European Network of Expertise (NoE) on Omics in Cancer

(Joint Action JANE-2 – GA 101183265 – WP9)

Contribution to the European Commission Consultation on Revision of the *In-Vitro* Medical Device Regulation

Towards a Sustainable Regulatory Framework for In-house Omics Diagnostics under Article 5(5)

Recommendations

29th July 2026

What is JANE-2?

JANE-2 (Joint Action Networks of Expertise in Cancer)[1] is an ambitious initiative, stemming from Europe's Beating Cancer Plan, with the aim to implement seven new European Networks of Expertise in different cancer conditions, addressing: 1) complex and poor prognosis cancers; 2) palliative care; 3) survivorship; 4) personalized primary and secondary prevention; 5) omics technologies, 6) hi-tech medical resources; and 7) adolescents and young adults with cancer. It represents 121 partners across 29 European countries.

Why a Network of Expertise on Omics Technologies?

Omics technologies allow for the comprehensive study of biological molecules (DNA, RNA, proteins, metabolites, etc.) within cells. These cutting-edge technologies are revolutionizing precision medicine for patients with cancer, haematological malignancies, as well as rare diseases. These innovative tools go beyond supporting precision diagnosis and treatment. They also improve cancer risk prediction, early detection, and disease monitoring. Genomics and transcriptomics are currently the most widely used in clinical practice. However, emerging fields such as methylomics, proteomics, and metabolomics, as well as multi-omics integration, are rapidly advancing and poised to play a significant role in the future.

The ambition of the Network of Expertise (NoE) on Omics technologies[2] is to strengthen the fast integration of innovative omics technologies into EU healthcare systems to improve clinical decision-making in precision cancer medicine at the different steps of patient management in a sound and sustainable manner, achieving equitable access to these services for all EU citizens.

[1] https://jane-2.eu/
[2] https://jane-2.eu/omics-technologies/

Executive summary

The JANE2 Network of Expertise (NoE) on Omics Technologies welcomes the European Commission's proposal to revise the *In Vitro* Diagnostic Medical Devices Regulation (IVDR).[3] The proposed amendments represent an important acknowledgement that the current implementation of the IVDR has unintentionally created barriers to innovation, access to omics technologies and the sustainability of precision medicine services across Europe.

From the perspective of omics technologies, however, the current proposal should not merely be understood as a simplification exercise. It represents a necessary evolution in the understanding and implementation of Article 5(5). The legislative process should explicitly recognise that the hospital exemption is no longer simply a temporary derogation from the commercial market, but a complementary and explicit regulatory route serving different clinical, scientific and public health objectives.

Omics technologies fundamentally differ from conventional devices. They evolve continuously, rely on multidisciplinary interpretation, serve precision medicine that relies on the identification of molecular alterations/biomarkers that are too rare or where insights are too rapidly evolving to allow real-time commercial development. These characteristics require a regulatory framework capable of supporting continuous and agile innovation inside accredited healthcare laboratories while maintaining high standards of patient safety.

The proposed revision therefore provides an opportunity not only to reduce administrative burden but to establish a long-term European model for innovation-driven omics testing that complements, in a more agile manner, rather than competes with, commercially available solutions on the market. In this context, the JANE2 Network of Expertise on Omics Technologies stands ready to provide multidisciplinary scientific, clinical, ethical, legal, and implementation expertise to support the practical operationalisation of these recommendations and to contribute to the development of harmonised European approaches for omics diagnostics under the revised IVDR.

Key recommendation: beyond simplification, Article 5(5) should be established as a sustainable regulatory pathway for omics innovation and precision medicine in Europe.

[3] *https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14808-Medical-devices-and-in-vitro-diagnostics-targeted-revision-of-EU-rules_en*

1. Article 5(5) should evolve from an exemption into a recognised regulatory pathway

The proposed amendments to Article 5(5) collectively signal a significant evolution in the European approach to regulating in-house in-vitro diagnostics. By removing the obligation to justify the absence of an equivalent CE-marked device, allowing the transfer of in-house diagnostics between health institutions, reducing unnecessary administrative requirements for accredited laboratories and extending the scope of the provision to clinical trial laboratories, the Commission has acknowledged that the current interpretation of the hospital exemption no longer reflects the realities of precision medicine in the contemporary healthcare system.

