European Network of Expertise (NoE) on Omics

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

Contribution to European Commission Call for Evidence on the Digital Omnibus (part of the Digital Package on Simplification)

Key issues and recommendations

14 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 cancers, 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 multi-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.

Feedback from the JANE2 Network of Expertise on Omics Technologies

The JANE2 Network of Expertise on Omics Technologies welcomes the European Commission's Digital Omnibus initiative as a timely and essential effort to streamline the EU's digital rulebook. The use of omics technologies, including genomics, transcriptomics, proteomics, metabolomics, and multimodal integrative omics, depends fundamentally on cross-border data flows, interoperable digital infrastructures, and the responsible application of Generative Artificial Intelligence (GenAI). Moreover, it is essential that AI systems employed in this context undergo rigorous clinical validation and demonstrate clinical utility, safety, security, and health economic value to ensure their responsible and effective integration into healthcare and research ecosystems. In cancer care, including precision oncology, innovations in omics follow a complex pathway: from idea generation and early discovery through clinical research and validation to implementation as standards of care within healthcare systems. At every stage, regulatory fragmentation, legal uncertainty, national and regional regulations, and administrative complexity create barriers that slow innovation and weaken Europe's competitiveness. Simplification and harmonization are therefore not only critical but essential, as they require the careful and proportionate allocation of time and resources to establish clear, justified, and robust safeguards, safeguards that maintain ethical standards, patient trust, and fundamental rights to

trustworthy care, and that remain consistent over time regardless of differing interpretations or national contexts.

A central difficulty for the omics field lies in the fragmentation of data legislation. Large-scale datasets must be shared across borders for meaningful analysis and clinical translation, yet current rules under the Data Governance Act, the Free Flow of Non-Personal Data Regulation, the Open Data Directive, and their interplay with GDPR remain complex and sometimes contradictory. Smaller actors such as SMEs, start-ups, and academic consortia are disproportionately burdened, often lacking the capacity to navigate this regulatory labyrinth. The result is a "cliff edge" effect, where only large organizations can realistically comply, leaving innovative but resource-constrained projects at risk of omission.

Equally important are the ethical, legal, and social implications of omics research. Simplification should never be equated with deregulation. On the contrary, there is an urgent need for harmonized, clear rules on data subjects' rights, particularly in relation to consent, secondary use of data, and data portability. Omics projects frequently rely on dynamic consent models, federated data access, and cross-border clinical collaborations. Without a clear legal framework that supports these practices while ensuring patient protection, trust in omics-driven healthcare innovations will be undermined.

Artificial Intelligence (AI) adds a further dimension to this complexity. The application of AI-based tools enables addressing complex issues regarding omics technologies, such as processing, analysis, and interpretation of omics data, as well as integrating multiple omics sources and health data. They also enable significant advancements in biomarker identification, patient stratification, and novel targeted drug discovery. The AI Act provides an important framework, but its application to healthcare research and medical validation studies remains ambiguous. Greater clarity is needed on how the Act applies to algorithms developed in research environments but later validated for clinical use. Regulatory sandboxes, streamlined certification pathways, and consistent guidance across Member States will be critical to avoid delays in the safe deployment of omics-based AI tools.

Cybersecurity rules also play a decisive role. Omics infrastructures such as biobanks, federated data platforms, and cross-border data spaces are subject to overlapping reporting obligations under GDPR, NIS2, and sectoral health regulations. This duplication increases administrative costs without meaningfully improving security outcomes. A harmonized "report once" approach, with secure coordination among competent authorities, would improve efficiency, reduce burden, and strengthen resilience in practice.

Finally, the successful implementation of omics innovations into healthcare systems requires legal certainty across the Union. Divergent national interpretations of EU digital and health legislation create inefficiencies, leading to unequal patient access to validated omics tools and to fragmented innovation landscapes. Alignment with the European Health Data Space (EHDS) is essential to guarantee interoperability, trust, and consistency in how data-driven healthcare is rolled out in practice.

