European Network of Expertise (NoE) on Omics

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

Contribution to the European Commission's Call for *Evidence* on the Targeted Revision of the EU Regulation on *In Vitro* Diagnostic Medical Devices

(IVDR, EU 2017/746)

Key issues and recommendations

6th October 2025

What is JANE-2?

JANE-2 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 are revolutionizing the management of patients with solid tumors, haematological malignancies, as well as rare diseases. These innovative tools go beyond supporting precision diagnosis and treatment. They also improve cancer 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 multimodal omics integration, are rapidly advancing and poised to play a significant role in the future.

The ambition of the Network of Expertise on Omics (NoE) is to support the integration of innovative omics technologies into the standard of care at the different steps of cancer management in a sound and sustainable manner, achieving equitable access to these services for all EU citizens.

Addressing unmet urgencies and barriers to In-House *in vitro* diagnostic tests (IH-IVDs) / Laboratory-Developed Tests (LDTs), under *In* Vitro Diagnostic Medical Devices Regulation (IVDR, EU 2017/746).

The IVDR aims to ensure a high level of health protection for patients and users and efficient functioning of the internal EU market. For that purpose, IVDR introduced stricter requirements for clinical evaluations, post-market surveillance, and device traceability. Specific adapted requirements have been established for in-house developed tests, manufactured and used within EU health institutions, as regulated under Article 5.5. However, some of these requirements, defined under the "in-house exemption," create obstacles for the development of new, evidence-based tests. These barriers hinder diagnostics and delay timely access to treatments, especially for rare and complex conditions, including cancers. The expertise of the health institutions should be recognized, especially in this latter area. Most medical molecular laboratories within healthcare institutions already follow established standards, such as ISO 15189:2022 for standard-of-care omics testing, to guarantee the competence, precision, and reliability of the results produced by these laboratories. We believe that the additional requirements imposed by the **IVDR, on top of the ISO 15189:2022 criteria, lead to an**

unnecessary increase in healthcare costs, reduced availability of tests, and, consequently, a longer waiting time for patients to access new tests, without a substantial safety benefit. The IVDR should not restrict hospitals from maintaining their in-house solutions where appropriate, nor should it limit their ability to share these solutions and facilitate the transfer of technology within networks as part of clinical collaborations, including cross-border. Furthermore, rather than facilitating meaningful partnerships, the IVDR creates an unbalanced power dynamic between university laboratories and private industries, disproportionately benefiting the latter.

I. KEY ASPECT: The implementation of IVDR (EU) 2017/746 introduces strict regulatory requirements for in-house developed *in vitro* diagnostic tests (IH-IVDs) / Laboratory-Developed Tests (LDTs), significantly impacting their availability, cost, and accessibility in healthcare institutions.

ISSUE 1. Addressing Redundant IVDR Compliance: Recognizing ISO 15189:2022 for Efficient Patient Care and Laboratory Validation.

Under the **"in-house exemption"** (*Article 5(5)),* hospitals, clinical laboratories, and public health institutions are permitted to develop and use their own laboratory-developed tests (LDTs) without obtaining full CE marking, provided the tests are not commercially distributed to other institutions. The regulation aims to enhance patient safety and improve the quality of tests. However, laboratories accredited under **ISO 15189:2022 standards**, which already have extensive safety and documentation requirements in place, face duplicative compliance efforts due to the IVDR's failure to explicitly recognize that ISO 15189 standards can replace some IVDR requirements. The overlap between IVDR and IH-IVD under ISO15189:2012 has been well described by the Dutch Society of Laboratories (the requirements of ISO15189:2022 are even closer to IVDR).[1,2]

This results in redundant documentation and validation requirements. Consequently, laboratories must allocate resources to meet additional IVDR obligations, potentially at the expense of test development and patient care, without evident safety benefits. Hospitals may be forced to replace established in-house testing solutions with much more expensive CE-IVD-labeled alternatives, even though the laboratory-developed tests are validated in medical laboratories fulfilling ISO 15189:2022, which includes extensive risk assessments that already ensure patient safety and test quality.

