BBMRI-ERIC®

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European infrastructure for translational medicine

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Press release

MEDICAL RESEARCH INFRASTRUCTURES CONTRIBUTION TO HORIZON EUROPE

BBMRI-ERIC, EATRIS-ERIC and ECRIN-ERIC are ESFRI medical research infrastructures (RI) with an ERIC status (European Research Infrastructure Consortia[1]), established as high-quality service providers for academia and industry. Through these services we support discovery, translational and clinical research, underpinning a common objective – creating, developing and delivering substantial value to European patients.

With regard to the upcoming **Horizon Europe** framework programme, the medical ERICs have identified four critical success factors for optimal outcomes in the next funding period:

- *Avoiding undesired duplication and fragmentation;*
- *Safeguarding quality and enhancing reproducibility;*
- *Supporting public engagement by promoting responsible research policies;*
- *Enabling rigorous innovation management.*

1. Avoiding undesired duplication and fragmentation

The ERA suffers from substantial duplication and fragmentation of strategies, expertise and services. The lack of coordination amongst the many organisations and stakeholders involved in the medicines development pipeline results in competition rather than cooperation. National regulation and funding of medical research increases duplication and fragmentation, rather than collaboration.

Erik Steinfelder, Director General of BBMRI-ERIC says: '*A federated alliance of BBMRI, EATRIS and ECRIN guarantees the promotion of innovation and knowledge, and the involvement of all parties needed to push forward novel therapies in the European Research Area (ERA), and their optimal use in individual patients'.*

For the successful development of Horizon Europe, **researchers should have effective access to existing high-quality tools and coordinated services that have been developed by ERICs** to offer consistent and comprehensive support, as well as promoting interdisciplinary and multinational research aligned in the pursuit of excellence and impact.

2. Safeguarding quality and enhancing reproducibility

One of the fundamental principles of research is reproducibility. Recent studies[2][3] in the field of biomedical research show that findings from **an alarmingly high percentage of scientific papers cannot be reliably reproduced by other researchers.**

The tremendous effort in recent years to open up biomedical science, improve research efficiency and battle research waste through the European Open Science Cloud (EOSC) initiative and the FAIR principles (denoting Findable, Accessible, Interoperable and Reusable data) is welcome and timely, with all three medical ERICs having endorsed the EOSC declaration.

Jacques Demotes, Director General of ECRIN says *'Horizon Europe should develop policies and instruments to ensure that the methodology, quality and reproducibility of translational and clinical research are optimal in order to ensure more*

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[1] The community legal framework for a European Research Infrastructure Consortium (ERIC) is a specific legal form to facilitate the establishment and operation of research infrastructures with European interest. More information: https://ec.europa.eu/research/infrastructures/index.cfm?pg=eric

[2] Florian Prinz, Thomas Schlange, and Khusru Asadullah (2011) Believe it or not: how much can we rely on published data on potential drug targets? Nature Reviews Drug Discovery, 10(9): 712. C

[3] Iain Chalmers, Michael B Bracken, Ben Djulbegovic, Silvio Garattini, Jonathan Grant, A Metin Gülmezoglu, David W Howells, John P A Ioannidis, Sandy Oliver,
How to increase value and reduce waste when research priorities are set, The Lancet,Volume 383, Issue 9912, 2014, Pages 156-165,

cost-effective research outcomes and a trustworthy scientific basis for clinical decision-making. This can be achieved in part by fostering the use of quality services and research infrastructures with sufficient quality measures and processes in place.'

3. Supporting public engagement by promoting responsible research policies

Public engagement in biomedical research is key for better health outcomes. Despite increased involvement of patient organisations and advocacy groups as partners in H2020 or IMI-funded research projects, **public and patient engagement is still often perceived as a "tick-box exercise" for researchers seeking funding**, especially when patient participation comes too late in the proposal preparation process to make a difference.