The JANE2 experts also wish to underline the importance of considering the interplay between the Digital Omnibus and existing sectoral regulations, especially the *In Vitro* Diagnostic Regulation (IVDR)[1], the Medical Device Regulation (MDR), and the Artificial Intelligence Act. Omics technologies often operate at the intersection of these frameworks, for example when an AI-based omics platform is

[1] *Feedback from: The European Network of Expertise on Omics (21/03/2025 JANE2 response to EU rules on medical devices and in vitro diagnostics – targeted evaluation)*

developed as part of a diagnostic tool or integrated into a clinical decision-support system. Regulatory overlap and lack of coherence risk creating delays, additional costs, and barriers to patient access. Simplification measures should therefore ensure that compliance pathways across these interconnected regulatory regimes are coherent, predictable, and proportionate. Only through such alignment can Europe fully enable the safe, ethical, and effective integration of omics into research, clinical validation, and healthcare delivery.

Our recommendation is that simplification must never be an end in itself. It must translate into tangible, measurable outcomes: cutting delays, freeing resources, and creating faster, fairer, and more consistent pathways for healthcare innovation to reach patients. True simplification should deliver *real-world* impact, ensuring that regulatory clarity and proportionality drive trust, efficiency, and equitable access across all systems and countries. The JANE2 Network of Expertise on Omics strongly advocates for the creation of a one-stop shop mechanism for dossier submissions and compliance guidance within the health sector. At present, developers and researchers in omics must navigate a fragmented landscape of digital, health, and cross-sectoral laws, each requiring separate interpretations and procedures. This patchwork often leads to inconsistent national transpositions, additional requirements not foreseen at the EU level, and unnecessary delays in bringing innovations to patients. A dedicated, sector-specific interface, integrating the obligations under the Digital Omnibus, GDPR, the European Health Data Space, IVDR, MDR, and the AI Act, would provide clarity, predictability, and efficiency. By allowing stakeholders to engage with a single regulatory access point, the EU could both reduce administrative burden and avoid the risk of divergent or excessive national requirements. Such a mechanism would not only safeguard patients through coherent and proportionate oversight but also accelerate the safe adoption of omics technologies into healthcare systems across Europe.

CONCLUDING REMARKS

The JANE2 network recommends that the Digital Omnibus and forthcoming Digital Fitness Check not only reduce burdens but also institutionalize adaptiveness, harmonization, stakeholder inclusion, and ethical safeguards.

For omics technologies in cancer care, from idea generation, through clinical research and validation, to implementation as standards of care, this approach is essential to ensure:

- Legal certainty for innovators and clinicians, harmonized approach across Member States
- Cross-border interoperability for re-use of data, research and trials, paramount for innovation
- Patient trust and ethical robustness, and
- Global competitiveness of EU innovation in precision medicine, aiming public health benefits.

Only through such adaptive, harmonized, and ethically grounded digital laws can Europe achieve responsible and efficient uptake of omics in clinical cancer care.

The JANE2 Omics Technologies experts fully support the Commission's initiative and stand ready to contribute to the improvement and alignment of legal framework simplification in the healthcare sector, ensuring that patient safety, robust data protection, and the ethical use of health information remain at the heart of all developments.

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REFERENCES

JANE2 General:

1. ***Casali, P.G., H.Antoine-Poirel et al.*** *Health networking on cancer in the European Union: a 'green paper' by the EU Joint Action on Networks of Expertise (JANE) ESMO Open, Volume 10, Issue 2, 104126*

Incidental and Secondary Findings, Consent, ELSI

2. *Thorogood, A., B. Dalpé, et al. Return of individual genomic research results: are laws and policies keeping step? European Journal of Human Genetics, 2019; 27:535–546. PMID: 30980056.*
3. *Vears, D.F., M. Niemiec, et al. A practical checklist for return of results from genomic research in the European context. European Journal of Human Genetics, 2023; 31: 1461–1470.*
4. *Van El, C.G., W. Cornel, et al. Towards a European consensus for reporting incidental findings during genome diagnostics. European Journal of Human Genetics, 2016; 24(6): 739–745.*
5. *Kalia, S.S., B.S. Adelman, et al. Recommendations for reporting of secondary findings in clinical exome and genome sequencing (ACMG SF v3.2). Genetics in Medicine, 2023; 25(7): 1227–1237.*
6. *Ellard, H. et al. What does a consent conversation for whole genome sequencing look like? Experience from the NHS Genomic Medicine Service. European Journal of Human Genetics, 2024; 32: 1095–1103.*
7. *Cornelis, C. et al. Unsolicited findings in pediatric genomic testing: views on consent and return of results. European Journal of Human Genetics, 2023; 31: 1537–1546.*

