment Working Group to complement the work of the C&S working group already established.

In parallel with the workshops, the Staff Exchange Programme continued in 2023 totalling 18 visits and 25 visitors from 10 countries. The Programme aimed to foster a shared culture of research and innovation, while encouraging networking, professional development and providing opportunities for best practice exchange. Altogether, 10 EATRIS Countries participated either as visitors and/or as hosts. Countries with the most visitors were Portugal and Slovenia, and the countries that hosted most visits were Spain and Slovenia, therefore making Slovenia the most active country to utilise the Staff Exchange Programme. 11 exchanges were scientific by nature (wet-lab techniques or research methods including data analysis), and 7 exchanges were operational in nature (i.e. collaborative proposal

development, observing an event with the intent of reproduction in a different EATRIS node, attending an event with the objective of EU network building for technology transfer innovations, etc).

# ESFRI Landmark Monitoring and recommendations to implement for node professionalisation

In May 2023, EATRIS received feedback from the ESFRI Landmark Monitoring process. The Review Committee found that the performance of such a complex Landmark as EATRIS is fully satisfactory. In summary they stated that the mission of EATRIS is clear, well defined and there are multiple initiatives, programmes, projects and alliances in place or planned. The review committee also suggested several valuable improvement considerations including things to note in the performance and data collection from the nodes (KPIs, data collection, annual reporting, specialisation, etc).

#### What's coming in the future?

By the end of 2023, all EATRIS 14 National Nodes had developed Node Strategic Plans, that were added to the EATRIS Long-Term Sustainability Plan.

As we continue to build the translational medicine ecosystem in Europe, strengthening our national communities to sustain long term and steady growth has a key role. To carry forward with this aim, the Spotlight Programme was developed that will begin in 2024. Each country will have the opportunity to be "in the spotlight" for a 6-month period to bring more attention to the capacities of the national research infrastructure and its contributions to EATRIS, as well as highlighting the institutions and researchers while also exploring new opportunities. The 6-month spotlight will provide a possibility of hosting dedicated node events to

engage main national stakeholders (i.e. researchers, funders, policymakers, patients/citizens) and beyond (other EU representatives, EATRIS C&S members, and EATRIS nodes from other countries, etc). In addition, during this six months, the country in spotlight will also have an opportunity to co-lead various meetings and workinggroups of interest, engaging EATRIS community into wider efforts of the organisation.

In 2024, the EATRIS-CONNECT project will kick off, building on EATRIS-Plus' successes and momentum by including all 14 national nodes and focusing on Digital Transformation of the PerMed Ecosystem. This is the second Infrastructure Development project that carries with it further funding support to continue EATRIS National Communities development.

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## Institutions Overview

<ul><li>Platform participation in 2023</li><li>New institutions in 2023</li></ul>	АТМР	Biomarkers	maging & Tracing	Small Molecules	Vaccines
Name	AT	ğ	트	Sn	Va
BULGARIA					
Institute of Biology and Immunology of Reproduction, Bulgarian Academy of Sciences (IBIR-BAS)	•	•	•	•	•
National Center of Infectious and Parasitic Diseases (NCIPD)	•	•	•	•	•
Sofia University	•	•	•	•	•
CZECH REPUBLIC					
Central European Institute of Technologies (CEITEC)	•	•	•		•
Charles University		•	•		
Institute of Chemical Technologies Prague				•	
Institute of Experimental Medicine AS CR	•	•	•	•	•
Institute of Macromolecular Chemistry Prague (IMC ASCR)	•	•	•	•	•
Institute of microbiology of the AS CR, v.v.i	•	•	•	•	•
Institute of Organic Chemistry and Biochemistry, Czech Academy of Sciences	•	•	•	•	•
Masaryk University	•	•	•	•	•
Nuclear Physics Institute of the ASCR/UJF, v. v. i.	•	•	•	•	•
Palacky University - Institute of Molecular and Translational Medicine (IMTM)	•	•	•	•	•
St. Anne's University Hospital Brno	•	•	•	•	•
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)	•	•	•	•	0
CNCCS - IRBM Science Park	•	•	•	•	0
Fondazione IRCCS CRIBT		•		•	•
Fondazione IRCCS Fondazione Pascale	•	•	•	•	

<ul><li>Platform participation in 2023</li><li>New institutions in 2023</li></ul>	АТМР	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
Name	AT	Bio	<u>Ë</u>	Sm	Vac
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		•		•	
IRCCS 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)	•	•	•	•	•
Fondazione Policlinico Universitario A. Gemelli IRCCS	•	•	•	•	•
University Milano-Bicocca (UNIMIB)	•	•	•	•	•
LUXEMBOURG					
Integrated Biobank of Luxembourg (IBBL, LIH)	•	•	•	•	•
Luxembourg Institute of Health	•	•	•	•	•
Luxembourg Center of System Biomedicine	•	•	•	•	•
THE 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	•	•	•	•	•
University Medical Center St Radboud (UMCN)	•	•	•	•	•
University Medical Center Utrecht (UMCU)	•	•	•	•	•

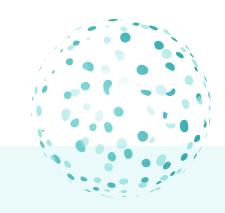
eatris Infrastructure eatris Infrastructure

<ul> <li>Platform participation in 2023</li> <li>New institutions in 2023</li> </ul> Name	ATMP	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
University Medical Centre Groningen (UMCG)		•	•	•	•
University of Technology Eindhoven (TU/e)	•	_	•		
Wageningen Bioveterinary Research					•
NORWAY		_	_	_	
Norwegian University of Science and Technology (NTNU)	•	•	•	•	
University of Bergen (UiB) and Haukeland University Hospital		•	•	•	•
University of Oslo (UiO) and Oslo University Hospital (OUH)	•	•	•	•	•
University of Tromsø (UiT) and University Hospital North Norway		•	•	•	
PORTUGAL		_	_	_	
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)	•	Ť	•		
Institute of Biomedicine (IBIMED)	_	_	_		
Instituto de Biologia Experimental e Tecnológica (IBET)	•	•	•		•
Instituto de Investigação e Inovação em Saude (i3S)	_	_	_	_	•
Instituto de Medicina Molecular João Lobo Antunes (IMM)		•	•	•	•
Instituto Pedro Nunes (IPN)	•	•	_	•	•
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)	•	•	•	_	•
University of Beira Interior, Health Sciences Research Center (CICS-UBI)		•	_	•	-
VectorB2B	•	•	_	•	-
SLOVENIA	•	_	_	•	•
Maribor University		_			
University of Ljubljana		•	_	_	•
University Medical Center Ljubljana, Department of Nuclear Medicine	•	•	_	•	•
SPAIN		_	•	•	•
August Pi i Sunyer Biomedical Research Institute (IDIBAPS)		_	•		
Bellvitge Biomedical Research Institute (IDIBELL)	_	•	•		
BioDonostia Health Research Institute	•	•	-	-	-
FIBICO, Foundation for Biomedical Research of Cordoba (IMIBIC)	•	•		-	•
Fundacion Instituto de Investigacion Sanitaria de Navarra (IdiSNA)	•	•	•	•	•
Fundacion Jimenez Diaz Institute for Medical Research (IIS-FJD)		•		-	
Galicia Sur Health Research Institute (IISGS)		•	-	-	6
Germans Trias i Pujol Foundation (IGTP)		•	•	•	
Germans mastr ajort outraation (iOTr)	•	•	•		•

<ul> <li>Platform participation in 2023</li> <li>New institutions in 2023</li> </ul> Name	АТМР	Biomarkers	Imaging & Tracing	Small Molecules	Vaccines
Health Research Institute Biocruces Bizkaia	•	•	•	•	•
Health Research Institute of the Balearic Islands (IdISBa)	•	•	•	•	•
Health Research Institute of the Puerta de Hierro Majadahonda-Segovia de Arana (IDIPHISA)	•	•	•	•	•
Health Research Institute of Santiago de Compostela (IDIS)	•	•	•	•	
Health Research Institute of Asturias (ISPA)	•	•	•	•	•
Hospital Clinico San Carlos (IdISSC)	•	•	•	•	•
Hospital de la Santa Creu i San Pau (IR-HSCSP)	•	•	•	•	•
Hospital La Fe (IIS-La Fe)	•	•	•	•	•
Hospital La Paz Institute for Health Research (IdiPAZ)	•	•	•	•	•
INCLIVA	•	•	•	•	•
Institute of Biomedical Research of A Coruña (INIBIC)	•	•	•	•	
Insitute of Biomedicine of Seville (IBIS)	•	•	•	•	•
Institut de Recerca Biomèdica de Lleida Fundació Dr. Pifarré (IRBLLEIDA)	•	•	•	•	•
INSTITUT HOSPITAL DEL MAR D'INVESTIGACIONS MÈDIQUES (IMIM)	•	•	•	•	
Instituto de Investigación Biosanitaria (IBS GRANADA)	•	•	•	•	
Instituto de Investigación Marqués de Valdecilla (IDIVAL)	•	•	•	•	•
Instituto de Investigación Sanitaria Aragón (IISAragon)	•	•	•	•	•
Instituto Ramón y Cajal (IRYCIS)	•	•	•	•	•
Malaga Health Research Institute	•	•	•	•	•
Research Institute Hospital Universitario 12 de Octubre (i+12 institute)	•	•	•	•	
University Hospital La Princesa (IIS-IP)	•	•	•	•	
Biomedical Research Institute of Murcia (IMIB)	•	•	•	•	•
Vall d'Hebron Research Institute (VHIR)	•	•	•	•	
Valencian Community Foundation for the Management of the Health and Biomedical Research Institute of Alicante (ISABIAL)	•	•	•	•	•
SWEDEN					
Chalmers University of Technology	•	•	•	•	•
Swedish National Infrastructure for Biological Mass Spectrometry	•	•	•		•
Karolinska Institute	•	•	•	•	•
KTH Royal Institute of Technology	•	•	•	•	•
Linköping University	•	•	•	•	•
Lund University	•	•	•	•	•
Protein Production Sweden (PPS), University of Gothenburg	•	•	•	•	•
Stockholm University	•	•	•	•	•
Testa Center	•	•	•	•	•
Umeå University	•	•	•	•	•
University of Gothenburg	•	•	•	•	•
Uppsala University and Uppsala University Hospital	•	•	•	•	•



# A message from the EATRIS Scientific Advisory Board (SAB)



The EATRIS SAB is formed of external scientific experts that provide independent feedback and advice on the scientific strategy of the organisation.









**Nicole Déglon** 



Catherine Larue Fatima Nunez Hugo

Hugo Van Heuverswyn

Petr Kocis

After launching the new 2023-2026 EATRIS Strategic Plan, the Research Infrastructure has continued its efforts to better serve patients and researchers on the road of Translational Medicine.

Throughout the year, EATRIS embarked on promising collaborations and secured high-level consortium partnerships, including notable ventures with CERN and successful grant acquisitions such as the IHI JU. These successes garnered increased recognition within the scientific community and unveiled new opportunities in Translational Medical Research.

In 2023, EATRIS reinforced its role as a "unifier" through granted scientific projects, as well as research platforms that better serve European research. EATRIS continues to foster science communication, and the importance of data quality (for data sharing) around events on Quality initiatives.

At the heart of EATRIS' mission lies a commitment to patients. In 2023, the organisation launched the Patient Engagement Resource Centre, providing researchers with essential tools to foster meaningful patient involvement in research. Moreover, patients with an ultra-rare disease may now benefit from new investigations using a potential drug-treatment within a public-private effort.

Celebrating a decade of progress, EATRIS marked its 10th anniversary with a two-day celebration in The Hague, bringing together stakeholders from across the globe. This milestone event highlighted EATRIS' global impact in a year when two new full members were welcomed into the fold: Croatia and Latvia.

As external scientific experts providing independent feedback and advice, we commend EATRIS for its dedication to translating strategic vision into tangible outcomes. We wish them continued success in addressing unmet medical needs, facilitating collaboration, providing vital resources and supporting researchers to share knowledge, platforms, and hubs for the benefit of the patients.

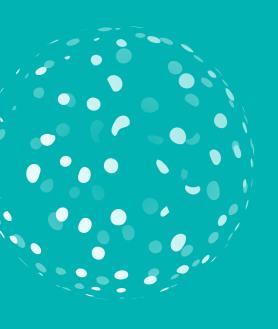
Catherine Larue (Integrated Biobank of Luxembourg, IBBL, LIH)

On behalf of the EATRIS Scientific Advisory Board Fatima Nunez (Hospital Sant Joan de Deu Barcelona), Hugo Van Heuverswyn (FlandersBio), Nicole Déglon (Lausanne University Hospital, CHUV), Petr Kocis (Alzheon Inc)



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# platforms





#### **ATMP**



#### CHAIRS:

Giuliana Ferrari (IRCCS Ospedale San Raffaele, Italy)
Maria Themeli (Amsterdam UMC, the Netherlands)

#### PLATFORM COORDINATOR:

David Morrow (Senior Scientific Programme Manager, EATRIS)

The year 2023 represented a critical and successful milestone for the ATMP Platform as we continued to progress our ongoing initiatives. We also developed new ones which aimed to fill the gap between basic research and clinical implementation of these promising therapies. Our ATMP platform outputs looked to address the main challenges in ATMP development that support the translation of these complex therapies into clinical development. The platform saw a growth in capacity to 51 institutions as Fundacion Instituto de Investigacion Sanitaria de Navarra (IdiSNA) from Spain became a new and valuable member.

2023 began with EATRIS' codevelopment of an Innovative Health Initiative (IHI) proposal with INSERM, Pfizer and UCB. This proposal, codeveloped with industry, consisted of 54 institutions including six EATRIS ATMP sites. The European Research and Development Ecosystem for Rare Disease (ERD2) proposal aimed to create a unique network of expertise and excellence, ready to assist industrial and academic ATMPs developers by enabling access to translatable, scalable, quality-controlled, and robust technologies, required to reduce the timeframe, the cost and accelerate

clinical development. While it was unsuccessful, key technical, training, and regulatory components were incorporated into the new Rare Disease Research Alliance (ERDERA) to begin in September 2024 and solidify EATRIS' key role in the development of these must-have platform technologies for ATMP translation in the EU.

EATRIS' commitment to safer and more effective gene editing approaches continued with our involvement in the EDITSCD project. Our platform strategy to support the translation of iPSC therapies also continued within the HEAL project towards trial readiness of an off the shelf HLA-iPSC product to treat heart failure by the project end.

The HAPLO-iPS COST action chaired by IDIBELL in Spain continued to grow in numbers boasting 130 researchers from 31 countries working collectively to unlock the full potential of human induced pluripotent stem cells from haplo-selected cord blood samples. The EATRIS Bulgaria node which leads the training aspect of this action, hosted the annual meeting to great success in 2023 welcoming induced pluripotent stem cell (iPSC) experts from across the EU and from South Korea.

In education and training, the ADVANCE course for ATMPs continued to grow, with over 1000 students from 51 countries benefitting from the online courses. The latest in-person iteration of this course took place in Ljubljana, Slovenia in June successfully organised by the EATRIS Slovenia node and consisting of an agenda of local and EU key opinion leaders in the ATMP space.