> *Recommendation 1: ISO 15189:2022 accreditation should be recognized as sufficient validation for in-house omics tests, eliminating redundant compliance steps that unnecessarily strain hospital laboratories. Only criteria not covered by the ISO15189:2022 standard, such as clinical evidence, should require additional validation. Moreover, national accreditation bodies should audit tests accredited to ISO15189, removing the need for additional audits by the national competent authorities. To further streamline compliance, regulatory flexibility should be prioritized, enabling hospitals to utilize previously validated instruments and software rather than requiring entirely new equipment for IVDR certification. This approach would alleviate administrative and financial burdens, promote timely patient care delivery, and ensure that safety and quality standards remain uncompromised.*

[1] https://www.vkgn.org/files/6619/Handvat_gebruik_LDT_IVDR_taskforce_vs1.0.pdf
[2] https://pathologie.nl/wp-content/uploads/2024/05/20231130-Versie-3_Handvat_in-huis_IVD_IVDR_taskforce.pdf

ISSUE 2. Addressing Ambiguities in IVDR for In-House Test and Cross-Country Harmonization.

The interpretation of the in-house exemption is not consistent, leading to **regulatory ambiguity** in its application. The IVDR legislation also lacks clarity on when a **CE-IVD kit transitions into being classified as an in-house test**. Modifications such as changes to nucleic acid extraction methods, incubation times, wash steps, or matrix compositions often occur. While the IVDR incorporates a risk-based classification system for IVDs (from Class A to Class D), this system primarily applies to the initial approval and conformity assessment of a device. It does not adequately address modifications made after the device is deployed, particularly within health institutions developing in-house tests. By failing to distinguish between low-risk and high-risk modifications, the regulation imposes unnecessary burdens that slow the development of new diagnostic solutions. Another example of a challenge in meeting the new standards is how to determine the amount of data needed for sufficient clinical evidence, especially for rare cancer conditions (Article 5.5, Recitals 29, 66, Annex XIII). Clearer guidelines and greater flexibility are needed to support IVD solutions for patients while maintaining safety and quality standards.

Another important concern is that **IVDR enforcement varies across EU member states**, creating **inconsistencies in compliance obligations**. Laboratories lack clear guidance on navigating IVDR requirements without unintentionally violating compliance rules. For example, in Ireland, hospitals and healthcare-focused institutions are permitted to develop in-house tests (LDTs). However, diagnostic laboratories located within institutions whose primary function is not healthcare, such as academic or research settings, private or public, are restricted from doing so. In other instances, some countries impose stricter documentation requirements than others, leading to unequal regulatory burdens and introducing **additional national requirements that go beyond IVDR**. For example, the requirements defined by the Belgian notified body for IVDR (FAMHP) demand additional documentation that induces an increased administrative workload, making compliance an even greater challenge for laboratories.[3]

Vanstapel et al. (2023) emphasize that the lack of harmonization between national authorities creates unnecessary complexity and prevents a unified EU-wide regulatory approach. Some of these national rules require extra documentation, stricter notification obligations, and additional reporting systems that are not explicitly required by IVDR but increase compliance costs for laboratories. Without evidence that these extra requirements improve patient safety, they risk imposing unjustified regulatory barriers on healthcare institutions.

> *Recommendation 2: Article 5(5) on in-house tests should not be treated as a mere "exemption" but rather as a structured, well-defined regulatory pathway, ensuring both flexibility for healthcare institutions and robust oversight without stifling diagnostic advancements.*
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> *Documentation requirements should be harmonized to ascertain that the General Safety and Performance Requirements (GSPRs) are met at the national level and preferentially across EU countries to prevent competitive disadvantages. The Medical Device Coordination Group (MDCG) could play a pivotal role in proposing and promoting harmonization and ensuring consistent use of terminology across Member States. Clear legal definitions are needed, particularly regarding IVDR implementation for hospital laboratories, such as precise*

[3] *https://www.famhp.be/en/human_use/health_products/medical_devices_and_their_accessories/health_institutions_and_healthcare (accessed 20/03/2025)*

terminology, differentiation between substantial and minor modifications, criteria for when a CE-IVD kit becomes an in-house developed test, and structured transition guidelines.

ISSUE 3. Addressing Barriers to Multi-Center Collaboration and Access to In-House Diagnostic Tests.

A major concern is *Article 5(5)(a)*, particularly the ambiguity surrounding the term "transfer". While institutions can share test results, protocols, and validation data, they are prohibited from transferring physical tests, **hindering multi-center studies, clinical research, validation efforts, and access to newly developed and validated omics tests**. Beyond the ban on LDT commercialization, some medical laboratories question whether the restriction extends to clinical research collaborations, data and knowledge sharing, or cross-institutional clinical use. According to MDCG 2023-1 guidelines, exchanging written procedures, test results, and validation data is allowed. However, the precise definition of "transfer" remains unclear and requires further clarification.[4]

Recommendation 3: Providing clarity on this issue and allowing the shared use of in-house tests could significantly lower the costs of developing omics testing while ensuring compliance with ISO 15189 and IVDR. Such regulatory flexibility would positively impact patients by enabling multi-center studies, advancing clinical research, and promoting cross-border collaborations that rely on consistent use of the same device to produce comparable results. Furthermore, multi-institutional data is critical for improving test accuracy, achieving robust clinical validation, and expanding patient access, particularly for rare cancers.

