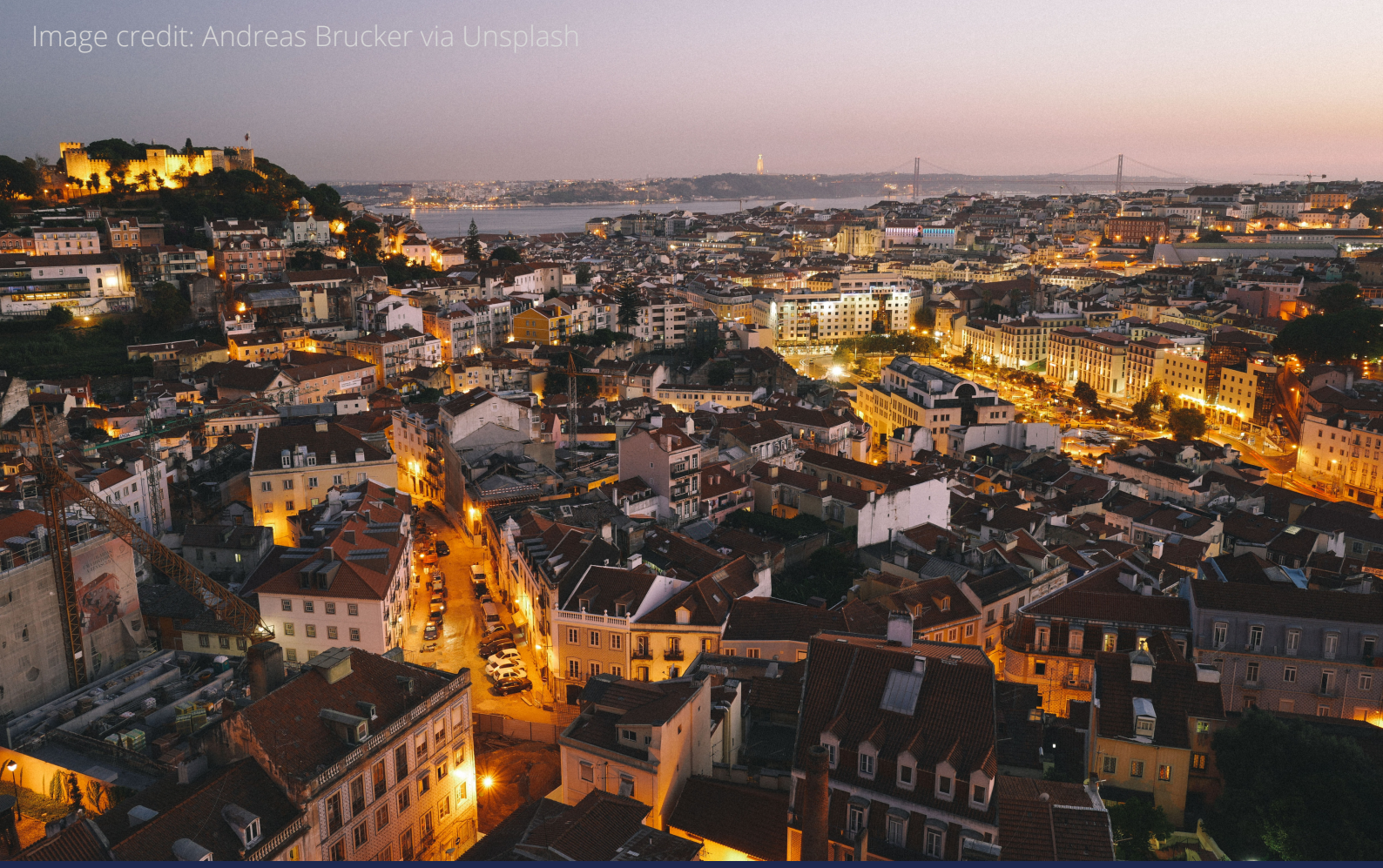


EATRIS-Plus Summer School

in Personalised Medicine

23-26 May 2022

eatris+

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

Our flagship project eatris+ aims to build further capabilities and deliver innovative scientific tools to support the long-term sustainability strategy of EATRIS as one of Europe's key European Research Infrastructures for Personalised Medicine.