JANE2 NoE on Omics Technologies strongly supports this policy direction. However, we believe the revision should go one step further by explicitly recognising that Article 5(5) is no longer functioning merely as a limited and temporary derogation from the general regulatory framework. Instead, it is progressively establishing a complementary regulatory pathway that serves a distinct public interest and fulfils objectives that cannot always be addressed through commercial IVD development.

This distinction is particularly relevant for omics technologies. Healthcare institutions and commercial manufacturers operate under different mandates and respond to different drivers of innovation. Commercial manufacturers develop products intended for large-scale deployment across diverse healthcare settings, requiring standardisation, industrial production and broad market applicability. In contrast, accredited hospital laboratories develop omics testing to respond to specific and often rapidly evolving clinical needs, rapidly integrating scientific advances directly into patient care and addressing rare or uncommon molecular alterations and highly specialised clinical questions, including those arising in clinical trials, for which viable commercial markets may never emerge.

These two innovation ecosystems should not be viewed as competing models but as complementary components of the European diagnostic landscape. Hospital-developed omics testing frequently generates the first clinical evidence for emerging biomarkers, supports translational and clinical research, and enables the implementation of precision medicine well before commercially available alternatives exist. Commercial manufacturers subsequently play a critical role in scaling validated omics tests and ensuring broad accessibility across healthcare systems.

The revised IVDR should therefore explicitly recognise that both pathways contribute synergistically to the integration of innovative omics technologies into the standard of care while maintaining patient safety and strengthening European competitiveness. The objective of Article 5(5) should not be to preserve an exceptional route tolerated only in the absence of commercial solutions, but to establish a stable and proportionate regulatory framework for innovation developed within accredited healthcare laboratories operating under robust quality management systems. Such recognition would provide greater legal certainty for healthcare providers while preserving the complementary relationship between public sector innovation and commercial development and ensuring the fastest possible patient access to innovative omics testing.

At the same time, the complementary relationship between hospital innovation and commercial development should be reflected in a structured transition pathway from in-house innovation to full IVDR certification. The proposed amendments appropriately recognise in-house diagnostics as a complementary regulatory pathway for genomic alterations and clinical applications that are not yet adequately addressed through commercial IVDR development, and they explicitly acknowledge the transfer of validated in-house diagnostics between non-profit healthcare institutions. While this evolution is highly desirable, it is in the primary interest of patients, EU citizens, healthcare systems and both public and private stakeholders that clinically validated in-house innovations can progressively transition towards full IVDR certification whenever broader deployment becomes feasible.

Industrial-grade IVDR assays remain essential for large-scale distribution across Member States and diverse healthcare settings, ensuring equitable and homogeneous access to high-quality diagnostics throughout the European Union. Article 5(5) should therefore not be interpreted as creating a permanently separate diagnostic market, but as enabling an innovation pathway that can generate evidence, address unmet clinical needs and support the emergence of future IVDR-certified solutions.

In practice, the discovery of predictive, prognostic or actionable omics biomarkers rarely depends on a completely novel assay developed entirely in-house by a single academic laboratory. Innovation more often emerges through the clinical use of advanced technologies, including commercially available research-use-only platforms, particularly next-generation sequencing, combined with local analytical optimisation, bioinformatics development and clinical interpretation. Potential clinical utility is frequently identified first in retrospective cohorts and subsequently confirmed through prospective clinical studies of increasing complexity, sometimes leading to the approval of new therapies, indications and companion diagnostics.

The revised Article 5(5) should therefore explicitly encourage a simplified and structured pathway connecting validated in-house omics innovations with industrial-grade IVDR development. Such a pathway should facilitate collaboration between healthcare institutions and economic operators to upgrade, validate and certify clinically valuable omics solutions, enabling their broader dissemination after rigorous collaborative evaluation. Future implementing measures could support proportionate procedures for the transfer of validation data, analytical evidence and technical documentation and encourage early interaction with notified bodies where appropriate.

Public-private collaboration during this transition phase should be recognised as a strategic component of the European innovation ecosystem. EU instruments such as Pre-Commercial Procurement, Public Procurement of Innovation and other innovation funding mechanisms can support the maturation of clinically validated in-house omics solutions towards full IVDR certification. Strengthening the connection between in-house innovation and commercial development would accelerate the translation of scientific discoveries into routine care, improve patient access to advanced diagnostics, enhance the sustainability of healthcare innovation and reinforce Europe's competitiveness in precision medicine.

