

European Federation of Pharmaceutical Industries and Associations (EFPIA) and Vaccines Europe

The right prevention and treatment for the right patient at the right time

Consultation Paper: Outline strategic research agenda for biomedical research public private partnership under Horizon 2020

Response from EURADIA: Alliance for European Diabetes Research

Stakeholder Consultation

1) The vision for the PPP is that it will address, in a collaborative and multidisciplinary way, the science, technology, regulatory, healthcare, social and other challenges that currently delay or prevent citizen/patient access to most effective and efficient diagnostics, prevention and treatment options.

Do you agree with this vision? Are there any additional opportunities to address key social and healthcare challenges that you feel should be considered for implementation through this PPP?

The vision of the SRA is in line with previous proposals by EURADIA – a multi-stakeholder alliance of non-governmental organisations working in diabetes at the European level and pharmaceutical industry - through the proposed European Platform for Clinical Research (EPCRD). The European Commission itself states that *biomedical and public health research contributing directly or indirectly to chronic disease prevention and treatment are some of the most important research areas.*

Health research in Europe is in urgent need of **better coordination**, with **common resources** and **overarching science policy**.

Europe has a history of excellence in clinical research that has been lost in recent years to the USA, due to a lack of training and professional opportunities. At the same time, European citizens are not offered equal participation in clinical studies that may offer them an improvement in health and quality of life. Renewed excellence in this critical area could be addressed through the creation of **disease-focused clinical research infrastructures**, under the umbrella of a proposed European Council for Health Research (The Alliance for Bio-Medical Research in Europe). **EURADIA proposes the model of a European Platform for Clinical Research in Diabetes (EPCRD) that would coordinate European efforts in this clinical research space, offering common resources, training and standardized protocols.**

6) There has been substantial work via the EMA and various think-tanks (e.g., Centre for Innovation in Regulatory Science (CIRS)) to define a better, more structured and more patient-responsive approach to defining B/R.

What more do you think needs to be done to improve patient engagement in the assessment of the benefit/risk of medicines?

Despite much media attention on diabetes a Europe-wide audit report The IDF – Europe/FEND Policy Puzzle has highlighted a lack of understanding of the problems of diabetes by politicians, policy makers, and by the public at large.

http://ec.europa.eu/health/major_chronic_diseases/docs/policy_puzzle_2011.pdf

Additionally, this report has drawn to attention a failure to adequately integrate basic and clinically relevant research across Europe, and an inability of healthcare systems to deliver research advances in an effective and cost efficient way.

Although diabetes is a seriously escalating problem, there is substantial evidence that early and comprehensive interventions for risk factor management can defer the onset and greatly reduce the impact of later complications. However, poor **adherence to conventional therapies** limits their efficacy often because medication cannot be adapted to the personal requirements of daily life. **Hence the need for more clinical studies conducted in the context of the environmental realities (diet, physical activity, altered diurnal patterns, shifts, and social life) of modern living and effective translation of research results to improve clinical outcomes.**

The integration of diabetes research across Europe has been hampered (compared with the United States for example) by variability of language, custom and practice at all levels of engagement. This has limited access to large numbers of people with diabetes and healthy control volunteers in single large centres and multinational programmes. **Clinical research from small studies to large-scale pharmaceutical trials or research into health care provision is more disjointed, laborious and less representative than it should be. Development of specific education for people with diabetes to become expert and engaged in the entire research process and to take such learning back to the national level is envisaged; such an initiative is underway with the IMI-funded EUPATI project [www.patientsacademy.eu]. Engaging patients in research across Europe would also improve access to health professionals and increase knowledge of the condition.**

With such a large population of people with diabetes along with their families and carers the use of social media could also be evaluated when applied to health research and health care delivery. A large-scale research platform such as EPCRD would be an ideal way to investigate this (including the effect of citizen science activities), health care delivery, public health messaging. Currently evidence on social media is mainly anecdotal; however, the democratizing effects of social media on e.g. organization, coordination, funding and ethics approval process should be considered particularly in relation to increasingly scarce resources and patients and families frustrated by the inadequacies of the current system and difficulties of access to clinical trials.

9) From your perspective do you agree that the areas outlined below represent major healthcare challenges for Europe? Do you think the current proposal will adequately address the needs in each of these? Are there additional activities that you feel are essential to deliver effective healthcare solutions for the treatment of the diseases listed below?

What are the main treatment gaps or unmet needs in the development of medicines in your therapeutic area? Are there any barriers in the delivery and availability of innovative treatments (lack of screening/diagnostics, reimbursement, lack of single medical file, patient care, adapted infrastructure, stigmatism, etc.)?

Diabetes

Section 3.4. Diabetes

Section 3.8. Autoimmune diseases

Section 3.9. Ageing-associated diseases

- The EURADIA DIAMAP report [www.DIAMAP.eu] identified unmet needs and established a pan-European plan to organise and invigorate diabetes research and its application for people with diabetes. The categorised road maps critically explored the pathways to translate epidemiological, genetic and basic science research through clinical research to innovation in care delivery.
- Evidence derived through the DIAMAP project concurred that the value of diabetes research would be enhanced by a more integrated, inclusive, and cohesive European approach with more emphasis on collaborative programmes that carry pre-clinical science through clinical evaluation and into new treatments and better care delivery. Such a Europe-wide approach would accommodate expert discussion to generate large-scale research questions in collaborative environments.
- Through a European Platform for Clinical Research in Diabetes (EPCRD) a large population of people with diabetes across Europe from disparate genetic and ethnic backgrounds could be made accessible to researchers by participation in a network with a centralised coordinating entity acting as a point of entry. Patients could become more engaged in the research process by participating in specially designed education programmes. The DIAMAP road maps have repeatedly highlighted as roadblocks the need for registries of people with diabetes, networks of specialist researchers, access to biobanks and human biological material (especially in relation to the rarer complications) and the need for more standardised evidence-based treatment guidelines.
- DIAMAP also stressed the need for better integration and coordination of academic and industry/SME-based clinical research efforts. Improved communication of research outcomes to national programmes and the European Commission would offer harmonization across Europe, as well as increasing return from investment at both the national and regional level.

The EPCRD would provide an opportunity for a pan-European organisational framework to bring this recommendation of DIAMAP to reality.

- creating **governance structures** in line with agreed European ethical principles
- developing a **support infrastructure** with operating procedures to assure quality control
- discussing and evaluating the components of a **minimal dataset**
- developing **information technologies and central access to data** with uniformly approved procedures
- broadening opportunities for structured **specialist education and training** among European diabetes investigators and healthcare professionals involved in research
- facilitating **partnerships between academic groups, pharmaceutical companies, SMEs, and patient groups** to achieve critical mass with respect to overcoming **key scientific questions and road blocks identified in the DIAMAP report**
- engaging experts in discussion **for hypothesis generation and organisation** for large studies
- enhancing the **availability of information** for researchers, national programmes, the European Commission and for people living with diabetes
- facilitating **the development of a highly informed diabetes patient population** who can translate the key messages at national level
- encouraging participation and investment by all key stakeholders including **entrepreneurs, industrial sponsors and national agencies**
- determining **the conditions for a central coordinating entity** that will encompass all the above.

About EURADIA

As a unique alliance of NGOs and healthcare companies, EURADIA's mission is to improve the lives of people affected by diabetes both now and in the future, through advocacy of diabetes research in Europe at the highest political and societal levels of influence, by improving coordination of European diabetes research and by shaping the allocation of resources for such research through increased awareness.

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