EATRIS continued its involvement with EUPATI to create a first cell and gene therapy education module dedicated to patients and our commitment to publish key opinion pieces continued in 2023 with a medical research archives editorial emphasising the crucial aspect of personalised medicine and patient stratification for ATMPs at the clinic. The platform finished the year by working with 19 researchers from 11 EATRIS countries and a network of leading EU institutions to submit a new COST action - CELLxTrack - to address the important use of imaging to track cell and gene therapies.

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#### **Biomarkers**



#### **CHAIRS:**

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

#### PLATFORM COORDINATOR:

Emanuela Oldoni (Scientific Programme Manager, EATRIS)

In 2023, three projects under the Biomarkers Platform - Beyond 1 Million Genomes (B1MG), Companion Diagnostics Expedited for SMEs (Codex4SMEs), and EATRIS-Plus - were successfully concluded.

The B1MG project facilitated signatory countries to realise a practice of personalised medicine and health, based upon a shared 'framework' and the infrastructure to safely access and integrate high quality genomic data and other health data across borders. During the project, experts across 25 countries produced recommendations, guidelines and best practices that can be used to realise the 1+MG vision. Some of these resources impact data governance, ethical, legal and societal issues, data models and quality, sequencing guidelines, technical infrastructure, implementation of genomics into healthcare, use cases and national resources. Consensus was reached at a European level by the 1+MG national experts for each area.

a successful milestone, yielding relevant outcomes. Over the course of the project, EATRIS demonstrated exceptional performance by delivering on 18 service requests including research services, regulatory support,

and translational assessments. This effort involved active collaboration with over 15 diagnostics SMEs across the EU. These achievements underscore the substantial impact of the project and EATRIS' capacity to offer valuable support to SMEs within the diagnostic landscape.

The EATRIS-Plus project concluded in December 2023, achieved its scientific ambition with the successful launch of The Multi-omics Toolbox (MOTBX): an open-access online tool facilitating translational research by aiding researchers both in academia and industry to locate pertinent resources for multi-omics analysis. Furthermore, the EATRIS-Plus Summer School on multimodal biomarkers and diagnostics took place in April in Lisbon. The four-day event featured a combination of insightful lectures and interactive workshops led by experts from across Europe, including key opinion leaders associated with the Biomarkers Platform.

The conclusion of Codex4SMEs marked In the context of transversal initiatives across the EATRIS platforms, a collaborative workshop called "Identifying Early Clinical-Relevant Predictive Biomarkers in Patients at Risk of Long COVID-19" was organised in June 2023, in partnership with

the Vaccines, Inflammation and Immune Monitoring (VIIM) Platform. Witnessing both communities come together to present their research and explore synergies was truly inspiring. As a tangible outcome of the workshop, a COST Action proposal titled: "LongCOVID-Net: A Network for Clinical Definition, Stratification, and Prevention of Long Covid" emerged and was subsequently submitted in October 2023.

The Biomarkers Platform was also involved in the preparation of EATRIS-Plus follow-up INFRADEV proposal **EATRIS CONNECT supporting digital** transformation in Translational Medicine - technologies (data, tools, and services) to create solutions for unmet medical needs.

In 2023, the Biomarkers Platform welcomed five new institutions: Biocruces (Spain), Instituto de Investigación Sanitaria Galicia Sur (IISGS) (Spain), Instituto de Investigación Sanitaria de Navarra (IdiSNA) (Spain), Institute of Biology and Immunology of Reproduction (IBIR) (Bulgaria) and the Universidade NOVA de Lisboa (Portugal). This brings the total number of EATRIS Biomarkers institutions to 88.

#### **Imaging and Tracing**



#### CHAIR:

Albert Windhorst (AmsterdamUMC/VUmc, The Netherlands)

#### PLATFORM COORDINATOR:

Sara Zullino (Scientific & SME Outreach Manager, EATRIS)

In line with the EATRIS Strategic Plan 2023-2026, the Imaging and Tracing Platform further consolidated the mission and the objectives of its three Working Groups (WGs) - Radiomics, EU Tracer Factory, and Cell Tracking.

The EU Tracer Factory brings together nuclear medicine scientists to foster a collaborative community supporting the exchange of insights in radiosynthesis and radiopharmacy. Through a comprehensive database of equipment and radiotracers free from competing interest, nuclear medicine experts offer guidance on well-established in-house practices. Presented at the European Symposium on Radiopharmacy and Radiopharmaceuticals in Coimbra the WG held a workshop to discuss its objectives, progress, and share expertise with the international nuclear medicine community.

The Radiomics WG focuses on addressing the technical challenges hindering the effective integration of radiomics into clinical routine. Building on the insights gained from two workshops held in October 2022 and June 2023, through surveys and discussions, the WG identified actionable problems and opportunities for collaborative work. Key focus areas include addressing the varying harmonisation methods

employed across different imaging modalities, such as PET and MRI, and across radiomics studies.

In the context of the Cell Tracking WG, the Imaging & Tracing Platform and the ATMPs Platform jointly developed a COST Action proposal: CELLxTrack: An Ecosystem to Track Cell- and Gene Therapies. The proposal is led by Technical University of Munich (TUM).

In 2023, two EU-funded initiatives started under the Imaging & Tracing Platform:

- The EUropean Federation for CAncer IMages (EUCAIM) project led by La Fe University and Polytechnic Hospital (Spain), aims to build a pan-European digital federated infrastructure of cancer-related images, which will be used for the development of AI tools toward Precision Medicine. Many partners are part of the "Al for Health Imaging" Network (Al4HI), a cluster of five large EU-funded projects on big data and Al in cancer imaging (CHAIMELEON, EUCANIMAGE, INCISIVE, ProCancer-I, PRIMAGE), whose data repositories EUCAIM is building on.
- TRUSTroke, coordinated by Vall d'Hebron Institute of Research (Spain), with CERN as a partner proposes a novel trustworthy by design and privacy-preserving Al-based platform to assist

clinicians, patients and caregivers in the management of acute and chronic phases of ischemic stroke. By integrating clinical and patient-reported data, the TRUSTroke project will therefore enable more personalised and effective management of stroke, as well as providing inter-hospital benchmarking and sharing best practices. As a direct outcome of this project, the UMBRELLA proposal was developed to address the Innovative Health Initiative (IHI) Call 5 Topic 3. UMBRELLA seeks to revolutionise stroke care by setting new standards in primary prevention, treatment accessibility, accurate diagnosis, management strategies, monitoring techniques, therapeutic target identification, and rehabilitation.

Building upon the success of the TRUSTroke project, EATRIS also engaged in further discussion with CERN that led to a long-term collaboration agreement that promises to unleash new opportunities in translational medicine.

In 2023, Fundacion Instituto de Investigacion Sanitaria de Navarra (IdiSNA) joined the Imaging & Tracing Platform, which now comprises 51 institutions.

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#### **Small Molecules**



#### **CHAIRS:**

Maddalena Fratelli (Mario Negri Institution, Italy)
Alfredo Budillon (Istituto Nazionale Tumori- IRCCS G. Pascale, Italy)

#### PLATFORM COORDINATOR:

Martin de Kort (Senior Scientific Programme Manager, EATRIS)

In 2023, the Small Molecules Platform saw the maturation of its scientific agenda focusing on drug repurposing. EATRIS' flagship initiative REMEDi4ALL provided strategic direction and successfully concluded its first reporting period with several early highlights towards establishing a sustainable platform accessible to the community. In March, the REMEDi4ALL Repurposing Concierge was launched to support the community in its (academic-led) repurposing efforts. With over 100 requests, the need for a one-stopshop solution for support and guidance to researchers, patients, funders and other stakeholders was confirmed. The repurposing resources were expanded by making available a curated list of in silico tools. In October, we saw the publication of the Drug Repurposing Guidebook in collaboration with the IRDiRC Task Force, with a specific focus on rare diseases.

Major progresses were made towards supporting the four demonstrator projects. Notably, a scientific advice procedure with Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) was entered for the ultra-rare disease Multiple Sulfatase Deficiency (MSD), enabled by securing unique access to historic industry data. Clinical

Trial Application (CTA) approval was obtained for the initiation of a transnational drug combination clinical trial in pancreatic cancer led by IRCCS Pascale in Naples. The rigor applied in these projects using the target product profile and gap analysis was extended as best practice to other initiatives, such as the global repurposing alliance NewFound. An example being the global repurposing alliance NewFound focusing on the use of existing drugs to address unmet need in neglected and rare diseases, such as tuberculosis.

In April, the new draft pharma legislation was published, anticipating non-profit organisations to become a more prominent actor in new therapy development. EATRIS answered to a consultation encouraging legislators to facilitate label extension and clinical adoption of successful public funded trials (e.g. the "repurposing articles" 48 and 84). An actionable agenda of addressing the policy barriers is under development with the REMEDI4ALL Policy Board.

In July, the portfolio of active projects expanded with the kick-off of SIMPATHIC, a 5-year project with the aim to enhance the efficiency of drug repurposing research and

development process for rare neurological, neurometabolic and neuromuscular diseases using patient-derived cells (iPSC) in drug screening and an innovative, patientcentric clinical (basket trial) concept.

EATRIS continued to explore collaborative opportunities with its peers such as EU-OPENSCREEN and NIH-NCATS to explore common interests and opportunities to develop a joint scientific and translational research-oriented agenda. In 2023 the platform welcomed 1 new institution. The total number of institutions participating in the platform is now 41 further maturing its catalogue of (repurposing) services and growing its portfolio to create a vibrant international community of practice, into a coherent and sustainable programme.

# Vaccine, Inflammation and Immune Monitoring



#### **CHAIRS:**

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

#### PLATFORM COORDINATOR:

David Morrow (Senior Scientific Programme Manager, EATRIS)

The Vaccines, Inflammation and Immune Monitoring (VIIM) Platform saw considerable growth in numbers and strength in 2023 as we welcomed 3 new institutions to the platform taking us to 29 top tier institutions. This included the Institute of Biology and Immunology of Reproduction, Bulgarian Academy of Sciences (IBIR-BAS) in Bulgaria, Fundacion Instituto de Investigacion Sanitaria de Navarra (IdiSNA) in Spain and the Protein Production Sweden (PPS), University of Gothenburg in Sweden.

Provision of vaccine development and immune monitoring services through the EATRIS co-developed ISIDORe project remained a successful output of the platform throughout the year. The ISIDORe project in 2023 saw multiple (sub) projects at different stages of development where EATRIS VIIM institutions provided cutting edge immune monitoring services to different pandemic preparedness projects. This included an Immunophenotyping, and T cell markers study provided by OUH from a Phase 2 clinical trial performed by IDIPAZ with a new adoptive cell therapy for COVID-19 patients. In addition, IMM provided cutting edge quantification of T and B cells to evaluate the COVID-19 vaccine effectiveness among healthcare workers in a specific region in Spain. IMM also provided whole genome sequencing to analyse the circulating SARS-CoV-2 levels in a cohort of healthcare workers in this same region of Spain.

EATRIS regulatory experts also provided regulatory advice and support to six projects for vaccines and therapeutics at different stages of development.

As we continued to cautiously exit the COVID-19 pandemic, the focus of the VIIM platform which represents the majority of the EATRIS COVID-19 Research Forum, switched its attention to Long COVID.

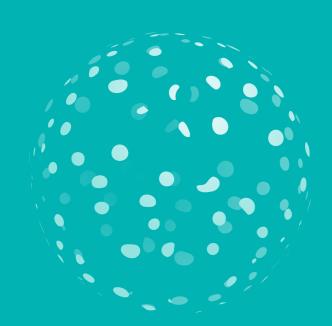
In June, a workshop was held in collaboration with the biomarker platform to understand the growing issues of Long COVID and how EATRIS could address them. The outcome of this workshop was the development of a new COST action titled 'LongCovidnet', consisting of 22 researchers from eight EATRIS countries and

coordinated by IGTP in Spain.

The EATRIS VIIM platform finished the year by working with Vaccines Europe and Sanofi to develop a new funding concept for IPROVE2 – a project aiming to develop an updated roadmap for vaccine development in Europe. This concept was submitted to the European Commission for consideration to be included in the next Horizon work programme in December.

The year 2023 saw the conclusion of the successful TRANSVAC-2 project and EATRIS hosted its final in person Vaccine Regulatory training course in the Netherlands. The content of this highly successful training course was also transferred to an online version on the EATRIS TransMed Academy education and training platform. TRANSVAC-2 saw EATRIS regulatory experts provide high level regulatory support for academics, and SMEs for their vaccine development projects over the project lifespan. This included preclinical advice, support for scientific advice at National Competent Authorities, and support for developing clinical trial applications in several countries.

# featured publications



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Featured publication from an EATRIS institute in the Czech Republic

# Fibroblast activation protein as a potential theranostic target in brain metastases of diverse solid tumours

#### **Key Messages:**

In this study, the authors demonstrate the presence of Fibroblast activation protein (FAP), a transmembrane serine protease typically expressed in tumourassociated stromal cells protein in brain metastases. FAP immunopositivity localised in regions rich in collagen and containing blood vessels and mainly originating from melanoma, lung, breast, renal cancer and sarcoma. The data published in this article supports the use of FAP as a promising theranostic target in brain metastases.

#### **Summary:**

Brain metastases are a very common and serious complication of oncological diseases. Despite the vast progress in multimodality treatment, brain metastases significantly decrease the quality of life and prognosis of patients. Therefore, identifying new targets in the microenvironment of brain metastases is desirable. Fibroblast activation protein (FAP) is a transmembrane serine protease typically expressed in tumour-associated stromal cells. Due to its characteristic presence in the tumour microenvironment, FAP represents an attractive theranostic target in oncology. However, there is little information on FAP expression in brain metastases.

In this study, the authors quantified FAP expression in samples of brain metastases of various primary origin and characterised FAP-expressing cells. The authors have shown that FAP expression is significantly higher in brain metastases in comparison to non-tumorous brain tissues, both at the protein and enzymatic activity levels. FAP immunopositivity was localised in regions rich in collagen and containing blood vessels. The authors have further shown that FAP is predominantly confined to stromal cells expressing markers typical of cancer-associated fibroblasts (CAFs). They also observed FAP immunopositivity on tumour cells in a portion of brain metastases, mainly originating from melanoma, lung, breast, and renal cancer, and sarcoma. There were no significant differences in the quantity of FAP protein, enzymatic activity, and FAP+ stromal cells among brain metastasis samples of various origins, suggesting that there is no association of FAP expression and/or presence of FAP+ stromal cells with the histological type of brain metastases.

In summary, this paper is the first to establish the expression of FAP and characterise FAP-expressing cells in the microenvironment of brain metastases. The frequent upregulation of FAP and its presence on both stromal and tumour cells support the use of FAP as a promising theranostic target in brain metastases.

#### Citation:

Zubal M., Výmolová B., Matrasová I. et al. (2023). Fibroblast activation protein as a potential theranostic target in brain metastases of diverse solid tumours. Pathology. Volume 55, Issue 6, October 2023, Pages 806-817. https://doi.org/10.1016/j.pathol.2023.05.003.