2. Omics technologies require regulatory flexibility by design

The regulatory framework for in-house diagnostics should recognise that omics technologies differ fundamentally from conventional *in vitro* diagnostics in both their scientific characteristics and their clinical implementation. While traditional diagnostic devices often remain technically stable over long periods, omics-based testing is intrinsically dynamic. Their clinical value depends on the continuous integration of new scientific evidence, technological improvements, and evolving medical knowledge, usually via clinical studies performed in healthcare systems.

Molecular testing for cancers is constantly discovered and/or refined as new predictive biomarkers for clinical actionability and new targeted therapies receive regulatory approval. Sequencing technologies continue to evolve, bioinformatic algorithms are regularly optimised to improve analytical performance, and variant interpretation changes as international databases expand and evidence accumulates. These developments are not exceptional events but represent the normal lifecycle of omics testing for cancer precision medicine.

Consequently, accredited diagnostic laboratories must retain the capacity to update analytical workflows, optimise bioinformatic pipelines, incorporate newly validated biomarkers and refine clinical reporting practices without facing disproportionate regulatory barriers each time scientific knowledge advances. Requiring extensive regulatory reassessment for every iterative improvement would delay the implementation of innovations that directly benefit patients and undermine the responsiveness that characterises precision medicine.

The current revision of the IVDR provides an opportunity to acknowledge this reality. Rather than treating laboratory-developed omics testing as static products comparable to conventional commercial devices, the legislation should recognise them as continuously evolving testing systems operating in a flexible manner within well-established accredited quality frameworks. Regulatory oversight should therefore focus on ensuring robust governance, analytical validity and patient safety while allowing proportionate flexibility for scientific and technological updates.

Such an approach would better align the IVDR with the pace of biomedical innovation and would strengthen Europe's ability to translate research discoveries into clinical practice, particularly in precision medicine for cancer care and rare diseases where scientific advances occur rapidly, and patient groups benefiting from newly identified omics biomarkers are often too small to support immediate commercial development.

3. The removal of Article 5(5)(d) should be maintained without compromise

JANE2 NoE on Omics Technologies strongly supports the Commission's proposal to remove Article 5(5)(d), which currently requires healthcare laboratories to demonstrate that the specific needs of the target patient group cannot be met by an equivalent CE-marked device available on the market. This amendment represents one of the most important improvements introduced by the revision proposal and should be preserved throughout the legislative process.

The existing requirement has proven difficult to implement in practice and offers limited additional value for patient safety. Determining whether an equivalent test exists is particularly problematic in the field of omics technologies, where clinical performance depends on the entire testing workflow rather than on a single analytical component. Two genomic assays may appear comparable because they analyse overlapping sets of genes, yet differ substantially in sequencing chemistry, laboratory workflows, bioinformatic processing, analytical sensitivity, variant filtering strategies, reporting methodologies and clinical interpretation. These differences may significantly influence diagnostic accuracy, therapeutic decision-making and patient outcomes.

Moreover, omics diagnostics, whether commercially available or developed in-house, are rarely used as isolated products. Their clinical utility depends on their integration into complex care pathways involving molecular tumour boards, specialised clinical expertise, laboratory interpretation, bioinformatics support, and continuous interaction between multiple disciplines (medical oncologists/haematologists, pathologists, molecular biologists, radiologists, geneticists, and other relevant experts). Therefore, assessing equivalence solely based on commercial availability does not fully capture the real-world clinical context in which these technologies are implemented, adapted, and evaluated. In particular, hospital-based development and modification of in-house solutions allow healthcare professionals to respond rapidly to evolving scientific evidence, emerging biomarkers, specific patient needs, rare clinical scenarios, and operational requirements identified through daily practice. These adaptations are assessed within the hospital environment, considering their impact on patient management, clinical workflows, and quality of care in real time. Maintaining the removal of Article 5(5)(d) without compromise is therefore essential to preserve the capacity of healthcare institutions to develop and adapt innovative diagnostic approaches when no suitable commercial alternative adequately addresses specific clinical needs.