Organised by:

University of Ljubljana
Faculty of Pharmacy

Infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde, I.P.

eatris
European infrastructure
for translational medicine

Programme
23 May
Day 1

Opening remarks 09.30-09.45

from Cláudia Faria and Rui Santos Ivo

Retrospective from the first EATRIS-Plus summer school 2021 + introductions 09.45-10.45

from Irena Mlinarič-Raščan

Biomarkers - from bench to the clinic - Session I 10.45-11.45
Chair: André Albergaria

State-of-the-Art & Introduction	**Alain van Gool**	10.45-11.15
Clinical applications of proteomic methods	**Marián Hajdúch**	11.15-11.45

Coffee break 11.45-12.15

Biomarkers - from bench to the clinic - Session I 12.15-13.15
Chair: André Albergaria

Economic and Regulatory aspects	**Beatriz Lima**	12.15-12.45
Clinical implementation	**José Cabeçadas**	12.45-13.15

Lunch 13.15-14.30

Workshop: EATRIS-Plus & the multi-omics toolbox 14.30-16:30
Chair: Emanuela Oldoni

With Marián Hajdúch, Alain van Gool, Beatriz Lima, José Cabeçadas

Programme
24 May
Day 2

Biomarkers in disease - Session II 09.15-12.00
Chair: Cláudia Faria

Oncology	**Marián Hajdúch**	09.15-09.45
Neurological diseases	**Emmanuel Brouillet**	10.45-10.15

Coffee break 10.15-10.45

Biomarkers in disease - Session II
Chair: Cláudia Faria

Pediatric and Neonatal Rare Diseases	**Ricardo Fernandes**	10.45-11.15
Cardiovascular Diseases	**João Pedro Ferreira**	11.15-11.45

Lunch 11.45-13.30

Introdcutions II 13.30-14.15

Workshop: Case-studies 14.15-16:15
Chair: Helena Baião and Cláudia Faria

With Emmanuel Brouillet, Ricardo Fernandes & João Pedro Ferreira

Programme
25 May
Day 3

Biomarkers as predictors of clinical outcome - Session III — 09.15-12.00

Chair: Irena Mlinarič-Raščan

COVID-19 Biomarkers implementation	**Eduardo Lopez-Collazo**	09.15-09.45
Therapy monitoring	**Laura García-Bermejo**	09.45-10.15

Coffee break — 10.15-10.45

Biomarkers as predictors of clinical outcome - Session III

Chair: Irena Mlinarič-Raščan

Cell Therapies	**João Lacerda**	10.45-11.15
Drug Repurposing	**Annika J Jensen**	11.15-12.00

Lunch — 12.00-14.00

Workshop: Artificial intelligence methods for personalised medicine — 14.00-16.00

Chair: Emanuela Oldoni

With João Íncio, Laura García-Bermejo & Jing Tang

Programme
26 May
Day 4

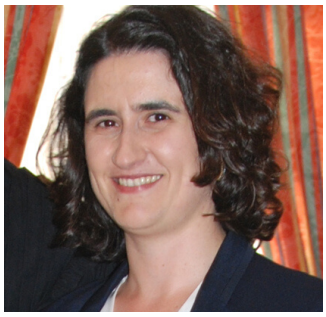
Keynote Lecture: Digital phenotyping for mental disorders by Heleen Riper	09.30-10.30
Coffee break	10.30-10.45
Round table: Digital biomarkers & patient-generated health data Chair: Emanuela Oldoni **With Ieuan Clay, Helen Ripper, Ildikó Vajda and Jing Tang**	10.45-12.15
Closing remarks	12.15-12.30
Lunch	12.30

Speakers

Rui S. Ivo

President of INFARMED, I.P., National Authority of Medicines and Healthcare Products Governor EATRIS PT

