European Commission's Call for Evidence on the European Data Union Strategy

Response of the 2nd Joint Action on Networks of Expertise on Cancer (JANE-2)

On behalf of the 2nd Joint Action on Networks of Expertise on Cancer (JANE-2), we welcome the European Commission's Call for Evidence on the European Data Union Strategy. This response has incorporated the inputs of JANE-2's partners and is a true reflection of at least 22 Member States' perspectives.

The Letta Report underscores the urgent need to foster the development of translational networks across Member States. It notes that *"national markets […] now represent a major brake to growth and innovation in sectors where global competition and strategic considerations call for swiftly moving to a European scale."* [1] While this observation is not made explicitly in the context of health - recognizing that health remains a national competence - it nevertheless carries significant relevance for the field.

JANE-2 is in the process of establishing 7 transnational and cross-cutting Networks of Expertise on cancer. These networks are designed to be integrated into national health systems following the conclusion of the Joint Action, thereby enhancing coordination and knowledge-sharing across borders. They will become operational post the end of the Joint Action (end of 2028).

The European Strategy for Data (2020) led to the creation of data spaces, such as the European Health Data Space (EHDS). It also paved the way for legislative measures that aimed to create a "single market for data that will ensure Europe's global competitiveness and data sovereignty."[2] One of its aims was to also improve healthcare. However, as the challenges faced by scientific community concerning the General Data Protection Regulation (GDPR) focused on its interpretation by Member States, it becomes imperative that any forthcoming EU strategy on a Data Union – strongly takes into account the needs of the scientific community and backs up the strategy with a concrete and detailed implementation plan. It should also ensure user-friendly and useful solutions, as well as leverage experiences gained in various EU projects on simplifications, including technical solutions to reduce administrative burdens.

While health is a national competence, with the way diseases are evolving, increasing in complexity and transcending borders – it becomes important to establish ways in which secondary use of health data can be safely collected and used at supranational level (outside the area of serious cross-border threats and other exceptions) – including for example, via EU health networks.

The sustainability of transnational EU health networks such as the JANE-2 NoEs will depend on whether the future European Data Union Strategy enables the development of federated, interoperable, and multimodal data infrastructures that support longitudinal research and care pathways for at-risk populations.

What is JANE-2? JANE-2 is an ambitious Joint Action, stemming from Europe's Beating Cancer Plan with the aim to create seven new Networks of Expertise in the area of oncology focusing on: 1) complex and poor prognosis cancers; 2) palliative care; 3) survivorship; 4) personalised primary and secondary cancer prevention; 5) omics technologies; 6) hi-tech medical resources; 7) adolescents and young adults with cancer.

Who is involved? JANE-2 represents 121 partners (national representatives and competent authorities) from 29 European countries.

Duration of JANE-2: 4 years (November 01, 2024 – October 31, 2028).

[1] Letta, Enrico. 2024. "Much More than a Market" (Letta Report). Available here https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf
[2] A European Strategy for Data. Available here : https://digital-strategy.ec.europa.eu/en/policies/strategy-data

What are EU Health Networks: Health networks may be defined as networks involving a form of regular collaboration, at a distance, amongst healthcare professionals focusing on items pertaining to the mission of the network. To date, health networking at the EU level has only been attempted via the Cross-Border Healthcare Directive, through the creation of European Reference Networks (ERNs) focusing on rare diseases and rare cancers. Building on the ERN model, the 2nd Joint Action on Networks of Expertise (JANE-2) will be shaping seven new transversal health networks in oncology, that will transform the way cancer care will be delivered at EU level. These Networks of Expertise (NoE) will be the first of their kind as they will focus on transversal aspects of the disease (as opposed to the ERNs that were focusing on a specific disease). In addition to JANE-2, a parallel Joint Action is working towards the creation of a European Network of Comprehensive Cancer Centres (CCCs) that will aim to ensure timely and qualitative care provision to cancer patients – the Joint Action EUnetCCC.