The obligation to perform repeated market surveys and document the absence of equivalent commercial products also creates a considerable administrative burden for accredited laboratories. Resources are diverted towards regulatory justification rather than scientific validation, quality improvement and patient care, despite the fact that these laboratories already operate under internationally recognised quality management systems, including ISO 15189 accreditation, regular external quality assessment and continuous performance monitoring.

Importantly, removing Article 5(5)(d) does not reduce patient protection. The safety and reliability of in-house testing continue to be ensured through rigorous laboratory accreditation, analytical validation, clinical governance and professional accountability. These

mechanisms provide a more meaningful guarantee of quality than mandatory comparisons with commercial products whose clinical suitability may differ substantially from the intended in-house application.

For these reasons, the deletion of Article 5(5)(d) should be maintained without modification. Reintroducing equivalent requirements through implementing acts or future guidance would undermine the objectives of simplification, discourage innovation within accredited healthcare institutions and unnecessarily delay patient access to advanced molecular testing.

4. Cross-border sharing of in-house testing should become a recognised principle for European Reference Networks

JANE2 NoE on Omics Technologies welcomes the Commission's proposal to facilitate the transfer of in-house testing between healthcare institutions when this serves patients' interests. This amendment reflects the increasingly collaborative nature of modern healthcare and represents an important step towards improving equitable access to innovative omics technologies across Europe.

However, the revised IVDR should go beyond merely permitting such transfers on a case-by-case basis. It should explicitly recognise the collaborative development, validation, and sharing of validated in-house testing as an integral component of the European Health Union and of Europe's strategy for precision medicine. Cross-border collaboration should be established as a clear and implementable regulatory principle, particularly within European Reference Networks (ERNs), Comprehensive Cancer Centres, and other recognised structures of specialised healthcare cooperation.

The organisation of modern cancer care and precision medicine increasingly relies on interconnected networks rather than isolated healthcare institutions. Comprehensive Cancer Centres, European Reference Networks for rare cancers, and cross-border molecular tumour boards routinely share expertise, clinical knowledge, data, diagnostic approaches, and interpretation capacity to support patients with complex and/or rare cancers, paediatric malignancies, and uncommon molecular alterations. In many of these areas, expertise, infrastructure, and patient populations are necessarily concentrated within a limited number of specialised centres. Collaboration between institutions is therefore not an optional enhancement but an essential mechanism to ensure equitable access to high-quality diagnostics across Europe.

Restricting the use of validated in-house diagnostics exclusively to the institution in which they were originally developed no longer reflects how precision medicine is delivered in practice. Such an approach risks reinforcing geographical inequalities, duplicating development efforts, and limiting patient access to validated expertise that already exists elsewhere in Europe. The regulatory framework should instead facilitate the responsible transfer and use of validated omics solutions between qualified healthcare institutions operating under equivalent quality standards, particularly where this improves patient outcomes, addresses unmet clinical needs, strengthens sustainability, or enhances preparedness for future public health challenges.

In particular, cross-border sharing of validated in-house testing should become a recognised and facilitated practice within European Reference Networks. ERNs provide an existing governance framework where healthcare institutions collaborate under defined structures, share specialised expertise, and support patients requiring highly specialised care. Enabling validated in-house tests to circulate within these networks would ensure that innovation developed within one centre of excellence can benefit eligible patients throughout Europe, regardless of their geographical location.

For this principle to be effective in practice, the revised IVDR should provide greater clarity on the operational conditions enabling such collaboration. This should include transparent criteria for the transfer and use of validated in-house devices, requirements for demonstrating equivalent quality standards, mechanisms for sharing validation documentation and performance data, and clear allocation of responsibilities between the developing institution and the receiving healthcare institution. Such a framework should also support interoperability between laboratories by enabling the exchange of relevant technical documentation, analytical performance information, protocols, bioinformatics workflows, interpretation frameworks, and other elements necessary for reliable implementation of omics-based diagnostics.

Importantly, facilitating cross-border collaboration should not reduce accountability or patient safety requirements. While validated in-house devices may be shared between accredited healthcare institutions, the laboratory performing the test and issuing the clinical report should retain full responsibility for ensuring appropriate implementation within its own quality management system, including verification of performance, analytical validation where required, interpretation, reporting, and continuous monitoring of the test's clinical use.