To enhance efficiency, health institutions should be encouraged to form collaborative consortia, where resources can be pooled to achieve adequate validation volumes, especially for newly developed omics tests. These consortia would ensure joint compliance with IVDR regulations while reducing individual financial and administrative burdens. Additionally, hospitals should be permitted to transfer in-house devices to other legal entities, even across borders, under specific conditions such as collaboration with other health institutions or participation in clinical studies. Adopting this approach would streamline regulatory processes, alleviate financial and administrative constraints, and foster greater efficiency in healthcare delivery.

ISSUE 4. Challenges of Imbalanced IVDR Compliance with Increased Complexity and Administrative Burden while Limited Flexibility for CE-IVDR Kits and In-House Tests.

The flexibility of in-house developed approaches offers significant benefits for patients and should enable the rapid implementation of new tests to identify and investigate new disease-related genes more efficiently. However, manufacturers developing CE-IVDR kits face stringent regulatory requirements, including the submission of formal evaluation applications. The **excessive administrative burden** imposed by IVDR adds significant challenges on top of existing procedures for Quality Management Systems (QMS) and ISO 15189:2022 compliance, **creating unnecessary obstacles that hinder innovation and timely patient access to advanced omics testing.**

The complexity and administrative burden of IVDR compliance are further amplified by the role of EUDAMED (see **Issue 7**). Although primarily designed for registering commercial CE-IVDs, EUDAMED indirectly affects IH-IVDs and hospital-based omics testing by serving as the key reference for determining the availability of equivalent CE-IVDs. Under *Article 5(5),* laboratories **must not only prove**

[4] *https://health.ec.europa.eu/document/download/05b15d55-1bcf-4e17-99c4-15c706325847_en?filename=mdcg_2023-1_en.pdf*

that no equivalent test exists before using IH-IVDs but also regularly reassess this status, relying on the completeness and efficiency of EUDAMED data. Delays or gaps in EUDAMED can complicate these assessments, increase administrative workload, and create legal uncertainty, while inefficient management of these processes risks delaying approvals and disrupting the availability of compliant tests. Collectively, **these challenges slow technological development**, **delay the implementation of innovative omics, and raise healthcare costs** without providing clear additional safety benefits.

Article 5(5)(d) adds another layer of complexity by requiring laboratories to continuously justify the use of in-house IVDs over commercial CE-IVD alternatives, by establishing proof of non-equivalency of CE-marked devices that are available or will become available in the future. This obligation compels laboratories to frequently reassess the market, even when no suitable commercial test exists. Moreover, if a medical laboratory considers that its in-house device is more suitable, these kits will need to be extensively tested, which will lead to extra financial burden (personnel, administration,…). As a result, critical resources are diverted from technological developments and patient care, while offering little proven benefit to safety, especially in scenarios where LDTs are the only viable option. Additionally, minor modifications to CE-IVDs may reclassify them as in-house IVDs, triggering full IVDR compliance and further complicating operations.

Commercial solutions are inherently less adaptable than in-house tests when it comes to aligning with field-specific international guidelines or national reimbursement constraints. While customization options exist for some commercial solutions, they may constitute a modification, requiring compliance with *Article 5(5)* and its associated costs. For instance, some kits are compatible only with specific instruments (e.g., robots or sequencing platforms) and require tailored nucleic acid extraction methods, data analysis software, and more. Transitioning to CE-IVD-labeled solutions often requires substantial financial investment for hospitals, even when similar validated equipment is already available.