EU Health Networks – Networks of Expertise on Cancer – Services: Upon the conclusion of JANE-2 (end of 2028), the 7 Networks of Expertise on cancer will aim to provide the following services at national level:

- Guidelines/recommendations
- Advocacy/policy/awareness
- Healthcare organizational models
- Education (professionals, patients)
- Research promotion
- Quality criteria
- Patient and public engagement

Data stemming from EU Health Networks:

Health networks represent a significant opportunity for advancing research (outcome-based, artificial intelligence-based real-world research, clinical trials as well as patient-reported experience measures). Additionally, EU health networks will also provide a new interface that connects health care and research. The data generated through this emerging interface remains largely unexplored within the European Union (EU) context. However, with the development of EU health networks, the potential of using data stemming from health networks may become a reality, post-2028.

At EU level, funding has been invested in numerous projects and Joint Actions, including projects under the helm of Europe's Beating Cancer Plan as well as Horizon Europe's EU Cancer Mission (and other programmes), that focus on collecting and extracting data for scientific research purposes. Projects such as IDEA4RC (an Intelligent Data Ecosystem for Rare Cancers), the federated hub proposed by the Coordination and Support Action, UNCAN.eu (UNderstanding CANcer), ECHoS (Establishing of Cancer Mission Hubs: Networks and Synergies), and of course the potential data stemming from the forthcoming EU health networks, or via the interface of health care and research, among others, indicate EU's support in this area. The European Health Data Space (EHDS) will indeed try to streamline many of the challenges foreseen by the community, however the EHDS itself is uncharted territory.

Challenges foreseen by the oncology community - to be taken into consideration for the proposed new European Data Union Strategy:

1. **Fragmentation of interpretation of GDPR:** The fragmented interpretations of the GDPR across Member States, have led to huge impediments for scientific research across the European Union, and at country level. For example, the varied interpretations of GDPR recitals 33 and 157, that were meant to safeguard health research with respect to the secondary or ancillary use of data, have resulted in serious concerns from the scientific community.[3] The lack of a harmonized interpretation has already resulted in a direct impact impeding health research, specifically concerning observational (retrospective and prospective) research and biobanking, as well as from data

[3] Casali, P, Vyas, M. 2021. Data protection and research in the European Union: A major step forward. *Annals of Oncology.* https://doi.org/10.1016/j.annonc.2020.10.472

stemming from population-based disease registries. This example should serve as a note of caution for the proposed European Data Union Strategy.

> ***Recommendation 1:*** *The European Data Union Strategy needs to consider a revision of the rules of GDPR specific to the health research community, to:*
>
> *i. Harmonize the interpretations linked to health research, specifically concerning the secondary or ancillary use of data.*
> *ii. Provide a clear interpretation of the requirements of consent as a legal basis to support the use of personal data for research purposes (e.g., for personalized medicine, AI model development, public health purposes among others).*
> *iii. Provide technical solutions to reduce administrative burdens based on experiences gained in various EU projects on simplifications.*
> *iv. Recognize that personal data can be lawfully processed for research purposes, under specific conditions such as: (i) provided a Data Protection Impact Assessment (DPIA) has been performed and the identified risks addressed, or (ii) when the related data processing activities have been certified under Art. 42 GDPR, or (iii) when authorized by the Supervisory Authority of the project coordinator.*
> *v. Clarify the conditions to ensure privacy and data access as well as include mechanisms to foster public trust in the use of data for research purposes (e.g., transparent governance structures and patient representation in decision-making processes, etc.).*
>
> ***Recommendation 2:*** *The European Data Union Strategy should provide clear guidance on pending matters, including the notions of anonymization and pseudonymization, dynamic consent, opt-out applications, to harmonize interpretations across the Member States, including a concept of risk minimization instead of zero-risk adapted to the data 'sensitivity'.*