Rui Santos Ivo is the President of INFARMED since June 2019 and a member of the Management Board of the EMA and the Executive Board of EUnetHTA. He is the Vice-chair of the Valletta Permanent Technical Committee/Valletta Declaration. He is also an Invited Assistant Professor of Medicines Regulation, at the Faculty of Pharmacy of the University of Lisbon. He is an external elected member of the General Council of the University of Coimbra. Previously he was President (2014/2016) and Vice-President (2011/2014) of the Central Administration of the Health System (ACSS,IP) at the Ministry of Health, in Portugal. He was Coordinator of the Hospital Reform Project Team (2012/2015) and chaired the Governance College for the Public Health Subsystems (2015/2016). R. S. Ivo started his professional career as a hospital pharmacist at Hospital de Egas Moniz, in Lisbon. In 1993 he joined INFARMED, where he held various responsibilities, like Vice-president (1994-2000; 2016-2019) and President (2002-2005). In 2000/2002 he worked as Administrator at the Directorate of the European Medicines Agency and in 2006/2008 he worked for the European Commission as Administrator at the Pharmaceuticals Unit, Directorate General for Enterprise and Industry. He was the first Chairman of the European Union Heads of Medicines Agencies Management Group (2004-2005). His awards include: Imofariz Prize, Personality of the Year in the Pharmaceutical Sector (2004), European Correspondent Member, Académie Nationale de Pharmacie, France (2014) and Medal (gold) for distinguished Services, Ministry of Health (2015).



Claudia Faria

Prof. M.D. Ph.D

Claudia Faria received her medical degree from the University of Coimbra (Portugal) in 2001. She did her training in the Department of Neurosurgery at Hospital de Santa Maria – Centro Hospitalar Universitário Lisboa Norte (CHULN, Lisbon, Portugal), and became board certified Neurosurgeon in 2010. Due to her interest in the genetics of brain tumours, particularly in the pediatric population, she did her PhD at the Arthur and Sonia Labatt Brain Tumour Research Centre, The Hospital for Sick Children (Toronto, Canada) with Professor James T. Rutka. Using the genetic signatures of medulloblastoma (a malignant pediatric brain tumour) she studied the mechanisms of tumour recurrence and dissemination and identified novel small molecule inhibitors that were successfully tested in preclinical models of the disease.

Upon returning to Lisbon in 2014, Claudia Faria became a clinician-scientist working as a Consultant Neurosurgeon at CHULN, as a researcher at Instituto de Medicina Molecular João Lobo Antunes (iMM) and as an Invited Assistant Professor of Neurosurgery and Neurology at Faculdade de Medicina da Universidade de Lisboa.
She founded the Brain Tumor Bank at Biobanco-iMM in 2012 and became Co-Director of Biobanco-iMM in 2018, is responsible to supervise and coordinate the activities of scientific and technical committees, fostering the collaboration between medical doctors and researchers and promoting dissemination and fundraising actions for scientific research.

In 2016 Claudia Faria was appointed President of the Portuguese Neuro-Oncology Association (APNO) and Chair of the Young Investigators and Innovators Group of the European Society for Pediatric Oncology - Brain Tumor Group (SIOPE BTG).

Since 2018 she is the Portuguese representative on the Board of National Directors of the European translational network EATRIS-ERIC and in November 2020 she was elected Chair of the Board of National Directors of EATRIS.

Irena Mlinarič-Raščan

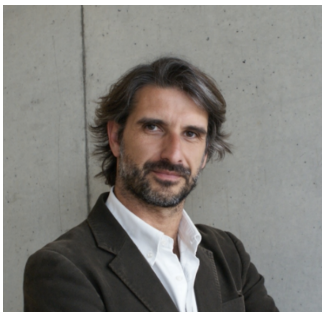
Prof. Ph.D. MPharm.

Prof. dr. Irena Mlinarič-Raščan, MPharm, is dean of the Faculty of Pharmacy, University Ljubljana, Slovenia, and National Director of EATRIS.SI and President of the UNESCO National Committee. She is a full professor in pharmacogenomics, immunology and cell biology. Irena completed two postdoctoral fellowships at the Mount Sinai Hospital Toronto and at the Tokyo University and was a guest professor at the Universities of Bern and Vienna. Her research work involves pharmacogenomics approaches in the individualisation of leukaemia and lymphoma therapies, focusing on thiopurine personalized therapy, identification of novel target molecules including prostaglandin receptor 4, proteasome and immunoproteasome, which further serve for lead design and optimisation.