This approach would enhance efficiency and sustainability by enabling European healthcare systems to share validated expertise rather than repeatedly developing similar assays independently. This is particularly important for rare diseases and innovative molecular testing, where patient numbers are limited, evidence generation can be challenging, and technical expertise is concentrated within specialised centres of excellence. Enabling trusted collaboration under common quality standards would reduce unnecessary duplication, accelerate access to innovation, and maximise the value of investments made in European healthcare expertise and infrastructure.

Furthermore, cross-border sharing of in-house testing should be considered within the broader context of European interoperability efforts, including initiatives supporting secure health data exchange, genomic data infrastructures, and collaborative research networks. The future of precision medicine depends not only on access to innovative technologies but also on the ability of healthcare institutions to connect expertise, data, and diagnostic capacity through trusted and interoperable frameworks. Therefore, JANE2 NoE on Omics Technologies encourages the Commission to strengthen the revised Article 5 framework by moving from a permission-based approach towards a clear recognition that cross-border collaboration and sharing of validated in-house testing represent a fundamental principle of European precision medicine. Establishing such a framework would ensure that regulatory requirements support innovation, reduce inequalities, and enable patients across the European Union to benefit

from clinically validated diagnostic solutions developed within Europe's leading centres of expertise.

5. ISO 15189 accreditation should become the primary regulatory assurance mechanism

JANE2 NoE on Omics Technologies welcomes the proposed reduction of documentation requirements for accredited laboratories developing and using in-house diagnostics under Article 5(5). This represents an important step towards a more proportionate regulatory framework that recognises existing quality assurance mechanisms within European healthcare systems. Nevertheless, the revision provides an opportunity to further strengthen regulatory coherence by explicitly recognising ISO 15189 accreditation as the principal mechanism for demonstrating compliance and quality assurance for health institutions developing in-house omics diagnostics.

Medical laboratories accrediting their molecular tests under ISO 15189 already operate within comprehensive quality management systems specifically designed to ensure the competence, reliability and continuous improvement of omics services. Accreditation encompasses all critical aspects of laboratory practice, including analytical and clinical validation, risk management, personnel competence, equipment qualification, traceability, quality assurance, documentation, corrective and preventive actions, participation in external quality assessment schemes and continuous monitoring of performance. These systems are regularly assessed by independent accreditation bodies and are subject to ongoing surveillance, ensuring that laboratories maintain high standards throughout the entire lifecycle of their diagnostic activities.

For laboratories operating under these internationally recognised standards, the duplication of equivalent quality documentation to satisfy separate and overlapping IVDR requirements generates unnecessary administrative burden without delivering a corresponding improvement in patient safety. Resources that could otherwise support innovation, validation of new biomarkers or implementation of novel technologies are instead diverted towards maintaining parallel documentation systems that frequently assess the same quality processes through different regulatory mechanisms.

This issue is particularly relevant for omics testing, where laboratories continuously optimise analytical workflows, update bioinformatic pipelines and incorporate emerging scientific knowledge into clinical practice for each specific omics technology. A proportionate regulatory framework should facilitate these improvements in a flexible manner while maintaining robust quality oversight, rather than requiring repeated administrative demonstration of quality processes that have already been independently verified through accreditation.

JANE2 NoE on Omics Technologies therefore encourages the co-legislators to establish greater regulatory reliance on ISO 15189 accreditation within the implementation of Article 5(5). Rather than duplicating existing quality assurance mechanisms, future guidance and implementing measures should adopt a principle of regulatory reliance, recognising accreditation as the primary demonstration of laboratory competence wherever appropriate. Regulatory oversight should concentrate on areas not already covered by accreditation,

thereby improving efficiency while preserving the high level of patient safety that remains the central objective of the IVDR.

Such an approach, supported by a harmonised and consistent application of the ISO 15189 standard across Member States, would reduce unnecessary administrative burden, promote mutual trust between healthcare institutions and competent authorities, and facilitate recognition of equivalent quality management systems. Ensuring greater alignment in the interpretation and implementation of ISO 15189 requirements across Europe would provide a stronger foundation for cross-border collaboration, enabling healthcare institutions to devote greater resources to innovation, quality improvement, and patient care.

