Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI_001280

The IVD Quality Alliance (iQuAL) – establishing an EU-wide quality-monitoring metastructure for in-vitro diagnostic medicine to support implementation of the IVDR

Overall opinion

The idea builds on the need to have appropriate harmonised, widespread quality assessment infrastructures for in vitro diagnostics (IVDs), which are indispensable public health tools for the prediction, diagnosis and prognosis of human disease within a highly regulated and increasingly digitalized and AI-driven ecosystem.

The idea of building the in vitro diagnostics Quality Alliance (iQuAL) infrastructure is ambitious and aims to go beyond the state of the art by addressing the geomapping of the distribution of in-house in vitro diagnostics (IH-IVDs) to provide dashboard technologies for visualization and developing regulatory frameworks from use-cases for harmonizing quality levels within Europe. Nevertheless, questions related to operational issues, IP matters and access to data would need to be addressed.

The expected impacts of the described idea would contribute to IHI objectives, for instance by enabling a better visibility on the availability of IH-IVDs and rare IVD tests with appropriate quality standards, documented by External Quality Assurance (EQA) data, which is even more important in times where there could be shortages of IVDs. Considering the contribution to the EU industrial and pharmaceutical strategy (IHI objective 3), it could also be interesting to envisage a pandemic preparedness and response element.

The implementation of an innovative diagnostics value chain and the need for a cross-sectoral approach is clear. The question of accessibility of the innovations to patients requires addressing market access practices and regulatory harmonization across national healthcare systems, including reimbursement schemes and Health Technology Assessment (HTA) practices considering the EU HTA regulation requirements.

To conclude, the SIP is of the opinion to keep the idea for consideration.