EPIRARE
European Platform for Rare Disease Registries

Deliverable D2.4

BRIEFING PAPER TO THE EUROPEAN PARLIAMENT

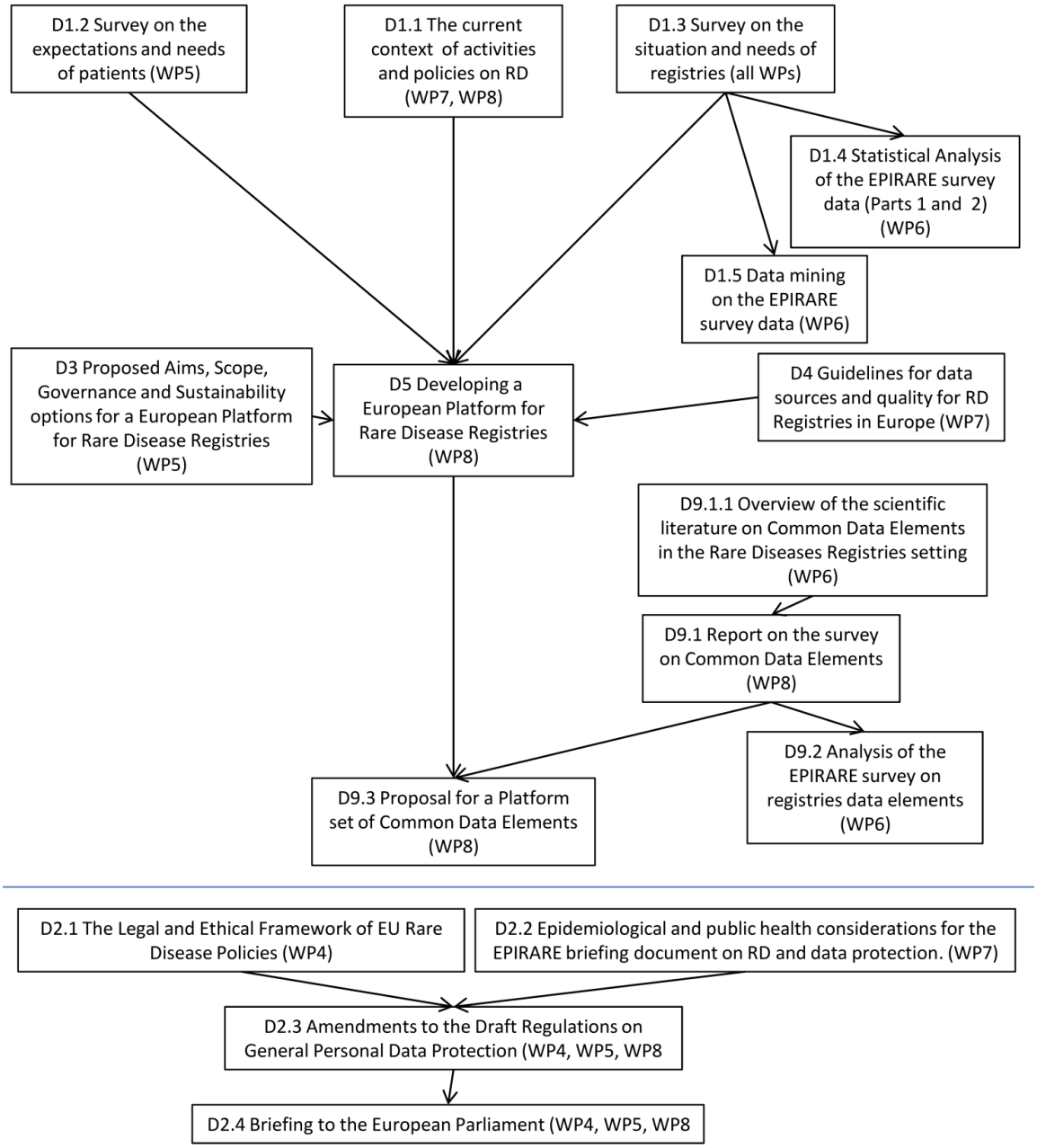
Angela Brand[1], David Townend[1], Monica Ensini[2], Flaminia Macchia[2], Emanuela Mollo[3], Sabina Gainotti[3], Luciano Vittozzi[3], Domenica Taruscio[3]

[1] Maastricht University, Maastricht (the Netherlands)

[2] EURORDIS, Paris (France)

[3] National Centre for Rare Diseases, National Institute of Health, Rome (Italy)

Overview of the documents produced by EPIRARE



Disclaimer

The issue: Rare Diseases Require Robust Research and Public Health Routes through the Personal Data Protection Regulation.

Research on Rare Diseases (RD) and the care of patients affected by them are characterised by specific needs. Indeed, due to the low individual prevalence and the scarcity of information related to each rare disease, collaboration and maximum use of limited resources is particularly meaningful. This is especially true for very rare diseases where no single institution, and in many cases no single country, has a sufficient number of patients to conduct fundamental, clinical and translational research.

Therefore, missing the opportunity of exploiting and sharing the small amount of data that are collected, will dramatically delay the improvement of health care of RD patients. Most importantly, it will result in discrimination of RD patients regarding their right to quality health care and will pose a serious ethical problem.

The EU Parliament and the health authorities in the EU Member States (MS) and beyond[1],[2],[3], have all agreed that it is necessary to establish structural links among Countries in an effort of collecting and sharing data regarding RD patients. The EU Council Recommendation on Rare Diseases urges MS to implement national plans to ensure that RD patients have access to high-quality care. MS should support, at all appropriate levels, including the Community level, registries and databases for epidemiological purposes; moreover, they have to foster priorities for basic, clinical, translational and social research in the field of rare diseases and promote interdisciplinary cooperative approaches through national and Community programs. In the EU Parliament and Council Cross-Border Health Care Directive, the EU Commission is bound to support, in particular in the area of RD, European Reference Networks between healthcare providers and centres of expertise in the MS, which, among other objectives, should reinforce research and epidemiological surveillance including registries. These legal measures clearly show that, in the area of RDs, high quality healthcare is tightly linked with research and robust data collection (registries and databases).

It is therefore necessary that the needs of research on RD for the collection and exchange of patient health data **are recognized in the new Personal Data Protection Regulation** now under discussion.

Failing to do so will contradict the spirit of the EU Parliament and Council Directive and of the EU Council Recommendation mentioned here above **and it might be argued that limited attention has been given to article 168 of the Union Treaty**, providing that all Union policies and activities should ensure a high level of human health protection.

[1] The **EU EPSCO Council** adopted a Recommendation on rare diseases on 9 June 2009;
[2] The **EU Parliament and Council** adopted the Cross-Border Healthcare Directive on 9 March 2011.
[3] **Australia, Canada, the European Union, France, Germany, Italy, Spain, the Netherlands, United Kingdom, and United States of America** have founded the International Rare Diseases Research Consortium (IRDiRC), which relies on common access to individual patients' samples and data, including the molecular and clinical ones, to discover new therapies for rare diseases.