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Featured publication from EATRIS institutes in Finland & Norway

# Robust scoring of selective drug responses for patient-tailored therapy selection



#### Key messages:

In this article published in Nature Protocols, Chen and al. developed a computational method for selective drug-sensitivity scoring (DSS) which enables normalisation of the individual patient's responses against normal cell responses that can be used as a proxy for potential drug toxicity, which can in turn be used to identify effective and safer treatment options. The power of the method is demonstrated in patients with leukemia treated across three cancer centers in Europe and the USA.

#### **Summary:**

Most patients with advanced malignancies are treated with severely toxic, first-line chemotherapies. Personalised treatment strategies have led to improved patient outcomes and could replace one-sizefits-all therapies, yet they need to be tailored by testing of a range of targeted drugs in primary patient cells. Most functional precision medicine studies use simple drug-response metrics, which cannot quantify the selective effects of drugs (i.e. the differential responses of cancer cells and normal cells). The authors developed a computational method for selective drug-sensitivity scoring (DSS), which enables normalisation of the individual patient's responses against normal cell responses. The selective response scoring uses the inhibition of noncancerous cells as a proxy for potential drug toxicity, which can in turn be used to identify effective and safer treatment options. Here, the authors explain how to apply the selective DSS calculation for guiding precision medicine in patients with leukemia treated across three cancer centers in Europe and the USA; the generic methods are also widely applicable to other malignancies that are amenable to drug testing. The open-source and extendable R-codes provide a robust means to tailor personalised treatment strategies on the basis of increasingly available ex vivo drug-testing data from patients in real-world and clinical trial settings. The authors also make available drug-response profiles to 527 anticancer compounds tested in 10 healthy bone marrow samples as reference data for selective scoring and de-prioritisation of drugs that show broadly toxic effects. The procedure takes less than 60 minutes and requires basic skills in R.

Featured publication from an EATRIS institute in Portugal

# Towards a scalable bioprocess for rAAV production using a HeLa stable cell line

#### Key messages:

In this work, cell line development and bioprocessing for the HeLaS3-based production of rAAVs is streamlined with a production system that provides a robust and scalable alternative to transient transfection systems. The work addresses the manufacturing challenges for rAAV based medicines.

#### **Summary:**

The majority of recombinant adeno-associated viruses (rAAV) approved for clinical use or in clinical trials are produced by transient transfection using the HEK293 cell line. However, this platform has several manufacturing bottlenecks at commercial scales namely, low product quality (full to empty capsid ratio <20% in most rAAV serotypes), lower productivities obtained after scale-up and the high cost of raw materials, in particular of Good Manufacturing Practice grade plasmid DNA required for transfection. The HeLa-based stable cell line rAAV production system provides a robust and scalable alternative to transient transfection systems. Nevertheless, the time required to generate the producer cell lines combined with the complexity of rAAV production and purification processes still pose several barriers to the use of this platform as a suitable alternative to the HEK293 transient transfection. In this work the authors streamlined the cell line development and bioprocessing for the HeLaS3-based production of rAAV. By exploring this optimised approach, producer cell lines were generated in 3-4 months, and presented rAAV2 volumetric production (bulk) > 3 × 1011 vg/mL and full to empty capsids ratio (>70%) at 2 L bioreactor scale. Moreover, the established downstream process, based on ion exchange and affinity-based chromatography, efficiently eliminated process related impurities, including the Adenovirus 5 helper virus required for production with a log reduction value of 9. Overall, the authors developed a time-efficient and robust rAAV bioprocess using a stable producer cell line achieving purified rAAV2 yields > 1 × 1011 vg/mL. This optimised platform may address manufacturing challenges for rAAV based medicines.

#### Citation:

Chen Y., He L., Lanevski A. et al. (2024) Robust scoring of selective drug responses for patient-tailored therapy selection. Nat Protoc 19, 60-82. https://doi.org/10.1038/s41596-023-00903-x

#### Citation:

Escandell J., Moura F., Carvalho S.B. et al. (2023). Towards a scalable bioprocess for rAAV production using a HeLa stable cell line. Towards a scalable bioprocess for rAAV production using a HeLa stable cell line. Biotechnology and Bioengineering, 120, 2578–2587. https://doi.org/10.1002/bit.28394

Featured publication from EATRIS institutes in Italy & Spain

#### Large T cell clones expressing immune checkpoints increase during multiple myeloma evolution and predict treatment resistance



#### Key messages:

Single-cell RNA and TCR sequencing of bone marrow (BM) T cells from patients with newly diagnosed multiple myeloma (MM) is used to define the phenotype of individual T cell clones throughout myelomagenesis. Large clonotypic expansions characterised by the expression of distinct combinations of immune checkpoint molecules were identified. Effect of Immune Checkpoint Inhibitors (ICB) treatments to each of these phenotypes in experimental MM models was also evaluated. The work supported the identification of T cell phenotypes that are predictive of survival in patients who received lenalidomide-based treatment combinations.

#### **Summary:**

Tumor recognition by T cells is essential for antitumor immunity. A comprehensive characterisation of T cell diversity may be key to understanding the success of immunomodulatory drugs and failure of PD-1 blockade in tumors such as multiple myeloma (MM). Here, the authors use single-cell RNA and T cell receptor sequencing to characterise bone marrow T cells from healthy adults (n = 4) and patients with precursor (n = 8)and full-blown MM (n = 10). Large T cell clones from patients with MM expressed multiple immune checkpoints, suggesting a potentially dysfunctional phenotype. Dual targeting of PD-1 + LAG3 or PD-1 + TIGIT partially restored their function in mice with MM. The authors identify phenotypic hallmarks of large intratumoral T cell clones, and demonstrate that the CD27- and CD27+ T cell ratio, measured by flow cytometry, may serve as a surrogate of clonal T cell expansions and an independent prognostic factor in 543 patients with MM treated with lenalidomide-based treatment combinations.

#### Citation:

Botta C., Perez C., Larrayoz M. et al. (2023). Large T cell clones expressing immune checkpoints increase during multiple myeloma evolution and predict treatment resistance. Nat Commun 14, 5825. https://doi.org/10.1038/s41467-023-41562-6

Featured publication from an EATRIS institute in Spain

Fractionated initial infusion and booster dose of ARI0002h, a humanised, BCMA-directed CAR T-cell therapy, for patients with relapsed or refractory multiple myeloma (CARTBCMA-HCB-01): a single-arm, multicentre, academic pilot study



#### Key messages:

In this paper, researchers from Norway demonstrate that imaging tumour angiogenesis using the radiotracer [18F]rhPSMA-7.3 is a promising approach for future diagnostic PET in brain cancer, as it reveals visible tumour uptake associated with neo-vascularization. The radiotracer [18F]fluciclovine was also investigated and found to have more suitable imaging properties than [18F]FET for in vivo PET imaging of Glioblastoma, based on higher tumour-to-background ratios.

#### **Summary:**

Glioblastoma multiforme (GBM) is a highly aggressive and deadly brain tumour, with a high incidence rate in the USA of 3 per 100,000. The standard therapy for GBM includes resection, chemotherapy, and irradiation, but a complete resection is usually impossible due to its infiltrative growth. As a result, a relapse of the patient is inevitable, and the average patient survival is only increased to 15 months. While some current MR sequences can detect metabolic changes within the tumour, high sensitivity in vivo metabolic characterization can only be achieved by positron emission tomography (PET). The paper discusses the use of two different PET radiotracers, [18F]rhPSMA-7.3 and [18F] fluciclovine, for the imaging of glioblastoma multiforme (GBM) in preclinical studies. The authors report that [18F]rhPSMA-7.3, which had not been previously used for GBM PET, showed visible tumour uptake that was associated with neo-vascularization, while mature vessels decreased leading to necrosis. The authors suggest that imaging tumour angiogenesis using [18F]rhPSMA-7.3 with respect to tumour grading might be an interesting approach for future diagnostic PET in brain cancer, although further research is needed to explain the mechanism behind its uptake. The authors also investigated the diagnostic efficacy of [18F]fluciclovine and compared it to [18F]FET. The results showed that [18F]fluciclovine had more suitable imaging properties than [18F]FET based on higher tumour-to-background ratios (TBR). This was confirmed by pharmacokinetic modeling, which showed higher rate constants and macro parameters when applying [18F]fluciclovine, making it more suitable for in vivo PET imaging of GBM. Overall, the paper suggests that both [18F]rhPSMA-7.3 and [18F]fluciclovine have potential for the imaging of GBM in clinical settings, but further research is needed to fully understand their mechanisms of uptake and to optimize their use in PET imaging.

#### Citation:

Lindemann, M., Oteiza, A., Martin-Armas, M., et al. (2023). Glioblastoma PET/MRI: kinetic investigation of [18F]rhPSMA-7.3, [18F]FET and [18F] fluciclovine in an orthotopic mouse model of cancer. European journal of nuclear medicine and molecular imaging, 50(4), 1183–1194. https://doi.org/10.1007/s00259-022-06040-z.

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scientific updates

Featured publication from an EATRIS institute in Italy

#### Neural stem cell transplantation in patients with progressive multiple sclerosis: an open-label, phase 1 study



Featured publication from an EATRIS institute in Italy

# Genotoxic effects of base and prime editing in human hematopoietic stem cells



#### Key message:

This prospective, therapeutic exploratory, non-randomised, open-label, single-dose-finding phase 1 clinical trial evaluates the feasibility, safety and tolerability of intrathecally transplanted human fetal Neural precursor cells (hfNPCs) in 12 patients with progressive multiple sclerosis (PMS). The study demonstrates that hfNPC therapy in PMS is feasible, safe and tolerable.

#### Summary:

Innovative pro-regenerative treatment strategies for progressive multiple sclerosis (PMS), combining neuroprotection and immunomodulation, represent an unmet need. Neural precursor cells (NPCs) transplanted in animal models of multiple sclerosis have shown preclinical efficacy by promoting neuroprotection and remyelination by releasing molecules sustaining trophic support and neural plasticity. Here, the authors present the results of STEMS, a prospective, therapeutic exploratory, nonrandomised, open-label, single-dose-finding phase 1 clinical trial (NCT03269071, EudraCT 2016-002020-86), performed at San Raffaele Hospital in Milan, Italy, evaluating the feasibility, safety and tolerability of intrathecally transplanted human fetal NPCs (hfNPCs) in 12 patients with PMS (with evidence of disease progression, Expanded Disability Status Scale ≥6.5, age 18–55 years, disease duration 2–20 years, without any alternative approved therapy). The safety primary outcome was reached, with no severe adverse reactions related to hfNPCs at 2-year follow-up, clearly demonstrating that hfNPC therapy in PMS is feasible, safe and tolerable. Exploratory secondary analyses showed a lower rate of brain atrophy in patients receiving the highest dosage of hfNPCs and increased cerebrospinal fluid levels of anti-inflammatory and neuroprotective molecules. Although preliminary, these results support the rationale and value of future clinical studies with the highest dose of hfNPCs in a larger cohort of patients.

#### Key messages:

In this article, Fiumara et al. compare state-of-the-art base and prime editors (BEs and PEs) and Cas9 in human hematopoietic stem and progenitor cells with respect to editing efficiency, cytotoxicity, transcriptomic changes and on-target and genome-wide genotoxicity. Their findings raise concerns about the genotoxicity of BEs and PEs and warrant further investigation in view of their clinical application.

#### **Summary:**

Base and prime editors (BEs and PEs) may provide more precise genetic engineering than nuclease-based approaches because they bypass the dependence on DNA double-strand breaks. However, little is known about their cellular responses and genotoxicity. Here, the authors compared state-of-the-art BEs and PEs and Cas9 in human hematopoietic stem and progenitor cells with respect to editing efficiency, cytotoxicity, transcriptomic changes and on-target and genome-wide genotoxicity. BEs and PEs induced detrimental transcriptional responses that reduced editing efficiency and hematopoietic repopulation in xenotransplants and also generated DNA double-strand breaks and genotoxic byproducts, including deletions and translocations, at a lower frequency than Cas9. These effects were strongest for cytidine BEs due to suboptimal inhibition of base excision repair and were mitigated by tailoring delivery timing and editor expression through optimised mRNA design. However, BEs altered the mutational landscape of hematopoietic stem and progenitor cells across the genome by increasing the load and relative proportions of nucleotide variants. These findings raise concerns about the genotoxicity of BEs and PEs and warrant further investigation in view of their clinical application.

#### Citation:

Genchi A., Brambilla E., Sangalli F. et al. (2023). Neural stem cell transplantation in patients with progressive multiple sclerosis: an open-label, phase 1 study. Nat Med 29, 75–85. https://doi.org/10.1038/s41591-022-02097-3

#### Citation:

Fiumara M., Ferrari S., Omer-Javed A. et al. (2023). Genotoxic effects of base and prime editing in human hematopoietic stem cells. Nat Biotechnol. https://doi.org/10.1038/s41587-023-01915-4

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### The Multi-omics Toolbox (MOTBX) launches to Empower Multi-omics Research and Analysis Inherent to Research for the Translational Medicine Community



Personalised medicine (PM) research aims to tailor interventions to individual patients, leveraging their predicted responses for optimised treatment outcomes. The accelerated progress of PM relies heavily on validated patient-specific biomarkers. Achieving this necessitates a nuanced comprehension of individuals' molecular profiles; a goal facilitated by comprehensive multi-omics methodologies. However, the realisation of multi-omics potential faces significant hurdles within the biomarker landscape, demanding strategic efforts to overcome systemic bottlenecks.

As part of the EATRIS-Plus project, we developed the <u>Multi-omics Toolbox (MOTBX)</u>, a ground-breaking open-access web platform designed to streamline translational research. MOTBX is meticulously crafted to empower researchers in both academic and industrial settings, offering access to a range of resources essential for multiomics analysis. From detailed protocols and cutting-edge technologies to data analysis tools and quality standards, MOTBX aims to revolutionise the landscape of multi-omics research.

The inception of the MOTBX began with the assembly of a dedicated team comprising individuals with diverse backgrounds and expertise, including multiomics research, data science, clinical research, and website development. Through collaborative effort and ingenuity, the MOTBX team synergised their talents to create a robust and sustainable resource tailored to meet the unique needs of the multi-omics community.

Once developed, the -omics tools have applied in two real-world scenarios.

Firstly, resources provided within the MOTBX were applied in an established cohort of 127 healthy individuals in the Czech Republic with genome sequences available. Information available on this healthy individual cohort has been augmented during the project with transcriptomic, proteomic and metabolomic data.

Secondly, the MOTBX resources were applied for data quality control and statistical analyses, in a cross-omics study, that integrates different -omics data,



to analyse a cohort of 150 trios of paediatric patients (individual paediatric patient and both parents) suffering from neurodevelopmental disorders, together with their parents, for genetic variants using whole genome and exome sequencing. After stringent quality assessment of the plasma samples, 40 suitable patients-parent trios were selected and was investigated for metabolic changes using mass spectrometry.

