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ERN Coordinators Group

ERNs SUPPORT "CALL TO ACTION" –

CZECH PRESIDENCY OF THE COUNCIL OF THE EUROPEAN UNION

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EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW PREVALENCE AND COMPLEX DISEASES

Share. Care. Cure.



Publications Office

The 2nd Strategy Assembly of Coordinators and Project Managers of the 24 European Reference Networks for Rare and Complex Diseases, held in Lyon, France on Tuesday, November 22nd, 2022, **unanimously endorsed** the "Call to Action" from the Expert Conference on Rare Diseases organized by the Czech Presidency of the EU Council in Prague (October 25th – 26th, 2022).

We call upon the European Commission and the Governments of the EU Member States to regularly work with the 24 ERN Coordinators and the over 1500 medical teams already members of the ERNs, recognized for their expertise both in medical practice and research, to:

- Further develop, adopt, and implement an **Action Plan on Rare Diseases** to support and complement on-going and future efforts to significantly reduce unmet needs of EU citizens living with a rare or complex disease.
- Develop and support initiatives for accessibility of all EU citizens to state-of-the-art tools and technologies facilitating early diagnosis and targeted treatments.
- Adapt Orphan Drug and Paediatric Drug regulations, as well as Medical Device Regulations, to the urgent needs of patients with rare diseases, in collaboration with all stakeholders, including improvement of a rapid access to rare disease treatments.
- Implement sustainable and proportionate investment from national and EU budgets into strengthening the capacities of existing ERN centres to offer earlier access to patients with rare diseases, a prerequisite to the sustainability of the ERNs as cross-borders networks of excellence.
- Implement without further delay a pilot project between ERN centres leveraging network-based health data, powered by digital tools, interoperable infrastructures, and data sharing. In this pilot project Centres of Expertise should be recognized as trusted universal sources of data and knowledge, already respecting the principles of General Data Protection Regulations.
- Initiate a new EU regulation to facilitate the legal requirements for non-interventional studies, replacing the need for local ethics approvals by a system of lead national ethics committees as already accomplished in the recent EU Clinical Trials Regulation. This will be of eminent importance to clinical research in rare diseases.
- Facilitate policies of person-centred and integrated care with the aim to enable holistic wellbeing of people living with rare diseases and their families.

Pr Alexis Arzimanoglou, Chair of the ERNs CG

Pr Holm Graessner, Deputy Chair of the ERNs CG

Pr H el ene Dollfus, Past Chair of the ERNs CG



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