2. **Artificial intelligence (AI) and innovation**: Artificial intelligence is increasingly being leveraged in scientific research, particularly in the field of oncology. Cancer hospitals now generate vast amounts of electronic health data - often referred to as "real-world data" - which AI systems can analyse in novel and impactful ways. Key areas such as personalized medicine, omics technologies, and advanced medical tools (hi-tech medical resources) are likely to experience the most significant transformation. It can also support other areas such as personalized prevention (including collection of data from wearables, lifestyle apps, personal devices, globally so called Internet of Things (IoT) etc.), personalized survivorship plans among others. Additionally, areas such as clinical guidelines, training, medical reporting, among others, may also be assisted. These are the areas that will also be addressed by the 7 Networks of Expertise on cancer – via services they will provide the community. As this field rapidly evolves, it is essential to establish harmonized regulations that, while protecting patient data, will also enable innovation in healthcare. Additionally, while the recently adopted Artificial Intelligence Act (AI Act) is a landmark achievement for the European Union, its implementation presents challenges for the scientific community (in spite of there being exemptions for scientific research).

> ***Recommendation 3****: The European Data Union Strategy needs to:*
> *i. Ensure secure, tiered access to different types of data (from raw annotated data to harmonized structured datasets such as genomic data, imaging data etc) for AI training, to stakeholders, including industry, to support health research purposes as well as clinical applications. AI models should be endorsed with proof of robustness, should be certifiable, explainable and collaborative with fair accessibility. Frugal AI should be promoted.*
> *ii. Propose initiatives focusing on training for stakeholders regarding the integration of AI into clinical care, particularly for healthcare professionals.*

iii. *Recognize the distinct regulatory needs of machine-learning (ML)-based AI and large language model (LLM)-based generative AI. It should also ensure tiered access frameworks that distinguish between data use cases – e.g., for deterministic ML training vs adaptive generative AI development.*
iv. *Address the inclusion of health data stemming from wearables, lifestyle apps and personal devices. These data sources capture behavioural and environmental exposures essential for prevention, yet they pose distinct challenges in terms of interoperability, consent, and governance. The Strategy should further promote multisectoral data integration frameworks that combine health, genomic, behavioural, and contextual data under harmonized, privacy-respecting standards.*

Recommendation 4: *The European Data Union Strategy should propose initiatives that aim to address the regulatory and operational challenges posed by the application of Regulation (EU) 2024/1689 (Artificial Intelligence Act) – including:*

i. *High-risk classification burden: Medical AI systems are currently subject to strict technical, legal, and human oversight requirements, which increases costs and hinders innovation.*
ii. *Regulatory overlap: The coexistence of AI Act with MDR (Medical Device Regulation), GDPR and EHDS creates legal complexity and duplicative compliance efforts.*
iii. *Data access and quality constraints: Access to high-quality, bias-free (such as ethnic, gender, socioeconomic background, age or rural populations), representative health data required by the AI Act is hampered by fragmentation, privacy rules, and national restrictions.*
iv. *Prohibited or restricted use cases: Use cases such as emotional recognition or biometric categorization are banned or heavily restricted, limiting innovation in personalized or behavioural health.*
v. *Mandatory human oversight: Clinical decisions cannot be made solely by AI, limiting autonomous applications in areas like remote care or emergency triage.*

3. **Interoperability and standardization – reducing fragmentation**: The growing fragmentation of data governance due to overlapping legislative frameworks (GDPR, EHDS, Data Act, AI Act, Network and Information Security 2 Directive (NIS2), etc.) complicates cross-sectoral innovations, especially those requiring data from multiple domains. Furthermore, data sources such as Electronic Health Records (EHRs) contain structured and unstructured data, and are very heterogeneous also in terms of format across and within Member States. They are written in different EU languages, and the quality of their data is highly variable. Finally, different standards and data models are currently available for ensuring data standardization. Thus, there is a need to ensure interoperability and standardization across data providers, especially in the context of secondary or ancillary use of data for research purposes.