> *Recommendation 4: A streamlined, risk-based framework for post-approval modifications to in-house omics test devices is crucial to address the administrative burdens highlighted. Implementing tiered regulatory requirements would help minimize unnecessary obligations for low-risk modifications while maintaining rigorous oversight for high-risk changes to safeguard safety and efficacy. Additionally, clear and actionable guidance on generating clinical evidence would improve compliance efficiency and reduce administrative complexity without compromising patient care. This balanced approach aligns with the need for regulatory flexibility in managing CE-IVDR kits and in-house tests, ensuring that healthcare institutions can prioritize technology development and implementation of new standards to improve patient care.*

II. KEY ASPECT: The implementation of IVDR introduces regulatory challenges to in-house IVD development and data sharing in hospitals: interplay between IVDR, GDPR, and CTR

The interplay between the IVDR, the General Data Protection Regulation (GDPR), and the Clinical Trial Regulation (CTR) creates significant challenges for hospitals and research institutions developing and using in-house *in-vitro* diagnostics (IH-IVDs). These regulations, while designed to ensure patient safety and data security, impose restrictions that hinder data sharing, collaboration, and the efficient development of diagnostic solutions within healthcare settings.

ISSUE 5. Complexity in Combining IVDR and GDPR Requirements.

GDPR gives very little room for where the data can "travel" and with whom it can be shared, and IVDR gives very little room for where the hardware/software can be hosted, which dramatically hinders possibilities to collaborate between institutions when it comes to medical care or developing IVD solutions. While the IVDR might serve commercial interests and product development, which is good for the EU industry, we feel that the ecosystem to support it is still not fully developed and mature.

Additionally, depending on the country and legal interpretation, GDPR imposes strict requirements on how patient data can be transferred and shared, while IVDR enforces stringent rules on the hosting and validation of software and hardware used for IH-IVDs. The combined requirements impose cumulative and compounding regulatory burdens, making it increasingly difficult for hospitals and research institutions to collaborate across borders, share clinical data, and co-develop or validate new omics tools. As a result, institutions encounter significant barriers to leveraging shared expertise and pooled resources to enhance patient care.

> *Recommendation 5: To harmonize compliance with both GDPR and IVDR, the EU should establish a binding framework for GDPR-compliant data governance. This framework should incorporate secure, pan-European cloud hosting and consortium-based models that receive joint approval under both regulations. By providing clear, standardized pathways for compliant data sharing, these measures will empower hospitals and laboratories to store and exchange data responsibly, while also advancing precision medicine through the controlled use of (gen)omics data.*

ISSUE 6. Complexity in Interplay Between IVDR and CTR (Clinical Trial Regulation).

There is a significant disconnect between the application of IVDR to clinical performance studies for IVDs and the EU Clinical Trial Regulation (EU No. 536/2014). While the Clinical Trials Information System (CTIS) has recently been implemented as a single entry point for submitting and assessing clinical trial data across EU Member States, creating a more harmonized process, IVDR still relies on country-specific evaluations for studies assessing IVD products. The electronic system outlined in *Article 69* of IVDR, which would allow a single application to be electronically submitted and assessed across all Member States, has not yet been implemented. As a result, clinical performance studies for IVDs must still be submitted separately to each national Competent Authority, leading to fragmentation, inefficiencies, and inconsistencies in regulatory assessment across the EU. This might lead to different interpretations of regulations by different national Competent Authorities across different EU countries, potentially leading to fragmented feedback regarding the same study, competitive (dis) advantages, and delays in Clinical Performance Studies implementation in the EU.

This significantly increases the administrative burden for the set-up of interventional Clinical Trials, which also assess an IVD as a companion diagnostic in the EU, as these studies now need to be compliant with both the Clinical Trial Regulation and IVDR, following two separate submission/evaluation paths, increasing the risk for potential delays and study-related costs without significantly improving patient safety. This might potentially lead to a decrease in the number of Interventional Clinical Trials assessing an IVD as a companion diagnostic conducted in the EU, thus reducing access to clinical trials for EU patients.

> *Recommendation 6: To streamline the submission process for clinical performance studies assessing IVD products across the EU, a centralized, single-entry system for IVDR applications*

and interventional clinical trials involving IVD companions should be mandated. Currently, the lack of a unified submission platform leads to duplicative regulatory reviews, where each Member State independently evaluates the same study, causing delays, inefficiencies, and inconsistencies in regulatory decisions. A harmonized EU-wide system, similar to the Clinical Trials Information System (CTIS) for pharmaceuticals, would eliminate redundant submissions, accelerate approval timelines, and enhance regulatory alignment across Member States. Furthermore, clear and consistent EU-wide guidelines for interpreting IVDR requirements are essential to reduce regulatory uncertainties. The current variation in national interpretations of IVDR leads to inconsistent documentation requirements and competitive disparities between countries. Standardized submission and evaluation criteria, along with a dedicated EU regulatory body or task force to oversee implementation, would help ensure uniformity, improve regulatory predictability, and facilitate clinical development in diagnostic testing while maintaining patient safety and compliance.

