



# Alliance for Biomedical Research in Europe

## **Major changes are needed in order for patients to benefit from precision medicine**

Precision medicine approaches the treatment of disease via an individual's genes, environment, and lifestyle. It will allow the accurate prediction of which treatment and prevention strategies for a particular condition will work for whom – either as an individual or a group. It is therefore patient-centred as opposed to the former 'one size fits all' approach, and as such it needs a totally new approach, says a White Paper from the BioMed Alliance.

A different framework, where individualised patient care rather than drug development is at the centre of the process, is essential. And patients must remain the focus through the discovery process, the Alliance says. «The concept that therapeutic interventions are developed with the sole purpose of market access needs to be revisited. This new approach should cover not only pharmaceuticals, but also other modalities such as surgery, diagnostics and screening.»

The current regulatory framework has resulted in a dramatic increase in the cost of conducting randomised trials without an increase in patient safety. «Investigator-led trials are increasingly difficult to conduct and the number of new interventions as well as of optimised therapeutic strategies that can be tested has decreased dramatically. This development represents a major threat to our health care system.»

Conceptual changes are needed, according to the White Paper, to address the missing link between regulatory trials and healthcare systems. "Drug development protocols are usually written with the aim of bringing a new agent to the market for a very specific clinical situation. They do not test the optimal integration of a new drug into existing therapeutic strategies, such as how to combine treatment, in which sequence, and for how long. While short-term regulatory trials are needed to demonstrate therapeutic benefit, they may not address real-life issues (such as those arising from disease progression) and may fail to capture rare or delayed safety outcomes arising from drug exposure."

Two major issues that must be addressed at European level in order to achieve a successful transition to precision medicine, says the White Paper. The establishment of Europe-wide clinical population registries will enable real-life testing of treatment strategies and avoid the expense of active long-term follow-up. And treatment in real life based on patient-centred evidence such as optimal dose, duration, sequence, combination and quality of life needs to be optimised.

"It is urgent that European bodies that have the capacity to stimulate such changes get their acts together if we want to make precision medicine a viable option, rather than a chance happening that generates false hope for patients and the scientific community," says the White Paper. Such a change will not only maximise the potential of scientific advances for individual patients, but also for bring economic benefit to health care services through the ability to target new and established treatment to those who are certain to benefit from it, the Alliance concludes.