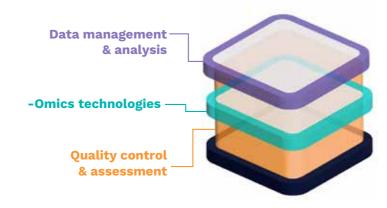
By providing the research community with this tool, EATRIS becomes the driving force behind advancing multi-omics research and expediting the adoption of PM solutions. The MOTBX is a resource that has been built with, and for the community. This means that researchers are not only welcome to use the MOTBX, but to support its further development by actively contributing with valuable resources.

EATRIS-Plus and external resources to enable high-quality research in personalised medicine

#### **Multi-omics Toolbox (MOTBX)**



A knowledge hub for clinicians and personalised medicine researchers from academia and industry



- Tools and services to adopt FAIR practices for multi-omics data management and analysis.
- A collection of best practices and validated protocols for individual –omics technologies.
- Resources to help implement quality control and quality assessment processes.

BUILT WITH THE COMMUNITY, FOR THE COMMUNITY



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 871096

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## HAPLO-iPS COST action -Unlocking the full potential of human induced pluripotent stem cells from haploselected cord blood samples.

At the heart of the EATRIS mission is to bring the right experts and teams together to work on the challenges that prevent the translation of the therapy or technology that can provide real patient benefit. Three years ago, Dr Anna Veiga, the Director of the Barcelona Stem Cell Bank, and Group Leader, Regenerative Medicine Program, Bellvitge Biomedical Research Institute (IDIBELL) approached EATRIS with a simple question: What groups across EATRIS are working on human induced pluripotent stem cells (HiPSCs) from haplo-selected cord blood samples?

Today, there exists a global, critical need for tissue meant for transplantation in patients with organ failure and with degenerative diseases, where currently there are no treatments available. Cell therapy can now represent an alternative to organ transplantation and for the first time, a potential effective treatment for degenerative diseases (such as heart failure, macular degeneration, type 1 diabetes, or Parkinson's disease, among others). The generation of these HiPSCs offers a unique opportunity to obtain an unlimited supply of specialised cells. The use of patient cells for the generation of HiPSCs and their derivatives for treatment can ensure immunological compatibility and minimise the risk of rejection. However, the time and cost necessary to produce customised HiPSC lines and their derivatives in GMP conditions are excessively high and the road to clinical application besieged with many challenges.

Anna, and her experienced team at IDIBELL, work to support the fact that an alternative to the use of patient-specific HiPSCs would be a HiPSC collection from allogeneic healthy donors that

could be expanded and differentiated to treat many different patients. This collection could in fact comprise lines with enough diverse and compatible homozygous human leukocyte antigen to reduce the risk of immune rejection in a high percentage of the population. These homozygous human leukocyte antigen-matched iPSC lines would in fact allow the delivery of off-the-shelf cells for the manufacturing of cell therapy products for multiple diseases and reduce time and costs.

To achieve this goal, a new initiative, the HAPLOiPS project was born, led by IDIBELL in Barcelona, and co-chaired by EATRIS, to create a first of its kind collaborative network through a European Cooperation in Science and Technology (COST). The aim of this multistakeholder network is, to provide a framework for HiPSC generation of HiPSC homozygous for frequent HLA haplotypes, compatible with a significant percentage of the population to be used for cell therapy clinical trials and to create a data collection system (REGISTRY) for such lines.

As of today, this initiative consists of over 130 researchers from 29 EU countries in addition to Israel and South Korea. At the heart of the action are HiPSC researchers from 14 EATRIS institutions representing all current EATRIS membership countries. With this dynamic community growing around this critical topic, EATRIS C&S will have the pleasure to host the next annual meeting in May 2024 in Amsterdam. At this meeting, progresses towards clinical translation of homozygous HLA haplotype HiPSCs will be discussed. The story has only just begun!

# **EATRIS Quality Initiative**

The EATRIS Quality Initiative (EQI) is an umbrella term for EATRIS activities addressing reproducibility, standards and reference materials. By involving EATRIS member facilities in international consortia which address data quality and reproducibility in translational medicine, the EQI aims to improve overall scientific conduct while simultaneously helping increase credibility and visibility of the EATRIS community as go-to-provider of high-quality data.

> Several EATRIS facilities have participated in the Food and Drug Administration (FDA)-driven community effort SEQC2 (Sequencing Quality Control Phase II), which assessed analytical issues and developed a best practice process for the generation and bioinformatics analysis of massively parallel human sequencing data. Special interest groups continue to work on their projects, such as one that is set out to develop reference material for DNA sequencing, and another that addresses the reliability of targeted RNA sequencing in the manuscript drafting stage, with the submissions expected in 2024. Behind all these efforts is the MAQC Society (www.theMAQC.org).

In 2023, Andreas Scherer, EATRIS Biomarker platform Co-Chair and Chair of the EATRIS EQI, was the President of the MAQC Society, and organised the annual society meeting in Helsinki, Finland, focusing on AI in Personalised Medicine, with Toni Andreu as one of the keynote speakers. Currently, the Society discusses further projects, and it will be a task of the EQI to quality assessment, guideline development, disseminate the planned projects within EATRIS to recruit participants who can contribute with technology platforms and/or bioinformatics.

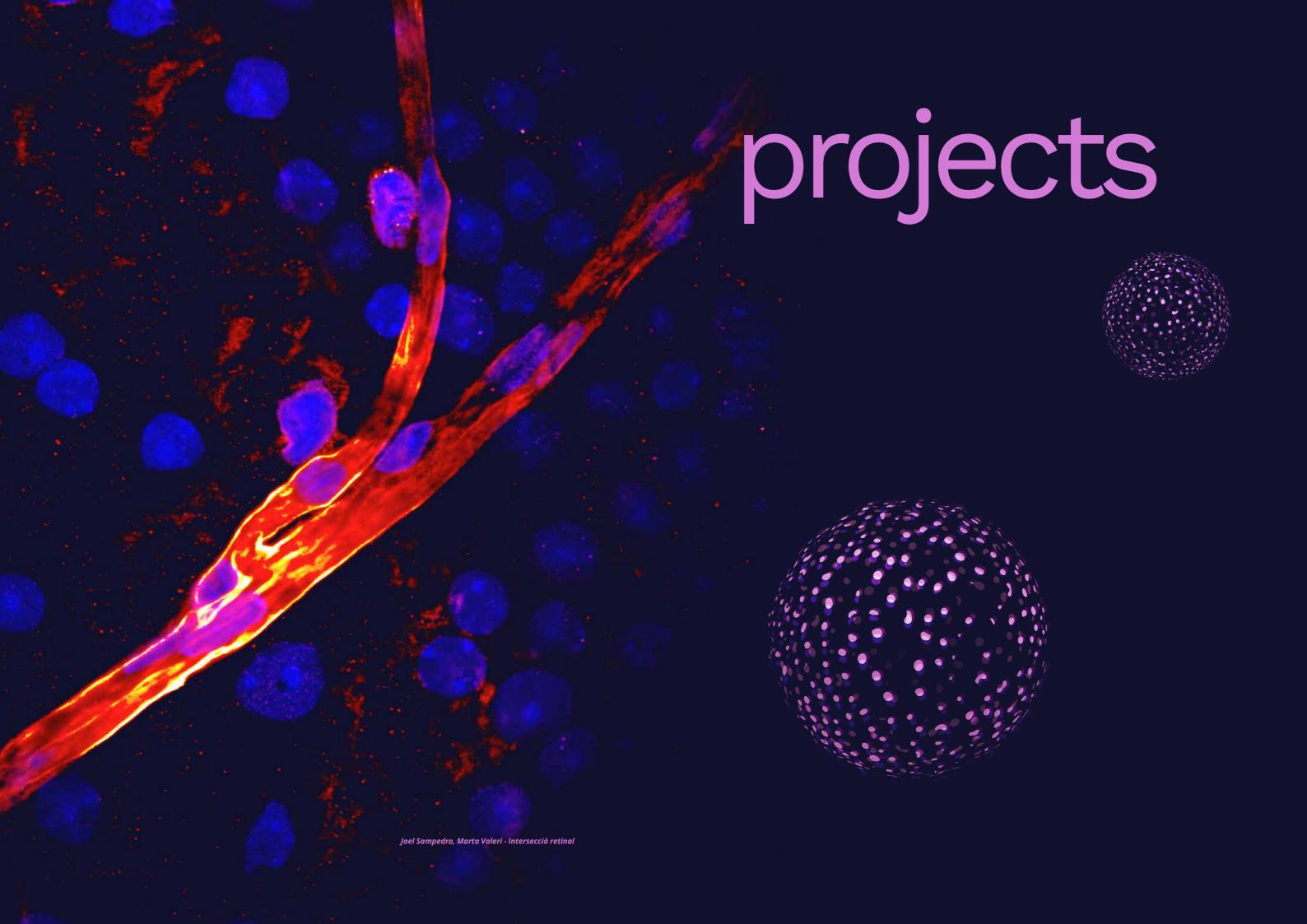
As part of the EATRIS-Plus project, EATRIS facilities also collaborated with the Fudan University in Shanghai, China, to improve and implement the Fudan Quartet Quality Data Portal, which is aimed at facilitating multi-omics data quality assessment. The lead of the Fudan team, Professor Leming Shi, was also Stakeholder in the EATRIS-Plus project. Several publications based on this collaboration were released in 2023.

An important outcome of the EATRIS-Plus project was the MOTBX, as mentioned in the previous section.

Additional efforts took place with the kickoff of the four-year-EU co-funded iRISE project for improvement of reproducibility in science which was launched in Berlin in 2023. Partners of the project include EATRIS, and several EATRIS facilities.

If you work or plan to work in studies on or reproducibility, please get in contact with EATRIS, so that we can gain a comprehensive overview of activities in the field, and can help brand your facility and/or project.





# Project Overview

#### **EATRIS** is a partner in the following projects:

- Training
- Industry Collaborations
- Personalised Medicine
- Quality and Reproducibility
- Research Infrastructure Development

•	Connecting well-established data resources of the COVID-19 data platform	BY-COVID	MAR DEC 24 31 2021 2023
•	Providing cutting edge cancer research services across Europe	🤾 canSERV	SEPT AUG 01 — 31 2022 2025
• •	Delivering innovative scientific tools to support the long-term sustainability strategy of EATRIS in PM	eatris <del>'</del>	JAN DEC 01 31 2020 2023
•	EDITSCD - Assessing efficacy and safety of genome editing approaches for sickle cell disease	EDITSCD	SEPT AUG 01 31 2022 2027
•	Creating an effective rare disease research system for progress. innovation and for the benefit of everyone with a rare disease	** EUROPEAN JOINT PROGRAMME RARE DISEASES	JAN AUG 01 31 2019 2024
•	Demonstrating an operational EOSC Platform for researchers	<b>EOSC</b> Future	APR MAR 01 31 2021 2024
• •	Creating an open collaborative digital space for life science	EOSC-Life	MAR AUG 01 31 2019 2023
•	A European foundation to accelerate data-driven cancer research	∽eosc cancer	SEPT FEB 01 28 2022 2025
•	Strengthening the coordination and networking of the established European Research Infrastructure Consortia (ERICs)	ERIC2	SEPT AUG 01 31 2023 2027
•	Strengthening the research and innovation capacity of the European Reference Networks (ERNs)	@ ERICA	MAR FEB 01 28 2021 2025
• •	European Federation for cancer images	EUCAIM CANCER MAGE EUROPE	JAN DEC 01 31 2023 2026

•	Hub to support clinical drug development and treatment monitoring of immune-inflammation and infectious diseases	GSK	DEC 01 31 2025
•	HEAL - HLA-homozygous iPSC-cardiomyocyte aggregate manufacturing technologies for allogenic cell therapy to the heart	HEAL	SEPT FEB 01 28 2022 2026
•	Improving reproducibility in science	(iRISE	SEPT AUG 01 31 2023 2026
•	Integrated services for infectious diseases outbreak research	I S I D O R e	FEB JULY 01 — 31 2022 2025
•	Stimulating the wider uptake of structural biology across Europe	iNEXT DISCOVERN	FEB JULY 01 31 2020 2024
•	Appling innovative approaches to identify the molecular mechanisms in T2D patients	Recognised	JAN DEC 01 31 2020 2024
•	Building a sustainable European innovation platform to enhance the repurposing of medicines for all	REPURPOSING OFMEDICINES 4ALL	SEPT AUG 01 — 31 2022 2027
•	Improving the structure and integration of European Research Infrastructures (RIs) and Technology Infrastructures (TIs) for impact	RITIFI  Research Metalvation  Recording Metalvation  Parliment	APR SEPT 01 30 2023 2025
•	Accelerating drug repurposing for rare neurological, neurometabolic and neuromuscular disorders	SIMPATHIC 🦓	JULY JUNE 01 30 2023 2028
•	Trustworthy AI for improvement of stroke outcomes	trustroke	MAY JUNE 01 30 2023 2028

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# Reflecting on Four Years of EATRIS-Plus

The overarching aim of the EATRIS-Plus project was to support the long-term sustainability of EATRIS-ERIC by delivering innovative scientific tools to the research community, strengthening the infrastructure's financial model and reinforcing EATRIS' leadership in the European Research Area (ERA), particularly in the field of Personalised Medicine (PerMed) research and development.



PerMed research identifies interventions that can target individual patients based on their predicted response. This has substantial value for patients, as it can reduce trial-and-error treatments and increase effectiveness, which in turn helps to manage the rising healthcare costs of an already ageing population. In this process the role of multi-omic technologies is absolutely vital. Therefore the EATRIS-Plus project delivered an open access validated community resource for researchers - the Multi-omics Toolbox (MOTBX) that helps to expedite translational research by making it easier for academics, clinicians and industry to find relevant validated resources related to multi-omics analysis.

EATRIS-Plus had a strategic role in patient engagement via the Patient Advisory Committee (PAC) and launching the **Patient Engagement Resource Centre (PERC)** in order to promote the uptake and ease of access to researchers performing patient engagement activities. By engaging with patients, researchers play a pivotal part in shifting and improving research practices, they contribute to a more open and accessible research and empower patients to have an active role in research.

Another important development in impacting robust research practices is the EATRIS Commitment to Quality Certificate (ECCQ), that was developed and piloted through the project. The ECCQ was developed in collaboration with the

Enhancing Quality in Preclinical Data (EQIPD) project, and assesses efforts in providing quality research and is an important addition to EATRIS' Quality Initiative (EQI). In addition to the scientific endeavours, EATRIS-Plus helped expand, consolidate and exploit the translational academic capacities of the infrastructure to enable researchers to better address the scientific and societal challenges in the field of personalised medicine.

The EATRIS hub, as well as all current 14 national nodes, participated in implementing a plethora of joint activities. These included outreach to the various academic, industry, funders and patients to raise awareness of the opportunities and services through EATRIS. The ambitious capacity-building programme for 14 national nodes included 10 professionalisation workshops and supported the task of national nodes strategic plans development. Furthermore, the Staff Exchange Programme supported 25 visitors from 10 EATRIS nodes and member institutes in knowledge and best practices exchange creating numerous collaborations and providing a solid framework for exploitation in future similar settings.

Extensive outreach to industry was performed through organisation and participation in partnering and matchmaking events.