III. KEY ASPECT: Structural challenges in IVDR implementation and Notified Body capacity

ISSUE 7: Insufficient Number of Notified Bodies.

One of the main changes introduced with the IVDR is to increase the involvement of independent conformity assessment bodies (‘notified bodies'). However, the **severe shortage of notified bodies is causing significant delays** in conformity assessments, disrupting the availability of essential omics IVD devices. The demand for certifications far exceeds the capacity of existing notified bodies, creating bottlenecks, particularly as the number of devices requiring review continues to grow. This shortage slows down market access for critical IVD products, impacting healthcare providers and patients who rely on timely and accurate testing.

In addition to capacity issues, stakeholders face delays and inconsistencies in implementation due to a lack of preparedness and external disruptions, such as the COVID-19 pandemic and geopolitical conflicts. These factors have further strained the regulatory system, complicating the timely and efficient adoption of IVDR requirements.

The extension of the transition period is seen as a temporary solution that postpones rather than resolves the underlying structural challenges. While it reduces the immediate risk of omics testing shortages, it also delays the full adoption of IVDR’s stricter requirements, leaving regulatory uncertainties and system inefficiencies unaddressed. Without long-term solutions, such as expanding notified body capacity and improving regulatory coordination, the same challenges will persist once the transition period ends.

Another critical issue is the transition from national databases to the EUDAMED system. Although designed as a gradual and coordinated process, this shift risks becoming operationally problematic if not adequately supported by financial and technical investments. Without sufficient resources, integration between national systems and EUDAMED could lead to inconsistencies, delays, and disruptions in regulatory oversight, further complicating compliance efforts across the EU.

EUDAMED is primarily dedicated to commercial CE-IVDs, but it indirectly affects IH-IVDs and hospital-based omics testing. Hospitals must prove no equivalent CE-IVD exists before using IH-IVDs, and EUDAMED centralizes CE-IVD registrations, making it a key reference. Delays or inefficiencies in

EUDAMED could complicate market availability assessments, creating legal uncertainty for IH-IVDs. While not directly required to register, hospital labs may still rely on EUDAMED for compliance with IVDR *Article 5(5).*

> *Recommendation 7: The number of notified bodies should be increased to improve conformity assessments and avoid delays. We strongly advocate for strategic EU investments and the establishment of public-private partnerships to enhance their capacity and expertise. By securing targeted funding and fostering collaboration, these bodies can be strengthened to meet growing regulatory demands, particularly in rapidly advancing fields such as healthcare and precision medicine. This approach will ensure efficient, high-quality regulatory support for clinical development and assessments.*
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> *Additionally, transitional periods should be extended to provide producers with sufficient time to comply with regulatory requirements. To facilitate a smoother transition and prevent last-minute bottlenecks, clearly defined incremental checkpoints or milestones should be introduced within the extended timeline. These milestones would encourage early compliance, support gradual adaptation, and promote a structured approach to meeting regulatory obligations. By combining an extended transition period with phased compliance, stakeholders can benefit from a more efficient, predictable, and well-coordinated regulatory process.*

CONCLUDING REMARKS

The Joint Action JANE-2 welcomes the European Commission's call for Evidence for targeted revision of the IVDR (EU 2017/746) and appreciates the opportunity to contribute insights from the European Network of Expertise on Omics Technologies.

This paper reflects the position of the European Network of Expertise on Omics (as part of the JANE2 initiative, WP9) based on the experience of the partners of this consortium. It recognizes the flexibility of in-house developed approaches that offer significant patient benefits, enabling the rapid implementation of new tests to identify and investigate new disease-related genes more efficiently.

However, the consortium has highlighted several key barriers within the IVDR framework, including excessive administrative burdens on in-house tests, limited flexibility in test modifications, insufficient coordination with GDPR and Clinical Trial regulations, restricted collaboration between hospital laboratories, a shortage of notified bodies, and last but not least, the lack of a harmonized EU-wide application system for IVD performance studies. These issues impact technological developments, delay the implementation of new standards, increase financial pressure on healthcare institutions without improving patient safety, and induce regulatory inconsistencies across Member States.