Emanuela Oldoni

Ph.D

Emanuela is an enthusiastic scientist with a passion for new challenges. She is mainly interested in translational medicine because it permits a continuous exchange between the clinic and laboratory aspects. She got her PhD in molecular and translational medicine in 2018, at the University of Milan, leading a project about biomarkers in neurodegenerative diseases where she applied different methodologies and multi-omics approaches. After, she obtained a prestigious post-doc research fellowship, funded by ECTRIMS, about biomarkers and genetics in multiple sclerosis providing a rationale for personalised medicine. After 5 productive years as a researcher at academic laboratories, between Italy and Belgium, since Jan 2020 she has been working as Scientific Programme Manager at EATRIS. At EATRIS she combines her strong scientific background and her soft skills to facilitate industry-academic collaborations pursuing a common aim: innovation and improvement of human life.



André Albergaria

Prof. Ph.D

André Albergaria is a researcher specialising in Oncology. His scientific expertise is focused on epigenetic regulatory mechanisms in breast cancer, cancer therapy resistance, and biomarker discovery and validation. André holds a PhD from the Institute of Health and Life Sciences from the University of Minho and was a PhD resident at the Imperial College School of Medicine of London, UK, between 2006 and 2008. André has a Post-Graduation in BioBusiness, from AMC Graduate School and Amsterdam BioMed Cluster, Netherlands and worked as an Investment Consultant in the LifeSciences & MedTech Team of the company Portugal Ventures.

During the last 20 years of his scientific career, André has published more than 33 papers in peer-reviewed international journals. Actually, André is a Professor at the Faculty of Medicine of the University of Porto and is the coordinator of the i3S Translational Research and Industry Partnerships Office (Research and Innovation Unit), a group that works on the interface between the health care/pharma industry, clinicians and academic research teams. André is a member of the Portuguese Coordination of the Research & Innovation Agenda on Health and Clinical and Translational Research. He is a project evaluator for several public and private entities, including pharma companies, and is an expert member of the H2020 SC1 Programme Committee, a health expert at Perin – Portugal in Europe Research and Innovation Network and developed and contributed as a scientific expert to several European organisations/Consortium such as ICPerMed.

Alain van Gool

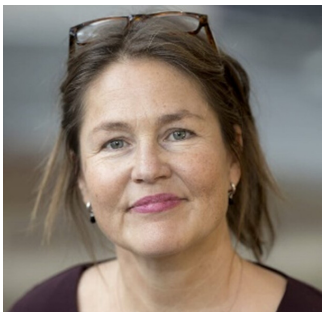
Prof. Ph.D

Alain van Gool is professor Personalized Healthcare and heads the Translational Metabolic Laboratory at the Radboud university medical center, with a strong passion in the application of biomarkers in translational medicine and personalized healthcare. After his study (biochemistry, 1991) and PhD (molecular biology, 1996) Alain worked at a mix of academia, pharmaceutical industries, applied research institutes, university medical centers in Europe, Asia and USA. He has been leading technology-based biomarker laboratories, cross-functional expert teams, therapeutic project teams and public-private consortia, many of which were focused on the discovery, development and implementation of translational biomarkers in a variety of therapeutic areas. His technical expertise resides most strongly in molecular profiling (various Omics approaches), analytical biomarker development and applications in translational scientific research.

Alain is a strong believer of open innovation networks and thrives to work with specialists to translate basic research to applied science. With that background, he currently also acts as Strategic Advisor to the Executive Board of Radboudumc, co-coordinates the Radboudumc Technology Centers, is Scientific Lead Technologies of DTL (the Dutch Techcenter for Life Sciences), is Chair Biomarker Platform of EATRIS (the European infrastructure for Translational Medicine), is co-initiator of Health-RI (the Netherlands Health Research Infrastructure for Personalized Medicine and Health), and Project leader and PI of the Netherlands X-omics Initiative, thus contributing to the organisation and coordination of local, national and European technology infrastructures. Complementing his daily work, he enjoys contributing to scientific advisory boards of start-up enterpreneurs, multinational companies, translational organisations, funding agencies and conference organisers.

