Statement of the ERN Board of Member States

on European Reference Networks (ERNs) & industry

(Updated statement adopted on 25 June 2019)

In recognition of the importance of the role of industry in improving the knowledge of rare conditions and developing diagnostics tools and therapies, the Board of Member States agrees with the engagement of ERNs with industry where appropriate, for example on clinical trials and research projects. However, as there is no legal provision for the collaboration between ERNs and industry, the Board of Member States offers the following guidance:

1. ERNs may develop collaborations with industry stakeholders but these cannot have any role in the governance structure of an ERN.

2. Facilitating some aspects of research will be an integral task of ERNs that may require collaboration with industry. Any research involving a Network[1] or any of its Members must be organised and funded in an open and transparent manner with full declaration of existent or potential conflicts of interest.

3. ERNs are expected to gather patients' data to facilitate research. The legal and practical conditions for access to this data have to be carefully defined for each specific research project, be transparent and not provide preferential treatment to any researcher or any other actor. The access has to respect patients' consent and rights and relevant national and European legislation on data protection, safety and security such as the General Data Protection Regulation (GDPR).

4. ERNs should preferably seek public funding but, once exhausted, they could also look for solutions enabling shared funding from more than one industry partner. In case of financial support coming from multiple Industry partners or when activities in several ERNs are jointly funded, an independent external body could preferably be responsible for governance and reporting. All funding must be open and transparent with full declaration of existent or potential conflicts of interest.

5. There should be no funding from industry directly allocated for management and running of the Network nor for any type of activity relating to the development of diagnostic and clinical practice guidelines or any other clinical decision-supporting tools, development of outcome measures as well as establishing and maintaining patient registries.

6. Based on the ERN Code of Conduct[2], each ERN should adopt procedures to define conditions for partnerships and project selection, policies for disclosure of conflicts of interest as well as governance rules.

7. Conflict of interest policy must respect relevant national and European legislation and follow the recommendations and guidelines developed by relevant independent organisations and recognised bodies.

[1] Research in this context is defined as: "research activity involving at least two ERN members from two different Member States for conditions or diseases covered by the ERN and specifically naming the ERN" (as agreed within the ERN Research Working Group and the ERN Working Group on Monitoring),

[2] To be developed by the ERN Working Group on Legal and Ethical issues and relations with Stakeholders and to be endorsed by the ERN Board of Member States (ERN BoMS).

8. Each ERN member must respect and follow the national and local legislation relating to conflict of interest.

9. Follow-up of all collaborations with industry could become an integral part of the monitoring of ERNs. As part of the annual report of the ERN, each case should be reported to the ERN Board of Member States (BoMS) and also made publicly available, including the origin and amount of the funding and its (planned) use, the relationship between the private sponsor and the members of the ERN and any potential conflict of interest.