To address these concerns, we propose a series of targeted regulatory adjustments to reduce administrative burdens while maintaining high safety and quality standards. **Among the key recommendations to create a more balanced and efficient regulatory environment that prioritizes compliance and operational effectiveness are:**

1. **Redefining Article 5.5 as a structured regulatory pathway rather than an exemption,**
2. **Recognizing ISO 15189:2022 accreditation for in-house omics tests,**
3. **Enabling controlled data-sharing frameworks compliant with GDPR,**
4. **Expanding the notified body capacity,** and
5. **Harmonizing submission processes for IVD performance studies.**

Without immediate action, **the current IVDR framework risks limiting accessibility to newly evidence-based omics technologies, increasing healthcare costs, and stifling European leadership in precision cancer medicine**. We urge the European Commission and MDCG to prioritize regulatory flexibility, ensure to facilitate the harmonization across Member States, and establish clear guidance that supports both high-quality and innovative omics testing with patient safety.

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Key Message:

JANE-2, uniting 121 institutions from 29 countries is the unique initiative of Europe Beating Cancer Plan that aims to establish 7 new European Networks of Expertise (NoE). The ambition of the NOE on Omics technologies is to support the integration of innovative omics technologies into the standard of care at the different steps of cancer management in a sound and sustainable manner, achieving equitable access for all EU citizens. However, it requires a structured regulatory framework that ensures quality, and safety while allowing flexibility.

The current IVDR (EU 2017/746) presents major challenges for in-house developed tests (IH-IVDs), which are critical for precision cancer medicine.

1. *Avoid Redundant Compliance by Recognizing ISO 15189:2022. Laboratories accredited under ISO 15189:2022 already meet rigorous safety and quality standards. IVDR does not formally recognize this, causing duplicative documentation and validation. Recognizing ISO 15189 accreditation as sufficient for in-house tests would remove unnecessary administrative burden, allowing laboratories to focus resources on innovation and patient care.*
2. *Clarify IVDR Provisions and Harmonize Implementation Across the EU. Ambiguities in applying the "in-house exemption" and inconsistent national interpretations create legal uncertainty and unequal regulatory burdens. Clear EU-wide definitions, harmonized documentation requirements, and structured transition guidelines are essential to ensure fair competition, facilitate compliance, and maintain high safety standards.*
3. *Facilitate Multi-Center Collaboration and Access to In-House Tests. The unclear definition of "transfer" under Article 5(5)(a) restricts collaboration between hospitals, hindering multi-center studies and clinical validation. Regulatory clarity should enable the controlled sharing of in-house tests among institutions, supporting research, reducing costs, and improving access to diagnostics, particularly for rare conditions.*
4. *Implement a Risk-Based, Streamlined Approach to Reduce Administrative Burden. IVDR imposes extensive, often disproportionate administrative obligations for both CE-IVDs and in-house tests, slowing innovation. A tiered, risk-based regulatory framework for post-approval modifications and clearer guidance on clinical evidence generation would reduce unnecessary burdens while maintaining safety and quality.*
5. *Harmonize GDPR and IVDR to Enable Secure Data Sharing. Overlapping restrictions between IVDR and GDPR on data hosting and transfer hinder cross-border collaboration. A pan-European GDPR-compliant data governance framework, including secure cloud solutions and consortium models, would enable responsible data sharing, supporting precision medicine and diagnostic innovation.*
6. *Integrate IVDR with the EU Clinical Trial Regulation. Separate, fragmented submission processes for IVD performance studies and clinical trials create inefficiencies. A single, centralized EU platform, mirroring CTIS for pharmaceuticals, should be established to harmonize IVDR submissions, reduce delays, and ensure consistent regulatory decisions across Member States.*
7. *Address Structural Bottlenecks: Expand Notified Body Capacity and Strengthen EUDAMED Implementation. The shortage of notified bodies and delays in EUDAMED deployment threaten timely market access for diagnostics. Strategic EU investment, public–private partnerships, phased transitional milestones, and increased notified body capacity are critical to avoid bottlenecks, ensure regulatory readiness, and support continuous diagnostic innovation.*

To address this, the EU should expand notified body capacity through public-private partnerships and structured training programs. Additionally, the transition to EUDAMED presents further challenges if not adequately resourced (e.g., establishing proof of non-equivalency for CE-marked devices). IVDR transitional periods should therefore include phased implementation checkpoints to mitigate regulatory bottlenecks. Addressing these issues that the European JANE2-network of expertise on Omics technologies raises is needed to prevent regulatory obstacles from restricting essential patient care and medical innovation in Europe. A position paper is attached, outlining key issues as well as recommendations to address these challenges.