Laura García-Bermejo
Ph.D

M. Laura García Bermejo, PhD in Cellular Biology and Genetics (1997, Alcala University and CSIC) and Master in Senior Management of Scientific Institutions (IESE 2019) is Head of the group Biomarkers and Therapeutic Targets at Ramon y Cajal Health Research Institute since 2006. Her multidisciplinary group includes basic and clinical researchers and is focused on translational research providing tools for implementation in clinical practice. She has launched 2014 a Core Facility for biomarkers, included in the IRYCIS Services Portfolio. In addition, Dr García Bermejo is co-chair of the Biomarkers Platform of EATRIS since 2016. From 2009 to 2012, Dr García Bermejo was appointed as Assistant Professor of Physiology at the School of Medicine in Alcala University and she is currently a professor in several university Master's Degrees (UAH, UAM, San Pablo CEU). Since December 2019, she is the Scientific Director of IRYCIS, leading more than 1,400 researchers.

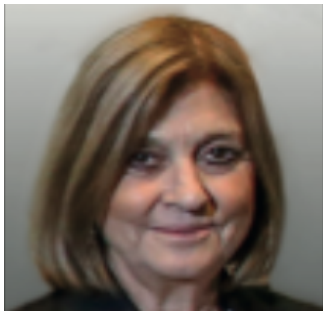


Annika Jenmalm Jensen
Ph.D

Annika Jenmalm Jensen is a pharmacist by training and finished her PhD in Medicinal Chemistry in 1998 at Uppsala University. She then joined the pharmaceutical industry first at Pharmacia, and later at Biovitrum, where she held various positions and for the last many years worked as a project leader. In 2009, Annika left Biovitrum and started to work towards the inauguration of Chemical Biology Consortium Sweden (CBCS) where she was the Director between 2010-2016. In 2016 she was appointed Infrastructure Director at SciLifeLab which she combines being a head of division at MBB, Karolinska Institutet. Annika has a passion for Drug Discovery and believes highly in performing the early preclinical research in close collaboration with academia.

Marián Hajdúch
Ph.D

Marian Hajduch is a scientist and medical professional mainly involved in molecular and translational medicine (disease area oncology and infectious diseases); long-term experience in project management; R&D and technology transfer activities, including the construction and management of large research infrastructures. Founding director of the Institute of Molecular and Translational Medicine, Palacky University in Olomouc, CZ. He has been involved as principal investigator, investigator or clinical site manager in 19 clinical trials; actively participated in the research and/or management of >50 national and international projects; established Cancer Research Czech Republic as a major charity to support cancer research in CZ; spin-off companies focused on manufacturing of molecular diagnostics, bioinformatics and drug development; leader/co-leader drug development initiatives with one registered drug on market, several products in clinical trials, >30 in vitro diagnostic products on market, several CE IVD certified. Former Chair of the Boards of National Director and current Czech National Director for European Translational Medicine Infrastructure (EATRIS-ERIC); participated in creation of national network for personalized medicine and cancer management policies. Published more than >360 papers, 20 books/chapters, >40 patents, >6500 SCI citations, H-index 41.



Beatriz Silva-Lima

PharmD, Ph.D

Beatriz Silva-Lima is PharmD and PhD in Pharmacology and is a full professor of Pharmacology and Regulatory Science at the Universidade de Lisboa, Head of Regulatory Science, Faculty of Pharmacy, and Dean of the Faculty of Pharmacy of the Universidade de Lisboa.