Recommendation 5*: The European Data Union Strategy should:*

i. *Foster interoperability and standardization of health data at the data source, and be aligned with the EHDS, GDPR, AI Act, Data Act, AI Act, NIS2 and any other legislations affecting this area.*
ii. *Propose solutions to coordinate and harmonize cross-domain data use, with particular attention to interdisciplinary research and AI development. Conceptual disease-specific models leveraging the cancer experience can be a pilot project that would contribute to the development of multilingual natural language processing (NLP).*

***Recommendation 6**: The European Data Union Strategy should use European health networks (such as the upcoming Networks of Expertise on cancer) as a use case to foster interoperability and improve data quality of data providers.*

4. **Data security and trust:** Data security and trust are cornerstones for health research. However, traditional perimeter-based security is not enough in the modern IT landscape. Even within the scope of the EHDS, there is no clear suggestion regarding which privacy-preserving solution should be used across the EU to provide appropriate safeguards for health data. Additionally, complying with different security requirements stated in the GDPR, EHDS, and NIS2 entails an increase in cost and expertise that are generally not available at hospitals. Additionally, there is also a need for clinician-friendly tools and data literacy.

***Recommendation 7**: The European Data Union Strategy should:*

i. Support the zero-trust model and federated learning as privacy preserving solutions identifying the proper safeguards to be in place.

ii. Support the development of interoperable, secure, intuitive platforms that simplify data use for healthcare professionals and should also promote training to help them navigate regulatory requirements and apply data-driven insights in practice.

5. **Data access:** Data access is a challenging issue for the research community due to: lengthy, heterogeneous and complex approval processes; different governance restrictions to data access; lack of interoperability/collaborations across data access applications. Currently, in most countries of the EU, it takes around 2-3 years to manoeuvre the administrative issues from the time of making the request to getting access to the data in an international multicentred study/project. It is also difficult to understand which is the organization/institution responsible to grant data access.

In the field of omics technologies, there is a strong emphasis on sharing of anonymized omics data, such as proteomics and metabolomics where the focus is on open sharing of data, in publicly accessible repositories (e.g., PRIDE (PRoteomics IDEntifications Database) and MetaboLights (Metabolomics Data Repository)).

Lastly, an area that is currently underrepresented in large-scale datasets is data stemming from patient-reported outcomes (PROs) including quality of life and symptom burden. These are essential components of health data and are crucial for ensuring person-centred care, particularly in the context of advanced disease and palliative care. EU projects such as EUonQoL: Quality of Life in Oncology, may provide insights regarding the future role of quality of life data in European health systems and underline the need to build infrastructures capable of routinely capturing and using PROs across care settings.

***Recommendation 8:** The European Data Union Strategy should:*

i. Promote tools to simplify the administrative burden leveraging on current experience from existing EU projects and initiatives.

ii. Aim to simplify contractual mechanisms for researchers under the GDPR, for instance, by recognizing the possibility of using unilateral commitment tools to comply with contractual obligations under Art. 28 and 46 of the GDPR while addressing the needs of research activities (such a tool has already been developed and proposed by the European Centre for Certification and Privacy precisely for this purpose).

***Recommendation 9**: The European Data Union Strategy should design and implement specific initiatives aligned with the Horizon Europe Strategic Pillar focused on supporting SMEs and researchers by driving initiatives related to open data, regulatory sandboxes, and funding opportunities for both the private and public sector (focusing on healthcare).*

***Recommendation 10**: The European Data Union Strategy should involve patient organizations/advocacy groups/citizens in finding solutions on how to simplify access of patient data for research purposes.*

6. **European Health Data Space**: The European Health Data Space is an incredible achievement of the European Union – the first common EU data space dedicated to health. Its aim is to create a secure, unified framework for the use and exchange of electronic health data across the EU. The legislation (the EHDS Regulation) entered into force this year, in March 2025, and we now have 6 years to create a strong common health data space that will give people control over their health data across borders, support secure data reuse for research and innovation, and create a unified market for electronic health records. In spite of it being an incredibly forward legislation that aims to improve the exchange of electronic health data at EU level, we are also aware of the challenges this poses. This data space represents new ground for the EU and it will also have to comply with the other existing legislations that impact the use of health data – for example – GDPR, Data Act, Data Governance Act, NIS2. Since a dedicated space for the exchange of electronic health data already exists at the EU level, the new European Data Union Strategy should adopt this space as the foundation for all health data initiatives and prioritize efforts that enhance and build upon this shared framework.

