About PerMed's Strategic Research and Innovation Agenda (SRIA)

Personalised medicine (PM) represents one of the most innovative new concepts in biomedical research and healthcare. It holds the promise of more effective early diagnosis, better and less-toxic treatments and improved medical services for patients. It also can serve as a potent engine to drive economic growth. **The aim of PM is to generate and implement innovations in diagnosis, therapy, prevention and ICT with economic value and fair access for citizens.**

PM approaches, particularly for diagnosis and treatment of cancer and rare diseases, are already being implemented. Yet in the case of other diseases full integration into healthcare systems is still far from being a reality. The exciting new developments at play can only be successfully implemented when handled cross-sectorally. For this purpose the PerMed SRIA has identified **five key challenges**:

1) ***Developing awareness and empowerment***

Through PM, the role of caregivers and patients will evolve. Patients and healthcare professionals have to be empowered and need to develop the required awareness about PM. A first step is to deliver best available evidence supporting the clinical and personal utility as well as the economic value of PM approaches to health systems.

2) ***Integrating Big Data and ICT solutions***

The development of personalised medicine will rely heavily on integrated Big Data analytics and ICT solutions to generate and integrate the required knowledge and infrastructure for new approaches. Technologies for data capture as well as the management and development of high-quality databases will be as instrumental as strategies to make sense of data for known and future purposes. Translational research infrastructures and data harmonisation of structured, semi-structured and unstructured health and lifestyle data will be a central component and, thus further European frameworks need to be created and supported by suitable legislation.

3) ***Clinical Research and Beyond***

In order to achieve its anticipated impact on the health and well-being of citizens, translation of discoveries and communication across the continuum of research are required. This starts with the integration of all the 'omics' data to generate and implement meaningful interventions and diagnosis. Such processes should be supported by re-classifying diseases at the molecular level and by developing pre-clinical models for validation. A European-wide process to evaluate and validate biomarkers would support Europe on its way of taking a global lead in PM.

Meanwhile, the development of new clinical trial designs adapted to new approaches will further improve the effectiveness of interventions. Collaborative pre-competitive and trans-disciplinary researches, as well as cross-sector collaborations, need to be promoted and supported by suitable funding mechanisms and measures.

4) Bringing Innovation to the Market

Innovative PM solutions also represent a higher uncertainty regarding going to market. There is a need to develop new risk-based approaches for their evaluation in a context that encourages systematic early dialogue with all stakeholders providing guidance for companies.

Beyond the required cross-disciplinary and cross-border collaboration an open innovation approach is to be supported. At the same time, an adequate policy, regulatory and legal framework is needed to ensure that challenges associated with PM are adequately addressed.

5) Shaping Sustainable Health Care

PM will rely on healthcare systems that are able to adapt to these approaches in a timely and socially acceptable manner, while enabling the participation of all stakeholders to increase effectiveness.

Training for health professionals is required as is the promotion of engagement and close collaboration between all stakeholders, including patients. Citizens will play an increasingly important role both for the adoption and control of electronic health record data and the development of surveillance and monitoring systems for personal health data.

On top of this, health research economics for PM needs to be supported and a flexible framework for pricing and reimbursement - equitable for all patients across the EU - must be developed.

ENDS

Note to editors

PerMed is a Coordination and Support Action (CSA), financed by the European Commission, of 27 partners representing key decision makers in research and research policy, industry, health care and patient organisations. A PDF version of this SRIA, including all links and hyperlinks, can be downloaded for free on the PerMed website: http://www.permed2020.eu

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