Beatriz has more than 20 years of experience as an expert in nonclinical and regulatory science at the medicines agency in Portugal, INFARMED, and at the European Medicines Agency. She has been up to July 2012 member of the Committee of Human Medicines, Committee of Advanced Therapies and Scientific Advice Working Party. She has been Chair of the Safety Working Party (SWP) and involved as Co-Deputy in ICH discussions on ICH M3R2, S6R1 and S1 guidelines on behalf of the European Commission. Since January 2014, for 4 years she Chaired the Scientific Committee of the Innovative Medicines Initiative (IMI), a public-private partnership between EFPIA and the European Commission, which funded through >5 billion euros >160 research projects developed by large consortia incorporating academia, industries, regulators, patients, the main stakeholders in medicines research and development. Since 2019 she is a member of the Emerging Issues Committee of the ILSI-HESI, USA. Areas of research: Regulatory Science on Nonclinical Safety, Oncology, Pharmacology of metabolic diseases. Beatriz is highly involved in international education in the area of regulatory science. i) Coordinates a second cycle Master Course on Regulatory Science in the Faculty of Pharmacy of the Universidade de Lisboa, ii) Co-coordinates with Prof Per Spindler (University of Copenhagen) and Dr Kirstin Meyer (Bayer Healthcare) a Nonclinical Module on Regulatory Guidelines of the European Master Course (IMI sponsored) SafeSciMet, iii) similar master IMI sponsored ECMDC, led by the Semelweiss University, Hungary, iv) integrates the PharmaTrain Course EUDIPHARM lead by the University of Lyon and is faculty at the Medicademy Regulatory course on Regulatory as well as to the MIND course (University of Copenhagen). Beatriz integrates the European Patient Academy PortugalPlatform. She is a member of NDA Advisory Board, UK, and Editor in Chief of the Regulatory Science Section of the Journal Frontiers. She provides advice to research groups on medicines development aspects, particularly non-clinical components including mechanistic aspects.

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Ieuan Clay
Ph.D

Ieuan Clay is Director of Science at Vivosense, where his work focuses on development and qualification of digital measures. He lectures at ETHZ and FHNW in Digital Health, and is an Editorial Board Member at Karger Digital Biomarkers. Following his PhD at the University of Cambridge which focused on technology and analytics development, he joined Novartis Research in 2010, where he built and led the Digital Endpoints group within Translational Medicine (early clinical portfolio), implementing new digital measures into more than 50 trials and advancing qualification of real-world gait speed with the EMA. In 2019, he joined Evidation Health, initially focusing on research strategy and then joining commercial to help build their Heart Health on Achievement health programs in collaboration with the American College of Cardiology. He then joined the Digital Medicine (DiMe) society in 2021 as Chief Scientific Officer, where he was responsible for scientific strategy and output.

Ildikó Vajda
Ph.D

Ildikó Vajda holds a PhD in neurophysiology and has worked for more than 8 years in the field of fundamental scientific research on neuronal plasticity. She then continued in the field of applied research and was modelling biological knowledge to be reasoned with by AI- agents for predicting eating behavioural patterns. Since 2011 she is working together with patient organizations, healthcare professionals, and IT experts to make healthcare more patient-centric. In the last couple of years, she has been advising hospitals on health innovations and is working since 2020 at the Dutch umbrella organization of patient organizations (the Netherlands Patient Federation). There she works on the implementation of personal health environments, digital data-sharing infrastructure and AI. She is the coordinator of the patient and citizen team of the Dutch AI coalition. Her expertise is at the intersection of (digital) health innovations, co-creation methods and AI ethics.

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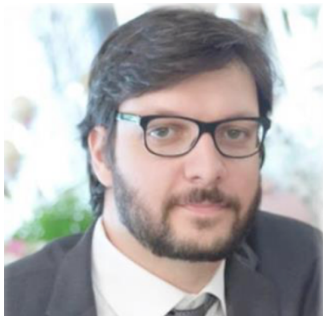
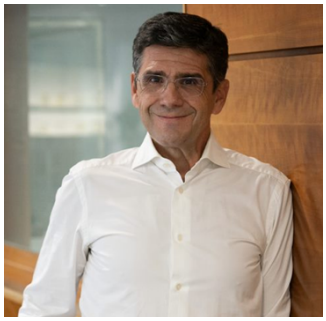


Joao Incio
MD Ph.D

Joao Incio is a medical doctor by background, having graduated from FMUP – Faculdade de Medicina da Universidade do Porto, and trained at Hospital S.Joao, in Porto. Joao has also spent years as an academic researcher in the fields of oncology, cardiovascular and metabolic diseases, including 6 years of doctoral/postdoctoral research at Harvard Medical School. Recently, Joao transitioned from being a physician-scientist to the commercial life sciences space, acquiring business strategy training in healthcare and life sciences at L.E.K. Consulting and the Imperial Consulting Group, and subsequently taking up the role of Associate Medical Director for Global Strategy at the biotech company Vertex Pharmaceuticals in London. Joao currently holds the position of Principal and Clinical Safety Officer at Sensyne Health, an Oxford-based clinical AI company delivering real-world data insights to life sciences companies & AI-powered software tools to support patient care and operations.