***Recommendation 11**: The European Data Union Strategy should use the EHDS as the framework for all initiatives tackling health data, and focus on developing initiatives that complement and strengthen this common data space.*

7. **Futureproofing of data stemming from EU health networks:** EU Health networks present a promising avenue for research, including the AI-based ones. To truly foster innovation and the exchange of knowledge, health care and research must synergize in ways that transcend conventional frameworks, creating a dynamic, entrepreneurial ecosystem. Still, this kind of integration remains a relatively novel and largely unexplored approach.

***Recommendation 12**: The European Data Union Strategy should futureproof how data (secondary/ancillary-use) stemming from such networks (or the interface of health care and research) can be easily collected, accessed and used.*

8. **Real-world impact of EU regulations on research:** Current experience signals a dichotomy between the intended impact of EU regulations on health research and their actual impact. Given the challenges faced with the GDPR and other legislations, directly or indirectly impacting the health sector, it is crucial that the EU sets up a mechanism for regular feedback from the health research community as well as discussions with key stakeholders.

***Recommendation 13**: The European Data Union Strategy should consider organizing a yearly public consultation and meeting with European researchers to assess the impact of EU regulations on research and identify areas of improvement. It should also consider launching pilot initiatives (e.g. within the European Health Data Space framework) that involve stakeholders - industry, patient organisations, ethics boards- to co-create contracts, pseudonymization standards, federated architectures, and federated learning pilots.*

Recap of JANE-2's 13 Recommendations for the European Data Union Strategy

1. The European Data Union Strategy needs to consider a revision of the rules of GDPR specific to the health research community, to:
   i. Harmonize the interpretations linked to health research, specifically concerning the secondary or ancillary use of data.
   ii. Provide a clear interpretation of the requirements of consent as a legal basis to support the use of personal data for research purposes (e.g., for personalized medicine, AI model development, public health purposes among others).
   iii. Provide technical solutions to reduce administrative burdens based on experiences gained in various EU projects on simplifications.
   iv. Recognize that personal data can be lawfully processed for research purposes, under specific conditions such as: (i) provided a Data Protection Impact Assessment (DPIA) has been performed and the identified risks addressed, or (ii) when the related data processing activities have been certified under Art. 42 GDPR, or (iii) when authorized by the Supervisory Authority of the project coordinator.
   v. Clarify the conditions to ensure privacy and data access as well as include mechanisms to foster public trust in the use of data for research purposes (e.g., transparent governance structures and patient representation in decision-making processes, etc.).
2. The European Data Union Strategy should provide clear guidance on pending matters, including the notions of anonymization and pseudonymization, dynamic consent, opt-out applications, to harmonize interpretations across the Member States, including a concept of risk minimization instead of zero-risk adapted to the data 'sensitivity'.
3. The European Data Union Strategy needs to:
   i. Ensure secure, tiered access to different types of data (from raw annotated data to harmonized structured datasets such as genomic data, imaging data etc) for AI training, to stakeholders, including industry, to support health research purposes as well as clinical applications. AI models should be endorsed with proof of robustness, should be certifiable, explainable and collaborative with fair accessibility. Frugal AI should be promoted.
   ii. Propose initiatives focusing on training for stakeholders regarding the integration of AI into clinical care, particularly for healthcare professionals.
   iii. Recognize the distinct regulatory needs of machine-learning (ML)-based AI and large language model (LLM)-based generative AI. It should also ensure tiered access frameworks that distinguish between data use cases – e.g., for deterministic ML training vs adaptive generative AI development.
   iv. Address the inclusion of health data stemming from wearables, lifestyle apps and personal devices. These data sources capture behavioural and environmental exposures essential for prevention, yet they pose distinct challenges in terms of interoperability, consent, and governance. The Strategy should further promote multisectoral data integration frameworks that combine health, genomic, behavioural, and contextual data under harmonized, privacy-respecting standards.
4. The European Data Union Strategy should propose initiatives that aim to address the regulatory and operational challenges posed by the application of Regulation (EU) 2024/1689 (Artificial Intelligence Act) – including:
   i. High-risk classification burden: Medical AI systems are currently subject to strict technical, legal, and human oversight requirements, which increases costs and hinders innovation.
   ii. Regulatory overlap: The coexistence of AI Act with MDR (Medical Device Regulation), GDPR and EHDS creates legal complexity and duplicative compliance efforts.
   iii. Data access and quality constraints: Access to high-quality, bias-free (such as ethnic, gender, socioeconomic background, age or rural populations), representative health data required by the AI Act is hampered by fragmentation, privacy rules, and national restrictions.
   iv. Prohibited or restricted use cases: Use cases such as emotional recognition or biometric categorization are banned or heavily restricted, limiting innovation in personalized or behavioural health.
   v. Mandatory human oversight: Clinical decisions cannot be made solely by AI, limiting autonomous applications in areas like remote care or emergency triage.