Innovation Hub concepts were developed in collaboration with EFPIA (Rare Disease Moonshot Initiative) to address white spots in

rare diseases where Public-Private Partnerships (PPPs) could add value. The Innovation Hubs practice as well as the Public-Private Collaboration workshop model were selected as Best Practice Examples in the European Commission Science Valorisation platform.

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The European Alliance of Medical Research Infrastructures (EU-AMRI) was launched in 2022 and collaborations with national nodes of BBMRI, ECRIN as well as other Life Science RIs took place in several countries.

Significant efforts were made to strengthen the EATRIS Training portfolio. Over 600 researchers were trained through Summer Schools in Personalised Medicine, the TransMed Academy online learning environment and the Public-Private Collaboration workshops, and the Strategic Plan for EATRIS Training Operations was developed to complement the EATRIS Long Term Sustainability Plan.

Efforts to expand EATRIS country membership were explored under the EATRIS-Plus project. While Bulgaria, Latvia and Croatia all became full members during the project, further engagement was solidified with Ireland through signing a Memorandum of Understanding (MoU) with Trinity College Dublin leading the newly launched Irish initiative - Translational Medicine Alliance Ireland (TMAI). Collaborations were also explored with Greece and an MoU signed with The Biomedical Research

Foundation (BRFAA) of the Academy of Athens.

In conclusion, EATRIS-Plus used cutting-edge academic expertise and technology services to help de-risk and improve the flow of academic and industry developments downstream towards the patient, reducing barriers to public-private and public-public collaboration, facilitating the development of novel patient-targeted diagnostic and therapy interventions necessary for the adoption of PerMed. The project significantly supported the development of analytical tools and operational models to reduce the cost and time associated with early medicines development, thereby enhancing biomedical innovation at European and global levels.

The EATRIS-Plus project was an invaluable sustainability-developing cornerstone to EATRIS-ERIC that involved all 14 national nodes. It further established EATRIS as a credible force and a key player in the translational medicine ecosystem and will have a positive impact on translating biomedical findings to patient benefit for years to come.



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 871096

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## Connecting with the drug repurposing community: Spotlight on the REMEDi4ALL Repurposing Concierge Service

REMEDi4ALL is an EU-funded EATRIS-led research initiative that is driving forward the repurposing of medicines in Europe. It is a 5-year, €25M Horizon Europe project, involving 24 European organisations that aims to develop an innovation platform supporting promising, high impact drug repurposing projects championed by patients in any phase of development and disease area.



The REMEDi4ALL Repurposing Concierge, launched in 2023, actively engages with the repurposing community to deeply understand its dynamics and address its challenges and needs. This service comprises a streamlined form allowing individuals involved in repurposing projects to introduce their initiatives and request preliminary meetings with REMEDi4ALL representatives. These meetings serve to offer a comprehensive understanding of REMEDi4ALL's mission and the broader landscape of drug repurposing. They also provide invaluable insights on how to integrate into the drug repurposing community and leverage REMEDi4ALL's resources, including patient engagement, regulatory guidance, access to compound libraries, and preclinical and clinical development expertise.

As a testament to its commitment, REMEDi4ALL ensures that all interested parties receive a dedicated 30-minute introductory call, affirming its commitment to fostering collaboration and advancement within the field.

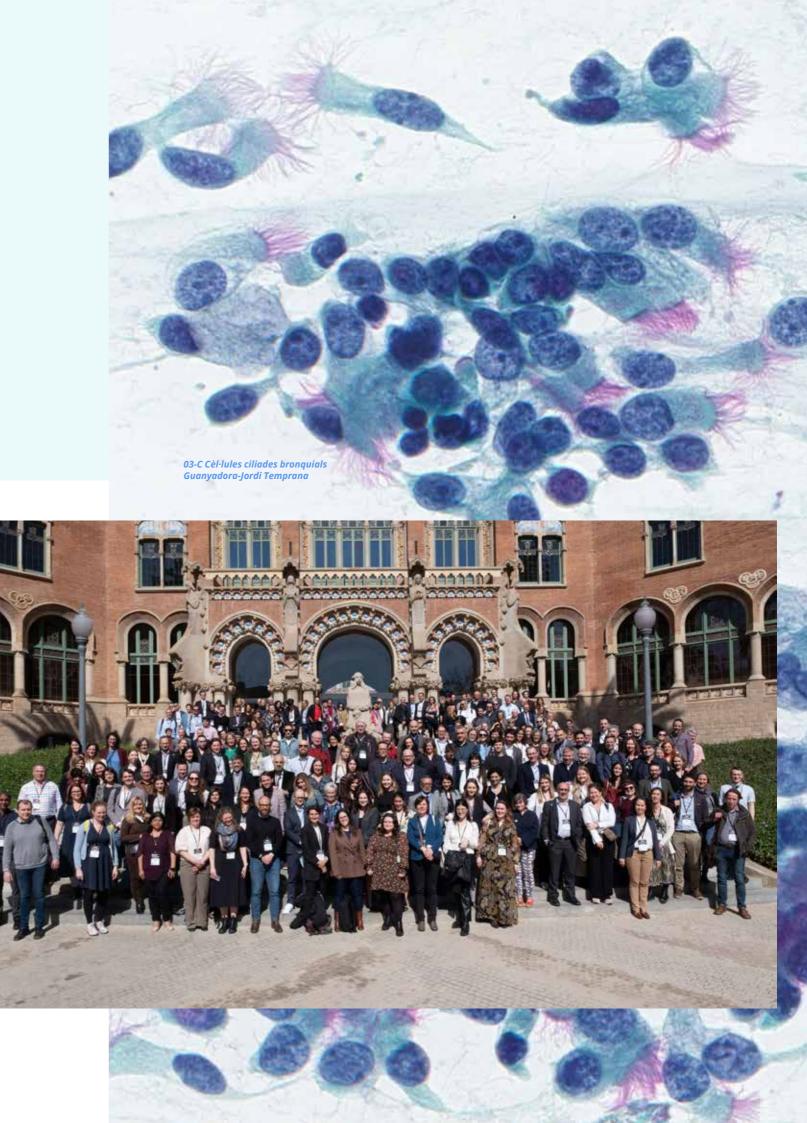
To date, the REMEDi4ALL Repurposing Concierge has handled over 100 requests with diverse members of the drug repurposing community, spanning a wide spectrum of needs. Notably, a high number of inquiries have come from the patient community, including patients themselves, caregivers, representatives from patient groups, in addition to stakeholders from life sciences companies and academic researchers.

our ability to intimately acquaint ourselves with the wider drug repurposing community and its requisites. This, in turn, empowers us to strategically shape our project portfolio, effectively magnifying our influence on the holistic drug repurposing ecosystem.

Explore the Repurposing Concierge here: https://remedi4all.org/repurposing-concierge/

The introduction of the Repurposing REMEDi4ALL Concierge significantly enhances

The REMEDi4ALL project has received funding from the European Union's Horizon Europe Research & Innovation programme under grant agreement No 101057442.





# User access and business development

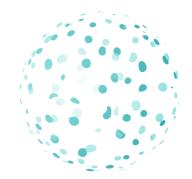
User access to EATRIS distributed infrastructure is provided to any researcher with a legitimate project regardless of their territory (except sanctioned territories such as Russia) or organisational provenance (public/private).

The EATRIS portfolio of users is diverse, with academia accounting for the most users (55%). EATRIS performs extensive outreach - relative to its overall funding envelope - including to industry. Biotechnology and pharmaceutical SMEs (25%) outreach is generally conducted at conferences and partnering events or via our network of National Coordinators (NCs). On average 100 companies are met per year at large partnering events and conferences, which yields around 15-20 requests annually from the private sector. These SMEs often have straightforward research requests that can be handled by the EATRIS Research Service. It allows companies and academics to quickly identify the main challenges they will face along their development programmes. This is especially true for complex products such as in the field of ATMPs.

Academic user engagement and marketing efforts go through EATRIS National Nodes and participating institutions, as well as EATRIS-ERIC

involvement in large scale initiatives like the European Joint Programme on Rare Diseases (EJP RD) or REMEDi4ALL. To encourage EATRIS members to make use of the EATRIS services and increase members' capacity to prepare high quality funding applications, EATRIS developed a Funding Opportunities database (accessible by EATRIS members only) that is updated monthly. Further visibility towards EATRIS services is gained through its internal community as ambassador of the Research Infrastructure and through relationship building with consultancy companies/grant writing companies.

Services dedicated to funders and charities are performed mostly centrally and include Translational Assessment efforts, expert advices and mentoring. Each service aims to improve the chances of success of the individual translational project funded by funders and charities. Those efforts are performed in cooperation with project teams to provide guidance on the development path ahead, to avoid pitfalls and ensure project outcomes are generated with patients in mind. For a while mentoring was restricted to Dutch users, but through EJP RD and REMEDi4ALL, these mentoring efforts have been developing further reaching out to a much larger community.



5-8 June, 20 meetings); BeHealth (26 Oct; 2 meetings); World Orphan Drug Congress (30 Oct, 7 meetings, Barcelona); NLS Days (27 Oct, 23 meetings, Copenhagen); Precision Oncology Europe Congress (14-15 Nov, 3 meetings, Berlin); Biofit 2023 (12-13 Dec, 11 meetings, Marseilles); Explorative calls with SMEs and Biotech companies (more than 20) totalling more than 100 exploratory discussions with SMEs and biotech companies in 2023.

- Funded projects: Targeted services provided to SMEs via Interreg North-West Europe Codex4SMEs (Regulatory Assessments: 3, Translational Assessments: 2, Research Services: (1); and EU-funded projects: ISIDORe (3); canSERV (first call under evaluation).
- Engagements with Innovation Hubs: Innovation Hubs for Gene Therapies, EATRIS Nordic ATMP Hub.
- **Conference partnerships:** Partnership with Advanced Therapies London 2024 has been extended to incorporate Advanced Therapies USA 2024.
- Other outreach events: EATRIS presentation of ATMP activities at EUCOPE Cell and Gene Therapy Meeting (28 June); EATRIS presentation of ATMP platform and facility tour at EDUCELL (Ljubljana, 6 June); Knowledge valorisation: the role of research and technology infrastructures (21 June), COST-Connect Event: "Coordinating Cancer research in Europe" (29 June), Campania Technology Forum, The frontier of cancer research in Campania, (online, 13 July), Technology Forum Life Sciences 2023, The European House Ambrosetti (Milan, 13 September).
- Collaborations and Workshops: The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) (3 March); Working closely with EFPIA and the Rare Disease Moonshot coalition: Workshop "Where to boost public-private partnership to unlock uncharted territories in rare disease R&D" (Brussels, 21 February), Hybrid workshop co-powered by EATRIS-Plus project, Research needs recommendations – translational track (Brussels and online, 22 September), EATRIS-Plus project: Presentation of the Multi-omics Toolbox (MOTBX) (27 September); Information Event | How diagnostics SMEs benefit from Codex4SMEs services (08 Feb, online); Regulatory Pathways for Diagnostic Tests in the United States and Europe (12 September, online).
- As a result, 24 SMEs and 18 pharma companies engaged EATRIS into services (consortium building, research services, expert advice and mentoring efforts).

## **1** Industry

In 2023, a more consolidated strategy was deployed to conduct outreach and business development activities to industry. This strategy was executed by the SMEs and Outreach Manager, who coordinated the efforts of the EATRIS C&S Science Team, with the support from the EATRIS nodes, especially the EATRIS National Coordinators in national events where the knowledge of the local ecosystem is crucial.

The team's effort spanned a spectrum of activities including significant interactions with industry and strategic collaborations:

 B2B and partnering events: DIA Europe 2023 (Basel, 12-14 Mar); Advanced Therapies Congress (London, 14-15 March, 23 meetings); ELIXIR Innovation and SME Forum: Al in Health Research (Utrecht, 13 April - 2 meetings); Cross-Regional Pitch & Match session: Next generation vaccines & immunotherapy (16 May, Leuven); Bio International Convention (Boston,

#### Best practice for public-private collaboration

EATRIS' experience in fostering public-private collaborations was highlighted in April 2023 by the European Commission with EATRIS feature on the EU Knowledge Valorisation Platform with two best practices examples:

EATRIS' innovative two-day training workshop and curriculum, bridging industry-academic collaboration gaps and offering hands-on skills, theoretical knowledge, and networking opportunities.

The EATRIS-GSK public-private innovation hub, fostering academia-industry partnerships for long-term benefits to patients and citizens.

### **2** Academia

In 2023, we focused on maintaining the various initiatives and tools developed in the two previous years. The funding opportunities database for members continued to be updated on a regular basis with relevant European funding calls with a translational dimension, and highlights were included in monthly digests for members as well as in weekly meetings with the nodes.

The main priority in 2023 was the piloting of expert centres and the inclusion of the centres in funding proposals on behalf of EATRIS in areas such as innovation management, regulatory affairs and health technology assessment in the field of in-vitro medical device/diagnostic medical device to our consortium building service. Under the Decentralise Expert Service Agreement (DESA), seven EATRIS institutions can now provide expert service on behalf of EATRIS to proposals and projects. During the summer 2023, we received nine requests for the expert service. While we identified capacities for all requests, five turned into funding applications.

ISIDORe and canSERV, the two flagship INFRASERV projects, represent the avenue where research services and expert services (i.e., regulatory expertise) can be accessed by academia. In 2024, we will keep sharing the availability of those high-need services to research institutions through our nodes and social media outreach.

# **3** Funders & Charities

In 2023, we continued offering our Translational Assessment and mentoring services to funders and charities. Five assessments were performed for ReumaNederland and two assessments for the Brain Foundation under a long-term collaboration agreement signed with the charity. In total, 11 assessments were performed including those performed for SMEs in the in vitro diagnostic field under Codex4SMEs. Additional expert advice was given to projects through various funding schemes including Codex4SMEs, ISIDORe and Human Plus.

Mentoring represents a new avenue to support proposals under development. Short-listed proposals after first-stage application to funding can benefit from mentoring in different fields such as regulatory, IP or translational feasibility (pre-clinical models, biostatistics, GMP production...) to help support second stage proposal development. Initially piloted through EJP RD with 30 Pls mentored under JTC 2020 and JTC 2022, additional efforts took place in November in Luxembourg for the EJP RD project. 18 pre-clinically focused rare disease research projects funded under JTC 2020 received some further guidance on the future requirements and challenges their projects will face from a development perspective. Some of those projects had already received mentoring when applying for funding. Furthermore, 11 projects short-listed by the Brain Foundation in the Netherlands under their subsidy programs 'Finding a cure' were mentored late 2023 – early 2024.

Special attention on mentoring needs to be given to REMEDi4ALL. In its first year of intense activities, the repurposing concierge was developed as a new kind of mentoring service provided to patient groups or charities, biotech companies, or individual Principal Investigators (PIs) to discuss the support needed for their repurposing activities. Since the launch of the repurposing concierge, 72 projects have benefitted from 30 minutes of high-level mentoring interactions with the EATRIS C&S REMEDi4ALL team. Notably, 34 of the requests received were directly from families or patient representatives, representing a new kind of interaction for the EATRIS team.

