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Topic idea submitted to IHI - Reference Number: TI_001280

Are you submitting the idea:
☐ **in your personal capacity?**
☒ **on behalf of an organisation?**

Please indicate the name of the group organisation: European Federation for Laboratory Medicine (EFLM)

Please select from the list below the type of stakeholders your organization represents:
Healthcare professional organisation/healthcare provider

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:
The IVD Quality Alliance (iQuAL) – establishing an EU-wide quality-monitoring metastructure for in-vitro diagnostic medicine to support implementation of the IVDR

2 Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field:
In-vitro Diagnostics (IVD) represents an essential component of modern medicine critical for effective health care, appropriate therapeutic measures and patient safety. IVD activities generate vast numbers of diagnostic results across Europe on a daily basis through thousands of established diagnostic laboratory tests and a constant stream of innovative candidate biomarkers used for prediction, diagnosis and prognosis of human disease in an increasingly personalized medical environment.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treat- ment and management of diseases, meeting the needs of end-users;SO4: exploit the full potential of digitalisation and date exchange in heath care;SO5: enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions;

Please select the keywords that are most relevant to your idea:
Detection;Diagnosis;Disease management;Digital health;Health technology;

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

In many EU countries, medical laboratories regularly (and in part mandatorily) monitor their analytical performance and proficiency by tight internal quality controls and external quality assessment (EQA) strategies. EQA Providers (EQAP) offer extensive programs for CE-marked and in-house IVDs (IH-IVDs) for longitudinal, near-real-time assessment of IVD performance and robustness.
The iQuAL project will identify, map and establish an EU-wide EQA landscape generating a data-secure IVD assessment ecosystem as a hub providing real-world comprehensive quality data accessible through the iQuAL structure. These IVD data can then be utilised by manufacturers to maintain post-market surveillance and meet regulatory requirements while reducing bureaucracy. Further objectives are the geomapping of the distribution of IH-IVDs providing dashboard technologies for visualization, developing regulatory frameworks from use-cases for harmonizing quality levels within Europe, and supporting research approaches into IVD commutability to generate a streamlined system for greater convergence between diagnostics and therapeutics within clinical trials and healthcare.

3 Expected impacts to be achieved by your idea

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific objectives, as described in the IHI SRIA:

Impacts *are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.*

IHI general objectives: *1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations; 2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to 'Europe's Beating Cancer Plan'; 3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.*

Manufacturers could perform post-market surveillance of CE-IVDs leveraging the information within a pan-European EQA data infrastructure, mapping networks for acquired and inherited disorders, including cancer, as precursors to European Rare Diagnostic networks, selected with national Competent Authorities based on EQA performance.
Monitoring the IH-IVD landscape allows stakeholders to have a clearer idea of where to prescribe available specialty and rare IVD tests (CE- and IH-IVDs), with appropriate quality standards, documented by EQA data.
Hospitals and healthcare providers will get access to reliable and transparent information on availability, analytical performance and reproducibility of IH-IVDs.
Initiation of iQuAL will generate momentum to participate in a broadening quality network of a multistakeholder environment built around a shared desire for provision of robust, reproducible, affordable biomarkers with theranostic, predictive and/or prognostic value. This will encourage communication and confidence, including sharing of specimen resources, allowing Europe to become an increasingly attractive market for clinical research.

4 Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors (*e.g.* pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?

Why does it require collaboration between private (industry) and public partners (*e.g.* academia, healthcare practitioners, patients, regulators)?

The implementation chain of an innovative diagnostics value chain often begins within the academic sector and involves many stakeholders, including basic and clinical researchers, start-ups (increasingly linked to European academic structures), SMEs, larger companies in diagnostics, including pathology, but also therapeutics (medicines, imaging, medical devices…), notified bodies and competent authorities. It also requires a cross-sectoral approach from many medical specialties.

Optimising a harmonised, widespread EQA infrastructure with low-response-time assessment for post-market performance needs support from a multitude of stakeholders to produce the benefit in the diagnostic process. As such, this proposal is ideally suited to a pre-competitive public-private partnership and will be of benefit to the whole of Europe and beyond.

It will contribute to an increasingly vibrant European Health industry by providing reliable reproducible biomarkers, from rare niche tests to widely used CE-IVDs across the whole spectrum of disorders, thus allowing accelerated access for patients to precision medical approaches.

Why is the contribution of industry needed to achieve the expected impacts?

***Contribution of industry**: Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through 'in-kind' contributions (e.g. their researchers' time, laboratories, data, compounds). At least 45% of each project's total costs have to be in-kind contribution.*

The vast majority of results and approximately 75% of the IVD repertoire is produced by the manufacturing sector in the form of CE-marked devices. Once an IVD device is introduced into the health care system, post-market surveillance data is generated by the diagnostic sector, either by complaint and/or incident reports. Systematically using independent external quality assessment data as parameters allows monitoring of IVD performance in a longitudinal and transversal setting. It also will provide data on IH-IVD devices regularly run in EQA schemes together with CE-marked tests potentially advancing diagnostic evolution and optimization.
The exploitation of the EQA system will lead to increased public-private communication and consequent confidence between HCP, manufacturers, notified bodies and authorities, and should lead to reduced bureaucracy in a sector which merits and requires this.