5. The European Data Union Strategy should:
   i. Foster interoperability and standardization of health data at the data source, and be aligned with the EHDS, GDPR, AI Act, Data Act, AI Act, NIS2 and any other legislations affecting this area.
   ii. Propose solutions to coordinate and harmonize cross-domain data use, with particular attention to interdisciplinary research and AI development. Conceptual disease-specific models leveraging the cancer experience can be a pilot project that would contribute to the development of multilingual natural language processing (NLP).
6. The European Data Union Strategy should use European health networks (such as the upcoming Networks of Expertise on cancer) as a use case to foster interoperability and improve data quality of data providers.
7. The European Data Union Strategy should:
   i. Support the zero-trust model and federated learning as privacy preserving solutions identifying the proper safeguards to be in place.
   ii. Support the development of interoperable, secure, intuitive platforms that simplify data use for healthcare professionals and should also promote training to help them navigate regulatory requirements and apply data-driven insights in practice.
8. The European Data Union Strategy should:
   i. Promote tools to simplify the administrative burden leveraging on current experience from existing EU projects and initiatives.
   ii. Aim to simplify contractual mechanisms for researchers under the GDPR, for instance, by recognizing the possibility of using unilateral commitment tools to comply with contractual obligations under Art. 28 and 46 of the GDPR while addressing the needs of research activities (such a tool has already been developed and proposed by the European Centre for Certification and Privacy precisely for this purpose).
9. The European Data Union Strategy should design and implement specific initiatives aligned with the Horizon Europe Strategic Pillar focused on supporting SMEs and researchers by driving initiatives related to open data, regulatory sandboxes, and funding opportunities for both the private and public sector (focusing on healthcare).
10. The European Data Union Strategy should involve patient organizations/advocacy groups/citizens in finding solutions on how to simplify access of patient data for research purposes.
11. The European Data Union Strategy should use the EHDS as the framework for all initiatives tackling health data, and focus on developing initiatives that complement and strengthen this common data space.
12. The European Data Union Strategy should futureproof how data (secondary/ancillary-use) stemming from such networks (or the interface of health care and research) can be easily collected, accessed and used.
13. The European Data Union Strategy should consider organizing a yearly public consultation and meeting with European researchers to assess the impact of EU regulations on research and identify areas of improvement. It should also consider launching pilot initiatives (e.g. within the European Health Data Space framework) that involve stakeholders - industry, patient organisations, ethics boards- to co-create contracts, pseudonymization standards, federated architectures, and federated learning pilots.

More information:
JANE – Policy Document: https://jane-project.eu/wp-content/uploads/2024/09/JANE-Policy-Document.pdf
JANE- Green Paper – https://www.sciencedirect.com/science/article/pii/S2059702924018970
Website: https://jane-2.eu/

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