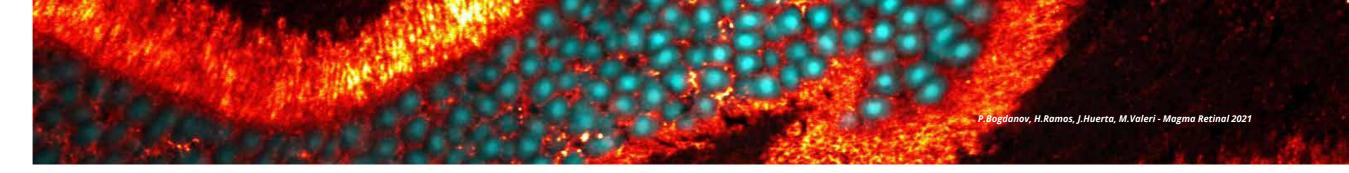
#### **Summary of activity**

SERVICES	2020	2021	2022	2023	
Grant support service					
Consortium building	23	35	22	21	
EATRIS C&S as partner	13	21	13	17	
<ul> <li>Letter of support</li> </ul>	10	7	5	4	
Project Advisory Board	NA	NA	NA	1	
Research Service	18	17	28	8	
Translational Assessment/Expert advice	6	29	29	29	
Industry Partnering	2	1	3	-	
Mentoring	15	0	15	84	
Hub Management	1	1	1	1	
INCOME C&S OFFICE	2020	2021	2022	2023	
Service fees (audited financial report)	€ 57,530	€ 50,246	€ 53,432	€ 115,413	
Grants	€ 885,042	€ 828,050	€ 1,618,068	€ 2,260,992	
INCOME INSTITUTIONS (BUDGET NEGOTIATED)	2020	2021	2022	2023	
EATRIS Affiliated partners	€ 296,487	€ 593,651	€ 228,797	€ 55,875	
Research services	€ 136,250	€ 851,131	€ 8,217,239	€ 341,373	
Users	6,978	2,010,329	2,620,121	2,640,373	

# **EATRIS Expert Centres**

# Digital Transformation





In 2023, EATRIS appointed seven EATRIS Expert Centres to provide high value added services historically offered by the EATRIS C&S team. Those expert services that are complementary to the existing laboratory research services offered by EATRIS institutions cover crucial areas such as innovation management, regulatory strategy, translational feasibility, and early health technology assessment. With seven newly appointed Expert Centres, EATRIS will continue serving Europe's translational research efforts and growing demand for expert services.

The nomination of the expert centres followed the adoption of the General Framework for the Decentralised Implementation of Expert Services by the EATRIS Board of Governors in May 2022. All seven institutions were selected based on their track records and expertise supporting innovation of Translational Research projects. They all signed the EATRIS Decentralised Expert Services Agreement (DESA), providing the framework for services offering on behalf of EATRIS-ERIC. Since their inception, in March 2023, nine proposals have been submitted with an Expert Centre as partner.

The institutions that were appointed as 'EATRIS Expert Centres' were:

Università Cattolica del Sacro Cuore, Italy.

Association for Innovation and Biomedical Research on Light and Image (AIBILI), Portugal.

Instituto Pedro Nunes (IPN), Portugal.

Istituto Mario Negri, Istituto di Ricerche Farmacologiche Mario Negri (IRCCS), Italy.

The Bellvitge Biomedical Research Institute (IDIBELL), Spain.

Germans Trias i Pujol Research Institute (IGTP), Spain.

Instituto de Medicina Molecular João Lobo Antunes (IMM), Portugal.

In 2023, EATRIS Digital Transformation achieved significant progress in advancing its initiatives, aligning with the strategic objectives outlined in the EATRIS 2023-2026 Strategic Plan. A cornerstone achievement was the publication of a comprehensive multi-year roadmap, serving as a guiding document that outlined strategic goals and milestones for Pillar 5: 'Accelerate the digital transformation of translational medicine.' This roadmap provided clarity, fostering alignment among stakeholders and informed decision-making.

The roadmap delineated EATRIS Digital Transformation activities across four key interest areas: data management and governance for translation, availability of high-quality datasets for regulatory purposes, artificial intelligence and innovation, and community collaboration and engagement. Initiating discussions on onboarding EATRIS Digital Transformation Services played a crucial role in ensuring seamless integration within the existing service catalogue, reflecting a proactive approach to enhancing EATRIS' overall capabilities.

Throughout 2023, the EATRIS Digital
Transformation Working Group (formerly the
EATRIS Digital Transformation Core Team) played
a pivotal role. Comprising 16 members from
the EATRIS community, representing three of
the five EATRIS Platforms and eight of the 14
EATRIS Nodes, the group met monthly to discuss
updates related to translational medicine.

Collaborative efforts, notably in projects like the MOTBX with the EATRIS Biomarkers Platform,

showcased EATRIS' commitment to addressing the research community's needs. The public release of the MOTBX marked a significant milestone, providing valuable solutions for generating and integrating multi-omics data.

EATRIS Digital Transformation actively contributed to projects such as EUCAIM, REMEDI4ALL, TRUSTroke, and EOSC4Cancer in 2023. Key accomplishments included partnering in the development of the Data Management Plan (DMP) for EUCAIM, delivering initial DMPs for REMEDI4ALL and TRUSTroke, and generation of the Stakeholder Forum in EOSC4Cancer.

The completion of projects like EOSC-Life, EOSC-Future, and HealthyCloud in 2023 showcased EATRIS Digital Transformation's integral role in the landscape. Notably, EATRIS Digital Transformation significantly contributed to the Strategic Agenda of the Health Research and Innovation Cloud as part of the HealthyCloud Coordination and Support Action, with the final release of this agenda in December 2023.

Looking forward to 2024, EATRIS Digital Transformation aims to deepen interactions with EATRIS platforms, ensuring data activities support strategic positioning. The operational growth of the EATRIS Digital Transformation Working Group and the cataloguing of capacities in the EATRIS services portfolio are key focus areas. The addition of capacities for Artificial Intelligence (AI) and Machine Learning (ML) activities related to translational medicine under the EATRIS Digital Transformation Expert Centre umbrella is of particular significance.

# Partnerships

Engaging with key global stakeholders to collectively address the high risk of failure in medicines development is essential to the core mission of EATRIS. Successful translational research requires cross-sectoral collaboration among diverse stakeholders, namely academia, industry, funders, hospitals, regulators and patient organisations.

# **Bridging the gap between science and policy**

## EATRIS initiates collaboration with social sciences and humanities

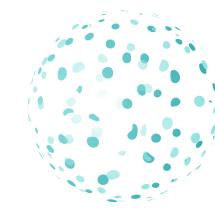


EATRIS, global publisher Taylor & Francis, and the European Alliance for Social Sciences and Humanities (EASSH) partnered to bring focused expertise across the life sciences and humanities. The objective was to engage in public debate, to strengthen the European research ecosystem, accelerate knowledge valorisation and improve interactions among public and private partners.

Participants from across academia, policy, and industry came together in April 2023 in Brussels, Belgium to reflect on the core principles of translational research at an interdisciplinary workshop co-convened by EASSH, EATRIS, and Taylor & Francis. The publicly available workshop report provides an executive summary of the findings. Some of which are the value of agreeing on a common definition for translational research, ways to support cross-disciplinary and cross-sectoral collaboration, and the role that funding and assessment frameworks can play in creating an enabling environment for translational research practices.

Gathering researchers from different disciplines to talk about how to translate research more effectively for society was an eye-opening experience. This demonstrated that translational approaches and mindsets are highly relevant beyond medicine, where the concept initially emerged.

Through a series of presentations and discussions, a set of key findings and recommendations emerged, which provide a pathway for further activity in this area. A follow-up webinar series is planned for 2024.



## EATRIS continues to advocate for gender equality at Research infrastructures in the ERIC Forum



The ERIC Forum brings together all European Research Infrastructure Consortia (ERICs) 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.

Following the successful set-up and implementation of the ERIC Forum (2019 to 2022), ERIC Forum 2, supported by Horizon Europe funding programme, kicked off in September 2023 to consolidate its achievements as well as expand coordination and cooperation among the ERICs. The project focuses on supporting the implementation of ERIC regulation and services and consolidating the integration of the ERICs in the European Research Area by deepening the Forum's contribution to research policies.

EATRIS will continue to lead the Forum's work around gender equality, initiated in 2021, by coordinating the delivery of a webinar series for all ERICs staff and maintaining the Forum's existing community of practice around gender equality.



# **Asserting EATRIS role in the global research environment**

# translation together



#### EATRIS international partnerships, Translation Together and NewFound

EATRIS is a partner in Translation Together (TT) – a unique collaboration of leading translational research organisations from around the world, namely NIH-NCATS (US), TIA (AU), AdMare Bioinovations (CA), AMED (JP), LifeArc (UK), FIOCRUZ (BR). TT envisions a global translational research community of diverse stakeholders empowered to translate discoveries effectively and efficiently into health interventions for the benefit of patients and society.

In 2023, most efforts took place through the Education and Training working group that met on a regular basis and performed an assessment of all training opportunities available at each organisation. The work resulted in the submission of a paper entitled "Building translational scientists through cross-continent training and educational activities from classroom to commercialisation" published as a pre-print on Zenodo in December 2023 with plans to submit it to the Journal of Clinical and Translational Science.

Additional efforts took place with TT partner in the US NIH-NCATS on the preparation of a European version of their Assay Guidance Manual Workshop. Through NCATS guidance, EU based faculty is being put together and new partnerships developed (workshop co-organiser EU-OPENSCREEN). Further to those actions, EATRIS' efforts towards identifying impact pathways and EATRIS impact working group was shared with the group in a dedicated meeting. Interest from the partners to form a larger working group was put forward with the overarching ambition to define collectively a framework for assessing the wider impact of Translational Research organisations.

The NewFound initiative, a joint venture with the Oswaldo Cruz Foundation (FIOCRUZ), EATRIS, the US National Institute of Health's (NIH) National Center for Advancing Translational Sciences (NCATS), and the Open Source Pharma Foundation (OSPF), continued to develop in 2023 with bi-weekly meetings and the inception of two projects. The first project related to Metformin in a TB clinical trial drew a large effort from the NewFound partners with the setting up documents such as a Target Product profile, clinical trial protocol and regulatory expertise provided to the project through EATRIS. These activities led to the expansion of the international network and involvement of additional experts from the TB alliance and clinical experts from South Africa, Singapore and India. A representative of Open Source Pharma Foundation (India) visited EATRIS in October 2023 to explore further collaborations. The three global partner organisations (NCATS, OSPF and FIOCRUZ) are also represented in the REMEDi4ALL Project Policy Board where an actionable agenda with global opportunities, barriers and incentives for drug repurposing are discussed. Another project that recently came to NewFound is on an ultra-rare disease called WOREE syndrome. NewFound partners will contribute expertise and clinical sites where possible studies can be performed and patient engagement activities will be facilitated for awareness and inclusion in those studies, as well as natural history studies.



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#### EATRIS Joins Forces with CERN and C-Path in Two Collaborations to Accelerate Translational Medicine and Healthcare Innovation for Patient Benefit

In 2023, EATRIS joined forces and entered into a long-term collaboration agreement with the European Organization for Nuclear Research (CERN). By combining the complementary expertise of both organisations, the partnership seeks to develop advanced technologies in areas of high medical need and facilitate significant progress in healthcare innovation.

CERN, the European Laboratory for Particle Physics, is operating the world's largest and most powerful particle accelerator. Its core mission is to provide cutting-edge technology and indispensable infrastructure to perform world-class research in fundamental physics by hosting numerous international collaborations that have led to revolutionary experiments and technological developments. Notably, CERN is also credited as the birthplace of the World Wide Web.

Alessandro Raimondo (Medical Applications Officer at CERN) comments: "We are excited about this collaboration and bringing CERN's world-class research expertise to the table with EATRIS. This long-term collaboration agreement holds the promise of having a meaningful impact on unmet medical needs, ultimately leading to a healthier future for all. We look forward to seeing the positive outcomes of our combined efforts in the world of translational medicine."

Sara Zullino (EATRIS Scientific & SME Outreach Manager) adds: "Through this partnership, EATRIS and CERN are set to propel the field of healthcare into uncharted territories. This collaboration aims to transfer the knowledge generated at CERN to society and pioneer new frontiers in health solutions. Together, we are embarking on a translational journey to revolutionise the way we approach scientific innovation and impact patients' lives."

Both organisations will leverage their infrastructure and technology platforms to support collaborative research initiatives and foster interdisciplinary projects, such as the TRUSTroke EU project that was launched in May 2023. The alliance with CERN marks a significant milestone in translational medicine and scientific collaboration, and bridges the gap between fundamental physics, research and healthcare intervention.



In 2023, we also signed a collaboration agreement with C-Path (Critical Path Institute) aimed at fostering actionable scientific and educational cooperation. This agreement marks a significant milestone in the pursuit of patient-centric innovation and the advancement of translational medicine research.

Cecile Ollivier, C-Path Managing Director for Europe, emphasised the importance of addressing the pressing challenges in medicines development early in the process, "When translational science and regulatory science work together it can lead to drug development trials that can quickly yield more effective, affordable and safe medical products for patients. Together, C-Path and EATRIS can overcome technical and operational gaps across the drug development lifecycle."



# Interview with Alessandro Raimondo, CERN's Knowledge Transfer Officer for Medical Applications





Please can you tell the EATRIS community a bit about CERN

CERN is the largest particle-physics laboratory in the world. Our work helps understand what the universe is made of and how it works, using complex instruments such as particle accelerators and particle detectors, as well as sophisticated computing tools and infrastructures. Our efforts extend beyond conducting world-class research in fundamental physics; we also accelerate innovation to maximize CERN's global positive return to society.

What strategies does CERN employ for fostering external collaborations, both within and outside the field of particle physics?

CERN is a model for open and inclusive international collaboration: the Laboratory unites scientific communities of all nations. Since our core mission is fundamental research, we need industrial and institutional partners to translate CERN technologies and expertise into societal applications. I work in CERN's Knowledge Transfer group, whose mission is exactly to foster opportunities for making a concrete impact on society, for example by liaising with relevant actors from various application fields and addressing their unmet needs with solutions powered by CERN technology.

Tell us about the collaboration between CERN and EATRIS.

In early 2020, I launched an exercise to identify the most relevant healthcare institutions in our Member and Associate Member States for potential knowledge-transfer partnerships. EATRIS emerged as one of the top 10 institutes capable of facilitating impactful healthcare technology transfer. Synergies were immediately evident during our initial contact, prompting us to continue our collaboration. This collaboration formalised with the participation in an EU project in 2022, culminating in the signing of a formal Collaboration Agreement in 2023.

In what specific ways has EATRIS collaborated with CERN thus far, and what are some notable outcomes or achievements from this partnership?

From your perspective, what are the existing gaps or challenges in the current landscape that CERN aims to address through collaborations with translational medicine infrastructures like EATRIS?

How do you envision this collaboration evolving in the future, and are there any new areas or initiatives on the horizon for CERN's in fostering healthcare innovation?

Is there anything else that you'd like to add?