6. Simplify documentation requirements for in-house IVDs

The successful implementation of the revised Article 5(5) requires a harmonised approach across all Member States. While the IVDR establishes a common European regulatory framework, divergent national interpretations and additional documentation requirements have resulted in significant regulatory fragmentation, creating unequal access to innovative testing and increasing administrative complexity for accredited healthcare institutions. JANE2 NoE on Omics technologies therefore calls for the removal of unnecessary national documentation requirements and for clear limits on the ability of Member States to impose additional obligations beyond those established in the Regulation. The implementation of Article 5(5) should be based on common European guidance and mutual trust in recognised quality systems, ensuring that accredited laboratories operating under equivalent standards are subject to comparable regulatory expectations throughout the Union. A harmonised approach would strengthen legal certainty, facilitate cross-border collaboration, support European Reference Networks and promote equitable access to advanced omics technologies irrespective of the Member State in which patients receive care. At the same time, reducing regulatory fragmentation would reinforce the integrity of the Single Market by preventing national implementation from becoming a barrier to innovation, scientific collaboration and the efficient delivery of precision medicine.

7. Innovation in hospitals should be recognised as an essential component of European strategic autonomy

The revision of Article 5(5) should also be viewed within the broader context of Europe's ambition to strengthen its strategic autonomy, resilience and global competitiveness in health innovation. Recent public health emergencies have clearly demonstrated that accredited healthcare laboratories are often the first organisations capable of rapidly developing, validating and implementing new testing solutions in response to emerging clinical needs. Their capacity to innovate in a flexible and agile manner complements industrial development and represents a critical element of Europe's preparedness infrastructure.

This role extends far beyond pandemic preparedness. In cancer medicine and other areas of precision medicine, hospital laboratories continuously develop novel molecular assays for newly identified biomarkers, specific subgroups of diseases and emerging therapeutic targets, often years before commercial products become available. These laboratory-developed tests enable clinicians to implement scientific advances rapidly via clinical studies, generate real-

world evidence and support patients with conditions for which commercially viable molecular solutions may never exist.

Maintaining this capacity is increasingly important for Europe's health security and scientific leadership. A regulatory framework that unintentionally discourages hospital-based innovation risks increasing dependence on commercial development alone, slowing the translation of research into clinical practice and reducing the resilience of healthcare systems when responding to rapidly evolving medical challenges. In highly specialised fields such as precision medicine for cancers and rare diseases, healthcare and research institutions provide an essential innovation capacity that complements rather than competes with industrial research and development.

Unlike commercial developers, hospital laboratories have a direct responsibility towards individual patients. Consequently, regulatory flexibility should be accompanied by equally robust requirements for quality assurance, professional accountability and transparent clinical reporting. Hospital-developed testing should therefore be recognised as strategic healthcare infrastructure that contributes to the implementation of several European policy priorities, including the European Health Union, the European Cancer Mission, the European Health Data Space and the Genome of Europe initiative. These initiatives all depend upon the capacity of healthcare laboratories to generate, validate and apply high-quality and innovative omics testing within clinical practice.

Recognising this contribution within the implementation of Article 5(5) would reinforce Europe's ability to translate scientific discoveries into patient benefit while supporting innovation ecosystems that combine academic excellence, clinical expertise and industrial development. Rather than viewing hospital-developed testing solely through the perspective of market regulation, policymakers should recognise them as strategic public assets that strengthen Europe's capacity for innovation, preparedness and equitable access to precision medicine.

8. Harmonise implementation across Member States

While JANE2 NoE on Omics Technologies strongly welcomes the Commission's proposal to modernise Article 5(5), we wish to highlight an important policy consideration for the forthcoming legislative negotiations and future implementation.

The current revision appropriately removes several unnecessary regulatory barriers that have constrained innovation within accredited healthcare institutions. However, these improvements could be undermined if future guidance or implementation measures were to recreate indirect obligations requiring health laboratories to replace validated in-house diagnostics whenever a commercial alternative becomes available.

For omics technologies in particular, innovation is a continuous process rather than a transitional phase. Laboratory-developed testing evolves alongside scientific knowledge, integrating new biomarkers, improved analytical methods and refined clinical interpretation as evidence emerges. Their value therefore derives not only from analytical performance but also from their integration within multidisciplinary discussion, close interaction between

multiple clinical, research and laboratory expertise, and their capacity to adapt rapidly to changing standards of care.

