



## Achieving Personalised Patient Care through In Vitro Diagnostics

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### MEDICAL INNOVATION OVER THE PAST 30 YEARS

has substantially improved the lives of Europeans, and the next 30 years are likely to see even more breath-taking advances in the prevention and treatment of diseases. With Europe's renewed commitment to the health of its citizens, in vitro diagnostic tests (IVDs) are sure to play an integral role.

New generations of diagnostic technologies allow for a better understanding of the diseases as well as of the way in which a patient may react to specific treatments. This increased knowledge is driving the personalisation of medicine, through which specific therapeutic interventions can be chosen based on specific patients' needs.

IVDs facilitate more effective intervention, often providing diagnosis before a disease has a chance to fully develop. They contribute to preventing unnecessary treatment and containing the spread of infectious diseases, thus not only benefiting the patients but also reducing the burden on healthcare systems.

Personalised medicine adapts healthcare to a patient's genetic predisposition or specific disease development and goes beyond the broad definitions of diseases. Such personalised care relies on companion diagnostic tests to help identify the way in which a patient will react to a specific treatment. Accurate and individualised diagnosis allows personalisation of treatments. This is already visible in certain fields, including oncology where molecular analysis has unveiled thousands of subtypes.

Importantly, such information can be used to predict whether a given patient will benefit from a treatment or, conversely, will the type of treatment be ineffective and possibly result in serious adverse reactions. This enables healthcare services to deliver "the right treatment to the right patient at the right time", improving patient outcomes and avoiding unnecessary costs.

*Committed to raising awareness of the important role of diagnostics in the entire healthcare equation, the European Diagnostic Manufacturers Association (EDMA) provides services and activities to members engaged in the research, development, manufacturing or distribution of in vitro diagnostic (IVD) products in Europe. Founded in 1979, EDMA advocates for an appropriate regulatory system and a realistic economic environment for healthcare in Europe.*

Delivery of these types of technologies requires certain adjustments at the regulatory level, which will be addressed during the revision of the IVD Directive and through enhanced coordination of the regulatory pathways for drugs and IVDs. To this end, consultations between Notified Bodies authorising IVDs and the European Medicines Agency (EMA) will aim to ensure regulator confidence in the safety and efficacy of drugs and companion diagnostic. High safety standards are already in place to secure appropriate levels of oversight before IVDs or medicines enter the market and updated rules-based risk classification for companion diagnostics are planned. New accreditation systems may also be introduced for laboratories that perform and analyse such tests.

Development of diagnostic technologies and creating a system for regulatory approval is not enough to ensure that patients get access to personalised care. When used in combination, companion diagnostics and personalised medicine contribute to value-based healthcare spending, benefitting healthcare providers and patients. It is thus equally important that reimbursement systems around Europe recognise the value of companion diagnostics and work to ensure that the tests needed for the use of crucial therapies are available to patients alongside the treatment.

The European Diagnostic Manufacturers Association (EDMA) – representing major companies engaged in the research, development, manufacturing and distribution of IVD products in Europe – fully supports the push for personalised medicine. It is an extension of its member companies' pre-existing commitment to healthcare through IVD innovation.

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DIAGNOSTICS FOR HEALTH

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