EATRIS plays a crucial role in leading efforts to identify the most suitable partners for transferring our technologies into the healthcare domain. By bringing together various stakeholders, EATRIS facilitates the exploration of optimal configurations to efficiently address societal unmet needs. The typical case is the EU project TRUSTroke where both CERN and EATRIS are engaged, together with many other partners.

At CERN, we are physicists, engineers, professionals in various domains, but we are far away from the medical world, its needs and priorities. We need to engage in a dialogue with the medical doctors and researchers in order to work on meaningful applications of our technologies, but there are not yet many opportunities to meet. In fact, for some years, CERN has coorganised a series of interdisciplinary conferences to bridge this gap: working with an organisation like EATRIS is actually way more effective, since they are already engaged in translational research.

CERN's cutting-hedge technologies are often not immediately transferable to the healthcare domain. That's why we need partners who are experts in application, enabling us to make the right match between the needs and a possible solution that we can offer. For this reason, EATRIS can play a pivotal role in helping us to steer our efforts towards addressing unmet needs coming from the field, even at the early stage when we are identifying the new technologies invented by our scientists.

It is a great pleasure to collaborate with a dynamic and welcoming organisation like EATRIS, as I could witness at the their 10th anniversary event in 2023.

# Listening to patients and fostering multi-stakeholder engagement

## Advocating for meaningful patient engagement in translational research

Building on partnerships initiated in 2019 with EUPATI and the European Patients' Forum, EATRIS has taken further steps towards raising awareness on the need to make meaningful patient engagement in translational research the 'new normal'. The year 2023 saw the launch of the Patient Engagement Resource Centre(PERC; patient-engagement.eu), an easy to navigate platform to help researchers get started with patient engagement. The platform is a result of multi-stakeholder collaboration and a co-creation effort through regular structured focus group exchanges with researchers, research staff and patients so that PERC could meet the needs of the research community. EATRIS co-organised several online sessions to disseminate PERC widely and ensure its uptake at the EU level and beyond and participated in several EU-wide events, such as the Patient Engagement Open Forum, a yearly event gathering patient engagement leaders, and the EATRIS 10th anniversary conference. Additionally, EATRIS continued to support patient education by offering training opportunities to patients to its regular training courses on medicines development in collaboration with EUPATI.

#### EATRIS maintains close dialogue with regulatory authorities

EATRIS remains dedicated to enhancing collaboration with the European Medicines Agency (EMA) to better support researchers in formulating regulatory strategies for therapeutic development. A primary focus is placed on the ACT-EU initiative, which aims to revolutionise the initiation, design, and execution of clinical trials in Europe.

Under the ACT-EU initiative, EMA has appointed EATRIS as a permanent representative of the ACT-EU multi-stakeholder platform Advisory Group (MSP AG). This group serves as a crucial forum for key stakeholders in clinical trials to regularly engage with relevant regulators. The objective is to foster increased collaboration, build mutual trust, and enhance the European clinical trials landscape for the benefit of innovation and patients.

EATRIS and EMA have collaborated on various EU-funded projects, including the development of training materials in rare diseases (European Joint Programme for Rare Diseases), Advanced Therapy Medicinal Products (former ADVANCE Programme), and regulatory science for academia (former CSA STARS). In the field of repurposing, the REMEDi4ALL project further intensified interactions with regulators, incorporating an EMA representative into the advisory board.

Additionally, EATRIS actively participated in an EMA-led workshop addressing the opportunities and risks associated with artificial intelligence in medicine. This involvement extended to contributing to subsequent consultation, with the aim of shaping relevant guidance for the future

#### Raising the voice of EATRIS for improved framework conditions

EATRIS seized several opportunities throughout 2023 to advocate for a stronger translational research culture and ecosystem in Europe. Those included formulating recommendations for Research Infrastructure Impact Assessment, responding to the EC's public consultation on the future Pharmaceutical Legislation and joining 32 other health organisations to share views on specific recommendations related to the European Health Data Space.

EATRIS' contributions to better knowledge valorisation and public private partnerships were also acknowledged through the selection by the European Commission of two EATRIS solutions (EATRIS yearly training on academia-industry collaborations and the EATRIS-GSK innovation hub) as best practices featured on the EU Knowledge Valorisation Platform. Furthermore, the European Strategy Forum on Research Infrastructures (ESFRI) also recognised EATRIS' continued efforts to build meaningful partnerships with industry in its latest report, which included EATRIS as one of the four case studies featured in ESFRI RIs Industry Cooperation Report published in June 2023.



# Normalising Patient Engagement



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Since 2019, EATRIS has made patient engagement one of its strategic priorities. As a representative of academia, EATRIS can play a meaningful role in building bridges and connecting academic researchers and patient groups, therefore supporting the normalisation of patient engagement practices.

We have built partnerships with key European organisations active in the field, and prioritised three main areas: supporting patient education; training researchers about meaningful patient education, and cocreating research with patients. Through our partnership with EUPATI and EPF as well as connections with EURORDIS we have provided regular opportunities for patients to join EATRIS-run training workshops, to expand their knowledge and understanding of medicines development.

We have co-authored two articles for the EUPATI Toolbox, an open access platform that provides information on key concepts in research and development for the general public in 14 languages. The platform is accessed by 6.5 million people. Our two articles, one on Personalised Medicine and another on Translational Medicine, have generated over 2,700 views within just over a year.

Co-creating research with patients is part of our patient empowerment strategy. From the start of EATRIS-Plus project, our partners the European Patients' Forum (EPF) and the European Aids Treatment Group (EATG) set up a Patient Advisory Committee who provided valuable insights and shared their expertise with project partners on topics such as health data sharing, personalised medicine and patient engagement approaches in academic research. Patient Engagement is also a commitment shared with our nodes across Europe, notably EATRIS-Latvia and

EATRIS-Spain, where the latter gathered 25 leading research centres to develop a strategy to incentivise patient engagement institutionally and nationally.

Our third priority area is to provide training for researchers on meaningful patient engagement. That is why this year, we launched the "Patient Engagement Resource Centre", or 'PERC', which can be accessed at patient-engagement.eu. The PERC is a result of more than a year of consultations and focus groups with over hundred stakeholders, including representatives from the patient community, academia and research funding organisations. The PERC is an easy-to-navigate platform to help researchers get started with patient engagement. It offers a curated collection of public resources, answers to frequently asked questions and showcases stories of successful collaborations between patients and researchers.

While academic researchers are gradually involving patients and citizens in their research, meaningful patient engagement practices are challenging to develop in academia for various reasons such as lack of human and financial resources, or limited awareness of the tools and services available to guide researchers in their patient engagement journey. Therefore we regularly organise collaborative events with other academic and patient organisations such as the webinar we co-organised with the EU-LIFE Alliance, EPF and EATG called: "It's Time We Talk About Patient Engagement".

EATRIS also has a seat on the organisation committee for the annual Patient Engagement Open Forum (PEOF) to bring forward the perspective of academic researchers. The PEOF 2023 Annual Conference was used as a strategic launch platform for the PERC, and for the 2024 event, the EATRIS Spanish node is invited to present their journey towards the national patient engagement strategy.

We aim to include patient and their advocates where possible when organising events at EATRIS. Our training workshops regularly include talks from patient advocates, and also have patients as participants. For the EATRIS 10-Year Anniversary Conference held in November in the Hague, we had a pleasure of welcoming the inspirational advocate and a mother of a child with Usher syndrome - Chloe Joyner (Founder of Usher Kids UK) - as a keynote speaker to kick-off a passionate panel discussion between researchers, patients and funders.

At EATRIS, we work to normalise patient engagement in biomedical research, promoting more robust research, changing current research practices and enabling science valorisation.



## Communications

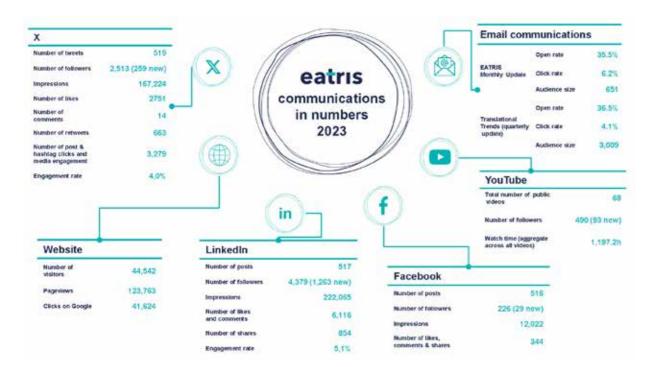
In 2023, EATRIS Communications continued to pursue a digital-first, visual-led, multi-channel strategy to sustain and expand awareness of the infrastructure. Our communication approach revolved around three pivotal pillars: Digital Presence, Audience Engagement and Events.

A new tagline, 'Science beyond barriers, Medicine beyond borders,' was unveiled. Upgrades to the website analytics platform were implemented, alongside the integration of Digital Node Reward Badges and the establishment of an 'EATRIS Branded Materials Inventory' following a comprehensive audit. Moreover, a mid-year assessment underscored our commitment to gender balance across our communication channels.

In the domain of audience engagement, metric-driven insights were used to implement a posting schedule that helped drive significant follower growth: +11% on X, +39% on LinkedIn, +23% on YouTube and +15% on Facebook. Our quarterly 'Translational Trends' update saw a significant surge in subscriptions (+42%) over the year, with email communications maintaining an impressive average open rate. Numerous successful campaigns were run, including the unveiling of the Strategic Plan 2023-2026, the launch of the EATRIS Expert Centres, Patient Engagement Resource Centre (PERC) and Multi-omics Toolbox (MOTBX).

EATRIS orchestrated a number of significant events in 2023. This includes the EATRIS' 10th anniversary conference in The Hague that

united over 200 attendees from the global translational medicine community, from parliamentary ministers to patient advocates to particle physicists. The event was a testament to EATRIS' dedication to catalysing transformative change in healthcare, fostering a shared vision to tackle the evolving challenges of modern medicine. We promoted and ran numerous other events over the year, both online and in person, including the EATRIS patient engagement webinar that attracted 120 people from 26 countries. Underlying these successful events, was the establishment of a comprehensive Standard Operating Procedure (SOP) in early 2023 for event management. This resource is also made available for our national nodes to ensure seamless execution of all our events.



Looking ahead, we aim to enhance our communication efforts by prioritising the nurturing and expansion of our audiences, showcasing our impact, and empowering our members to become effective EATRIS ambassadors in their respective communities. This approach will enable us to establish stronger audience engagement, while highlighting our contributions to society and equipping our members with the necessary tools to represent EATRIS effectively.

## EATRIS celebrates a decade as the European infrastructure for translational medicine



EATRIS marked its 10th anniversary of becoming a European Research International Consortium (ERIC) with a two-day celebration at the Museon-Omniversum in The Hague. The event united over 200 attendees from the global translational medicine community, from parliamentary ministers to patient advocates to particle physicists. The occasion gave an opportunity for the community to discuss how EATRIS can continue to reshape the way healthcare is delivered to society. The event underscored the collective commitment to help healthcare merge scientific advancements seamlessly with patient-centric approaches. Participants expressed determination to continue collaborating across borders, embracing innovation, and working shoulder-to-shoulder with patients on this journey. Find out more here: https://eatris.eu/eatris-10

# **Education and Training**

In 2023 EATRIS successfully designed and executed training activities to support the translation of biomedical discoveries into solutions for unmet medical needs and supporting the required collaboration of a multitude of professions in a truly interdisciplinary effort.

A total of four webinars, 24 live courses and five e-learning courses reached more than 1700 participants. In addition to those dedicated training opportunities, EATRIS has expanded the self-service resources which now include the MOTBX, the Orphan Drug Development Guidebook, the Regulatory Information System, the Innovation Helpdesk and the PERC. The latter alone attracted more than 5,000 visitors in 2023.

In 2023, a new e-learning course was launched on our educational platform on regulatory aspects of vaccine development. It covers mainly prophylactic vaccines including CMC (Chemistry, Manufacturing and Controls), preclinical and clinical phases I-II of vaccine development. In addition, it touches on scientific and regulatory aspects of therapeutic and cancer vaccines. With respect to node engagement, 2023 was another good year: all EATRIS nodes participated in our diverse training offers with a total of approximately 1,000 participants coming from EATRIS Member States. Additionally, EATRIS Portugual hosted the EATRIS-Plus Summer School in Personalised Medicine.

EATRIS Italy (Istituto Superiore di Sanita) and EATRIS Slovenia (University of Ljubljana) together with the training team, made 2023 a successful year for the ADVANCE project. The project aimed at training the next generation of Advanced Therapies specialists saw activities even though project funding ended in 2022. In January, we transferred the e-learning 'Cell & gene therapy (ATMP) development' to the EATRIS e-learning platform to offer the course long-term. A five-day Summer School on Gene and Cell Therapies took place in Ljubljana in June, thanks to funding accrued by EATRIS Slovenia. In May we were thrilled to learn that the ADVANCE project was selected as best practice project by the ERASMUS+ KA2 Strategic Partnership. For 2024, we are optimistic that we will be able to run up to three summer school editions via our nodes and partners.

## Game-changers: training team develops educational games



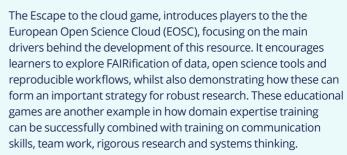




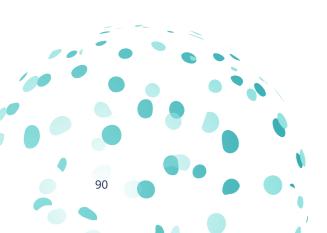


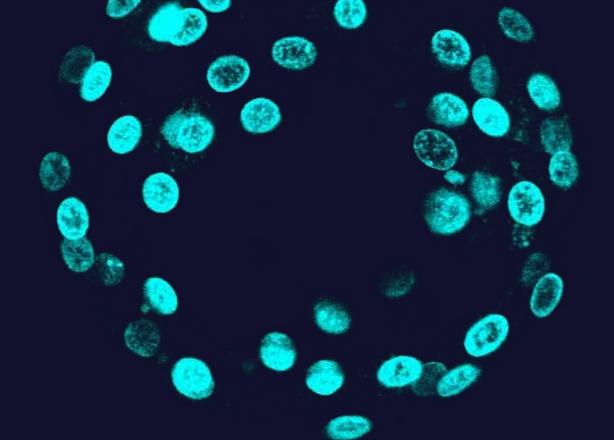
The highlight of 2023 was the successful pilot of two educational games: The REMEDi4ALL repurposing board game and the escape room style game "Escape to the EOSC cloud".

In the repurposing board game, a drug development team need to successfully deliver a repurposing candidate to a patient by building and playing the critical path. Important elements such as timely engaging with patients and regulators, as well as funding, commercialisation and freedom to operate need to be considered. Money and time can be won or lost along the way while 'boosters' and 'wild cards' can bring additional benefits or misfortune. The ultimate goal is to reach the patient within the allocated time and budget.