Commercial availability should therefore not automatically invalidate or replace a validated in-house diagnostic. Instead, the continued use of an in-house assay should be determined by clinical value, scientific evidence, quality assurance and patient benefit. Where accredited healthcare laboratories can demonstrate that an in-house test remains the most appropriate solution for a defined clinical purpose, Article 5(5) should continue to provide an appropriate regulatory basis for its development and use.

Recognising this principle is essential to preserving Europe's capacity for omics technologies innovation. It will provide legal certainty for healthcare institutions, encourage continued investment in translational research and ensure that regulatory policy remains aligned with the objectives of precision medicine. Most importantly, it will ensure that patient access to the best available molecular test is determined by clinical need and scientific excellence rather than by the existence of a commercial product alone.

In this respect, particular attention should be given to ensuring a harmonised interpretation and implementation of Article 5(5) across Member States. Greater consistency in the application of the IVDR and in the assessment of equivalent quality standards, including ISO 15189 requirements, is essential to provide legal certainty, facilitate cross-border collaboration between accredited healthcare institutions, and avoid fragmentation in access to innovative diagnostics across the European Union.

9. Reduce unnecessary regulatory burden for research

Performance studies involving in-house diagnostics should be governed by a proportionate, risk-based regulatory framework that facilitates rather than delays clinical research and integration of innovation into the standard of care. JANE2 NoE on Omics Technologies encourages the co-legislators to establish risk-based oversight and a single application process for studies that simultaneously fulfil the requirements of clinical trials and IVDR performance studies. The current separation of regulatory procedures creates unnecessary duplication, increases administrative burden and prolongs the time needed to initiate investigator-driven research, particularly in the field of precision oncology where diagnostics and therapeutics are increasingly developed and evaluated together. A harmonised, single-entry process would reduce complexity for sponsors, competent authorities and ethics committees while maintaining appropriate safeguards for participants. This approach should become the standard regulatory model across the European Union, supporting faster translation of scientific discoveries into clinical practice, strengthening Europe's attractiveness for academic and industry-led research, and reinforcing the objectives of the European Health Union and the Cancer Mission.

Recommendations

To ensure that the revision of the IVDR fully supports the fast integration of innovative and high quality Omics testing into the EU healthcare systems while maintaining a high level of patient safety, JANE2 NoE Omics Technologies calls on the European Parliament and the Council to strengthen the proposed revision of Article 5(5) and its implementation through the following measures:

1. Recognise Article 5(5) as a regulatory pathway
2. Maintain and confirm the deletion of 5(5)(d).
3. Enable and standardise the collaboration and transfer.
4. Rely on ISO 15189 instead of duplicate regulation.
5. Make regulation proportionate and future-proof for omics.
6. Avoid fragmentation across Member States, and support harmonized implementation across the EU.
7. Support orphan and breakthrough tests.
8. Protect research and Research Use Only innovation.
9. Recognise hospital laboratories as strategic European infrastructure.
10. Ensure that increased regulatory flexibility remains underpinned by robust quality management systems, laboratory accountability and transparent communication of the level of clinical evidence supporting in-house diagnostics.

Conclusion

The revision of the IVDR provides a unique opportunity to modernise the European regulatory framework for precision Omics testing.

For omics technologies, innovation increasingly originates within accredited healthcare laboratories working closely with researchers, clinicians and patients. These innovations complement the commercial market by addressing unmet clinical needs in a flexible and agile manner, accelerating translation of scientific discoveries and ensuring equitable access to personalised medicine.

The rapid evolution of precision molecular testing should be accompanied by transparent communication regarding the level of clinical evidence supporting newly implemented biomarkers, algorithms or analytical approaches. While innovation should be facilitated, implementation into routine clinical care should remain evidence-based and the limitations of available evidence should be clearly communicated to clinicians and patients whenever appropriate.

The revised Article 5(5) should therefore be viewed not as a relaxation of standards, but as the establishment of a proportionate, quality-based and innovation-oriented regulatory pathway. This increased flexibility should always remain grounded in the overriding principle of patient safety. Regulatory simplification should facilitate innovation without compromising

analytical quality, clinical validity or the reliability of diagnostic information used for patient management.

Such an approach would strengthen Europe's scientific leadership, improve resilience of healthcare systems and ultimately enhance patient care while fully preserving the high level of safety that remains the cornerstone of the IVDR, as well as stimulating European competitiveness in the field of Omics technologies.

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