João Forjaz de Lacerda
MD Ph.D

A graduate of the Medical School of the University of Lisbon, Dr. Forjaz de Lacerda completed his training in Hematology & Bone Marrow Transplantation at the Hospital de Santa Maria, in Lisbon, and at the Memorial Sloan-Kettering Cancer Center, in New York. He earned his Ph.D and Habilitation degrees from the University of Lisbon in 1998 and 2007, respectively. Dr. Forjaz de Lacerda is currently a Senior Attending Physician at the Hematology & Bone Marrow Transplant Service of the Hospital de Santa Maria, Full Professor of Medicine at the Faculty of Medicine of the University of Lisbon, Group Leader at the João Lobo Antunes Institute for Molecular Medicine, President of the Ethics Committee and Vice-President of the Clinical Research Center of Lisbon Academic Medical Center. He is the Coordinator of TREGeneration, a project funded by Horizon 2020 Programme.

João Pedro Ferreira

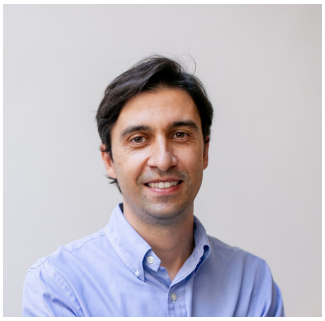
Prof. MD Ph.D

João Pedro Ferreira is a Full Professor of Medicine at the Faculty of Medicine of the University of Porto, Portugal and an Invited Professor at the University of Lorraine, France. He also works at the Heart Failure Clinics of the Vila Nova de Gaia Hospital, Portugal. He is a consultant for Boehringer Ingelheim and has received research support from Astra Zeneca, Novartis and Bayer.

José Cabeçadas

MD Ph.D

Jose Cabecadas earned his medical degree in 1983 from the Universidade Nova de Lisboa. And subsequently in 1989-1990 completed a fellowship at the department of Histopathology at University College London Medical School, under Professor Peter Isaacson. He is a specialist in Pathology since 1993 with currently holds positions of Senior consultant pathologist, Head of the Department of Laboratory Diagnosis at Instituto Português de Oncologia, Lisboa, and Coordinator of the Conselho de Investigação, IPOLFG. He is a member of the following societies: Sociedade de Ciências Médicas de Lisboa, Sociedade Portuguesa de Anatomia Patológica, Portuguese Division of the International Academy of Pathology, European Society of Pathology, European Association for Hematopathology (including a member of the executive committee 2010- 2014).



Ricardo M Fernandes

MD Ph.D

Ricardo Fernandes is a Consultant Pediatrician, Assistant Professor in Clinical Pharmacology and Pediatrics, and Clinical Researcher. His research background includes clinical epidemiology, clinical trial methodology, clinimetrics and synthesis research, with training and fellowships in the Netherlands and Canada. His research interests have focused on pediatric respiratory and allergic diseases, and methodology, including pediatric clinical trial design, analysis and reporting, outcome measurement and clinimetrics, data monitoring committees, systematic reviews and meta-analysis, and clinical pharmacology. He has been involved in the inception of research collaborations such as the StaR Child Health initiative and the Pediatric Emergency Research Networks, and has served with the Cochrane Collaboration and the European Respiratory Society. He is currently a Work Package lead and a National Hub lead in the conect4children/c4c IMI/IHI consortium aimed at creating a paneuropean clinical trial network. He serves as a Coordinator of the National Hub Forum, bringing together the 20 c4c National Hubs, and is a member of the c4c Network Infrastructure Office, which is the central coordinating office for the c4c network.

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