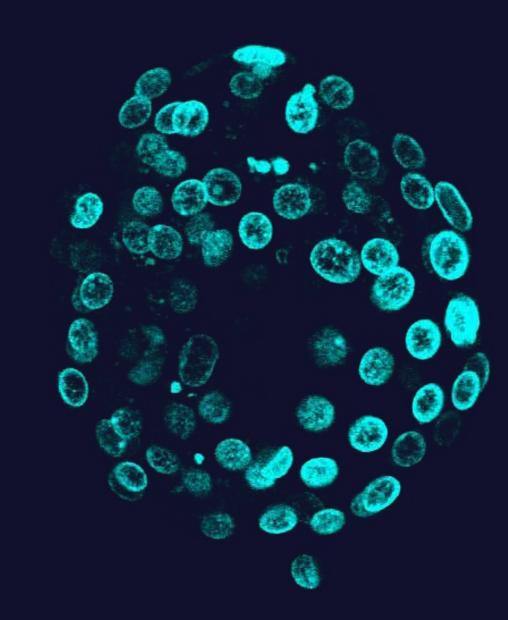








# financial summary





eatris financial summary eatris financial summary

# The amounts stated below have been derived from the audited financial statements of EATRIS ERIC.

Figure 1 - Income and operating result

	Annual report 2023	Annual report 2022	Annual report 2021
	€	<u> </u>	€
Contributions income	1,683,413	1,644,390	1,558,370
Grant income	2,310,904	1,618,068	872,438
Total income	3,994,317	3,262,458	2,430,808
Salaries and wages	1,794,840	1,394,556	1,289,956
Recharge to EU projects	-1,137,624	-746,874	-613,468
Sub total staff	857,508	657,003	563,072
Personnel expenses	1,514,724	1,304,685	1,239,560
Depreciation	7,109	6,358	7,060
Other expenses	596,212	647,395	405,612
Other expenses "project costs EU"	2,036,683	1,351,807	749,009
Total expenses	4,154,728	3,310,245	2,401,241
Total operating result	-160,411	-47,787	29,567



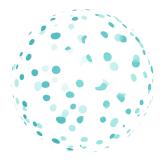


Figure 2 - Analysis of the balance sheet

Below we have included an analysis of the balance sheet as at 31 December 2022 versus 31 December 2021:

	2023	2022	Analysis
Activa	€ 000	€ 000	
Tangible fixed assets	26	20	
Current receivables	668	358	
Cash at banks	1,991	3,100	Cash and banks decreased mainly due to a decrease in the current liabilities.
	2,685	3,478	
	2022	2021	Analysis
Equity & Liabilities	€ 000	€ 000	
Reserves	509	669	The reserve decreased with a net of €160K, equal to the negative result of the financial year.
Current liabilities	2,176	2,809	The amount of the current liabities are € 1.819K, subsidies received in advance.
	2,685	3,478	

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# meet the community





Senior Science and Business Strategy Develope

Ben Lydall

Specialist



Alicia Soler Scientific Programme

Camilla Santinelli



Anna Niehues Translational Data

Operations &

Administrative



Anna Sanchez Innovation Manager Fauvel



Anne-Charlotte **Anton Ussi** Operations & Finance Director



**Danielle Tonnesen David Morrow** Senior Scientific Programme Manager



Donald Lo Development



Eliis Keidong Member **Director of Medicines Engagement Officer** 



Finance & Sustainability Grants Administrator

Emanuela Oldoni



Scientific Programme Manager Biomarker Platform



Director of Digital



Giovanni Migliaccio Ivette Corominas

Meet the EATRIS Coordination

& Support team



Head of



Lalageh Masihi

**Florence Bietrix** 

Head of



Frank de Man

**Executive Board** 

Advisor to the

Lauranne Duquenne Laure Boudaud **Education &** Training Manager

Piret Baur

Manager

**Communications** 



Rebecca Ludwig

Head of Training



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



Moa Drugge Human Resources



Patricia Carvajal Scientific Project



Rosan Vegter Senior Rare Diseases



Sara Zullino Scientific & SME Outreach Manager



Tamara Carapina Head of Legal and



Tanushree Tunstall Translational Community Data Manager



**Tomas Muñoz** Junior Legal Counsel



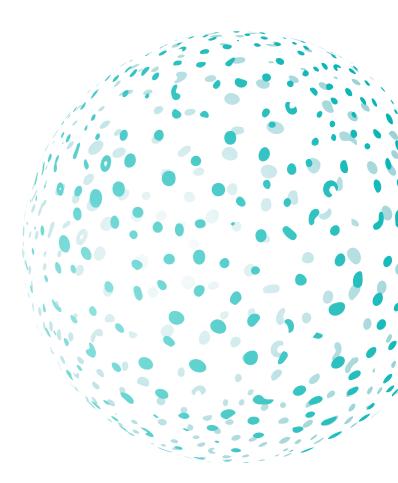
Toni Andreu Scientific Director

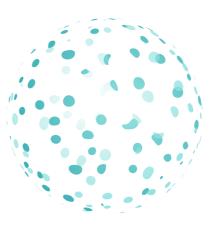
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## **Node Governance**

Country	Board of Governors	<b>Board of National Directors</b>	National Coordinato
BULGARIA			
	Yanita Zherkova	Rossitza Konakchieva	Georgi Georgiev
	Milena Glavcheva	Rumen Pankov	
CROATIA			
	Jelena Ilic Dreven	Fran Borovecki	Lozika Mašić
	Mateo Ante Bosnić	Nada Bozina	
CZECH REPUBLIC			
	Judita Klosakova	Marian Hajdúch	Katerina Sromova
	Marta Vandrovcová*		
	Marián Hajdúch		
FINLAND			
	Sirpa Nuotio	Seppo Ylä-Herttuala	Petri Mäkinen
	Jussi Pihlajamäki		
	Riina Vuorento*		
FRANCE			
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	Francesca Capone	Francesca Capone	
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<sup>\*</sup> Changed position in 2023 Alternate contacts (in italics)



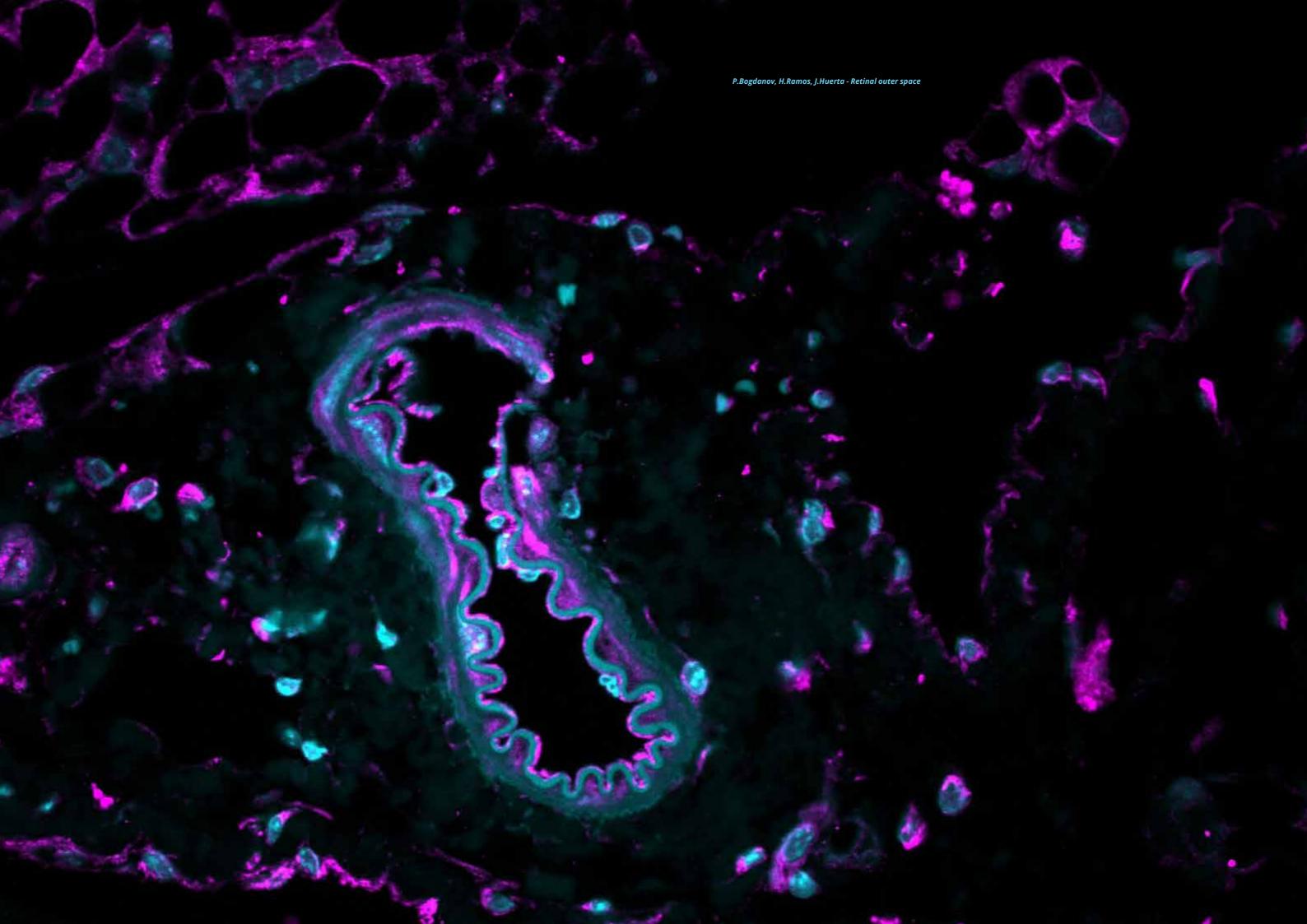


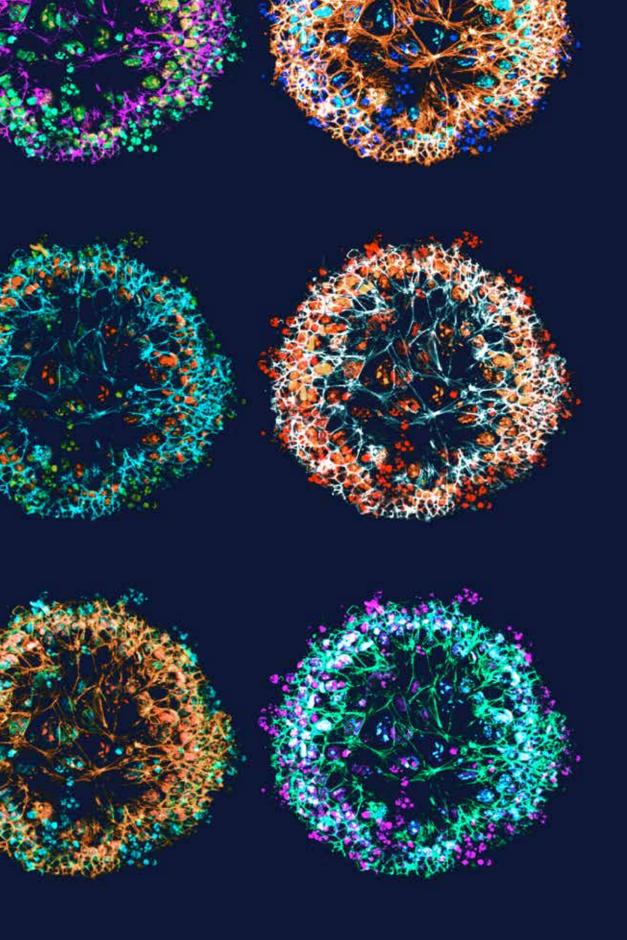
View the full 'Glossary, abbreviations and acronyms' webpage here: <a href="mailto:eatris.eu/glossary-abbreviations-and-acronyms">eatris.eu/glossary-abbreviations-and-acronyms</a>

# Abbreviations

Α	- AI	Artificial Intelligence
	ATMP	Advanced Therapy Medicinal Products
В	- 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 ——	- C-COMEND	Competency-based course on Translational Research and Medicines Development
	CAR-T Cell	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	EANM	European Association of Nuclear Medicine
	EARL	EANM Research Ltd.
	EATRIS	European Infrastructure for Translational Medicine
	EATRIS C&S	EATRIS Coordination and Support Office
	EC	European Commission
	ECRIN	European Clinical Research Infrastructure Network
	EFPIA	European Federation of Pharmaceutical Industries and Associations
	EIC	European Innovation Council
	EJP RD	The European Joint Programme on Rare Diseases
	EMA	European Medicines Agency
	EMMRI	Executive Masters in Management of Research Infrastructures
	EOSC	The European Open Science Cloud
	EPF	European Patients' Forum
	EPND	European Platform for Neurodegenerative Diseases
	EPTRI	European Paediatric Translational Research Infrastructure
	EQI	EATRIS Quality Initiative
	ERA	European Research Area
	ERIC	European Research Infrastructure Consortium
	ESFRI	The European Strategic Forum for Research Infrastructures
	ESMO	European Society for Medical Oncology
	EU	European Union
	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
F	- FEAM	Federation of European Academies of Medicine
G	- GDPR	General Data Protection Regulation
	GSK	GlaxoSmithKline
н ——	- HE	Horizon Europe
	HESI	Health and Environment Sciences Institute
	HTA	Health Technology Assessment
	HTS	High Throughput Screening
1	- IBBL	Integrated BioBank of Luxembourg

	ICM	Institut du Cerveau et de la Moelle épinière – Brain & Spine Institute
	ICO	Industry Contact Officer
	ILO	Industry Liaison Officer
	IMI	Innovative Medicines Initiative
	IMTM	Institute of Molecular and Translational Medicine
	ISCT	International Society for Cellular Therapy
J	— JTC	Joint Transnational Call
L	LAC	Latin American and Caribbean
	LoE	Letter of Engagement
	LS RI	Life Science Research Infrastructures
	LTP	Linked Third Party
м	MEB	Medicines Evaluation Board
	MIRCen	Molecular Imaging Research Center
	мотвх	Multi-Omics Toolbox
	MoU	Memorandum of Understanding
	MRCA	Master Research Collaboration Agreement
N	NC	National Coordinator
	ND	National Director
	NeurATRIS	French Node of EATRIS
	NHP	Non-human primates
	NIBSC	National Institute for Biological Standards and Control
	NIH-NCATS	US National Institutes of Health – National Center for the Advancement of Translational Science
	NTNU	Norwegian University of Science and Technology
P	PAC	Patient Advisory Committee
	PET/CT	Positron Emission Tomography – Computed Tomography
	PET/MRI	Positron Emission Tomography – magnetic resonance imaging
	PI	Principal Investigator
	PMC	Personalised Medicine Coalition
	PoC	Proof of Concept
R	R&D	Research and Development
	R&D	Research and Development
	RI	Research Infrastructure
	RIS	Regulatory Information System
	RITRAIN	Research Infrastructures Training Programme
s	SAB	Scientific Advisory Board
	SMEs	Small and medium-sized enterprises
	SOP	Standard Operating Procedure
т —	— TIA	Therapeutic Innovation Australia
	TNA	Transnational Access
	TRANSVAC	European Network of Vaccine Research and Development
	TT	Translation Together
U	— UMC	University Medical Centres
v	VHIR	Vall d'Hebron Research Institute
w	WP	Work Package
	WS	Workshop







European infrastructure for translational medicine

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