AI Act and Digital Health

8. *Aboy, M., R. Liddell, et al. Navigating the EU AI Act: implications for regulated digital health and care technologies. NPJ Digital Medicine, 2024; 7(1): 157.*
9. *Gilbert, S. The EU passes the AI Act and its implications for digital medicine are unclear. npj Digit. Med. 7, 135 (2024).*
10. *C Novelli, P Hacker, J Morley, J Trondal, and L Floridi, A Robust Governance for the AI Act: AI Office, AI Board, Scientific Panel, and National Authorities. European Journal of Risk Regulation.*

Data Governance and GDPR

10. Niemiec E, Minssen T, Boland PA, McEntee PD, Cahill RA. Legal and regulatory challenges in multi-country data-driven projects developing and validating medical AI systems in the EU. Expert Rev Med Devices. 2025 Sep;22(9):925-937. Epub 2025 Jul 16. PMID: 40623156.

11. European Parliament. The impact of the General Data Protection Regulation (GDPR) on artificial intelligence. STOA Study, 2020; PE 641.530.

12. Toma M, Bönisch C, Löhnhardt B, Kelm M, Bohnenberger H, Winkelmann S, Ströbel P, Kesztyüs T. Research collaboration data platform ensuring general data protection. Sci Rep. 2024 May 24;14(1):11887. doi: 10.1038/s41598-024-61912-8.

Patient Perspectives & Ethical Values

13. Saelaert M, Mertes H, Moerenhout T, De Baere E, Devisch I. Ethical values supporting the disclosure of incidental and secondary findings in clinical genomic testing: a qualitative study. BMC Med Ethics. 2020 Jan 30;21(1):9.

14. Sanderson, Saskia C. et al. Decision-making, attitudes, and understanding among patients and relatives invited to undergo genome sequencing in the 100,000 Genomes Project: A multisite survey study Genetics in Medicine, Volume 24, Issue 1, 61 – 74.

EU Frameworks

15. Regulation (EU) 2022/868. Data Governance Act. Official Journal of the European Union, 3 June 2022.
16. Regulation (EU) 2025/327. European Health Data Space. Official Journal of the European Union, 14 January 2025.

Summary EU Portal Submission: JANE-2 Network of Expertise on Omics Technologies

JANE-2, part of Europe's Beating Cancer Plan, unites 121 partners across 29 countries to advance seven European Networks of Expertise in cancer care, including a dedicated Network on Omics Technologies. This Network aims to integrate cutting-edge omics tools into routine cancer care to achieve equitable access for all EU citizens.

Omics technologies, such as genomics, transcriptomics, proteomics, metabolomics, and multi-omics, are transforming cancer diagnosis, prevention, and treatment. However, their success depends on cross-border data sharing, interoperable digital infrastructures, and the responsible use of AI. Today, fragmented and overlapping EU regulations (GDPR, EHDS, IVDR, MDR, AI Act, NIS2, and others) create unnecessary barriers, delays, and costs, particularly for SMEs and academic innovators.

The JANE-2 Network welcomes the Digital Omnibus initiative but stresses that simplification must not mean deregulation. Instead, it must deliver real-world impact: cutting delays, freeing resources, and enabling faster, fairer, and safer access to omics-driven healthcare innovations.

The Network calls for a coherent, predictable, and proportionate regulatory environment, ensuring consistency across Member States and sustained trust in patient data protection.

Key Recommendation: Create a one-stop-shop mechanism for regulatory submissions and compliance in the health sector. This single EU interface, integrating the Digital Omnibus, GDPR, EHDS, IVDR, MDR, and AI Act, would reduce fragmentation, avoid duplicate requirements, and accelerate the safe integration of omics technologies into European healthcare.

In essence: Simplification must never be an end in itself. It must translate into tangible results that improve efficiency, safeguard patients, and strengthen Europe's leadership in innovative, trustworthy, and equitable cancer care.