'Horizon Europe should enable a much needed cultural shift in the way academia, regulators, industry, and HTA bodies collaborate together with patient organisations' , says Francesco Florindi, Engagement Officer at BBMRI-ERIC, and adds: *'The programme should be the vehicle for increased multi-stakeholder and cross-sectoral collaboration, providing sustainable and meaningful opportunities for patients to participate in the research process.'*

4. Enabling rigorous innovation management

The translation of scientific discoveries into useful and innovative interventions for patients is at the heart of medical ERICs' mission, and a top-priority societal challenge. However, despite a strong scientific case, principal investigators often lack access to the methodology and services needed for the seamless development of their potential future treatment or tool, therefore resulting in increased research and funding waste. Additionally, academia may lack knowledge and tools to develop successful industry partnering strategies or long-term public-private collaborations. As a consequence, the medical innovation continuum is extremely expensive (drug development is estimated to be ca. USD 2.5 billion per new marketed drug[4]) time-consuming (the average period between the discovery and the development of a new treatment is 10 years[5]) and comes with enormous failure rates[6].

Antonio Andreu, Scientific Director of EATRIS says: '*Horizon Europe must ensure that funded projects include a rigorous innovation management plan, covering various necessary steps leading to market access and leveraging the following expertise: intellectual property, regulatory requirements, health technology assessment, ethics, trial protocol and management methodology. Such criteria would also imply the involvement of a wide range of stakeholders in project consortia.'*

Missions

We fully embrace the mission-oriented approach as suggested by Professor Mazzucato to tackle the research and innovation challenges ahead and as recently adopted in the Commission proposal for Horizon Europe. Cross-sector collaboration is of the utmost importance to generate impact for patients. The ESFRI roadmap and the development of the ERIC Forum[7] have already created a robust framework for supporting the scientific and technological needs of the scientific community

[4] DiMasi JA, Grabowski HG, Hansen RW (2016) Innovation in the pharmaceutical industry: New estimates of R&D costs; Journ Health Economics, 47; 20-33

[5] S. Morgan, P. Grootendorst, J. Lexchin, C. Cunningham, D. Greyso; The cost of drug development: A systematic review; Health Policy, Volume 100, Issue 1, 2011, Pages 4-17.

[6] DiMasi, J. A., Feldman, L. , Seckler, A. and Wilson, A. (2010), Trends in Risks Associated With New Drug Development: Success Rates for Investigational Drugs. Clinical Pharmacology & Therapeutics.

[7] https://www.eric-forum.eu/

WHO WE ARE

BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium)

BBMRI-ERIC operates the world's largest online directory of human samples (such as blood, tissues, cells or DNA, and associated clinical and research data), connecting more than 500 biobanks from 20 EU countries. Its mission is to facilitate research on human samples for personalised medicine, while keeping the highest scientific standards and, most importantly, preserving patients' and citizens' privacy. BBMRI-ERIC provides services to academia and industry to develop better treatments, test diagnostic tools and advance biomedical research. It has participated in 42 Horizon 2020 calls with an overall success rate of 26%. BBMRI-ERIC includes 21 National Nodes supporting biobanking at the local level. Its European headquarters are located in Graz, Austria.

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EATRIS (European Research Infrastructure for Translational Medicine)

EATRIS aims to create a global framework preventing research waste by supporting the dissemination of good research practices, based on quality, reproducibility and standardisation. EATRIS helps academia and industry de-risk and add value to their drug, vaccine or diagnostic development programmes. We do this by providing fast, tailored access to cutting-edge enabling technologies and expertise in translational research, focusing on preclinical and early clinical development of drugs, vaccines and diagnostics. Via our central hub in Amsterdam, users can access the vast array of clinical expertise and high-end facilities that are available within the 80+ top-tier academic centres across 12 countries in Europe. Solutions are provided in the fields of advanced therapy medicinal products, biomarkers, imaging and tracing, small molecules and vaccines.

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ECRIN (European Clinical Research Infrastructure Network)

ECRIN-ERIC supports the planning, set-up and operational management of multinational clinical research in Europe, providing access to patients and medical expertise throughout Europe. ECRIN addresses various challenges and obstacles, including infrastructure interoperability, regulatory and ethical requirements, multinational trial management and funding issues, by offering researchers support to prepare and implement multinational studies. Support areas include advice in study planning and in the preparation of funding applications, protocol peer-review, and operational services to multinational trial management. This is based on its distributed organization with expert staff located in each Member and Observer country, and on trial management tools developed by ECRIN. ECRIN participates in 40 H2020-funded projects, and its portfolio includes 50 multinational trials, with an average of seven countries per trial.

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