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Joint Action on Networks of Expertise on Cancer

Milestone number. 9.1

Annual Activity Report: Network of Expertise on Omics Technologies 28 November 2025

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TABLE OF CONTENTS

1	Executive summary	6
2	Introduction	7
3	Tasks	8
3.1	Task 9.1: NoE Governance, Dissemination and Sustainability	8
3.2	Task 9.2 : Technical & clinical support.....	10
3.3	Task 9.3 : Ethical, legal & societal implications	12
3.4	Task 9.4 : Training Centre	16
3.5	Task 9.5 : Synergies, collaborations & funding opportunities.....	18
3.6	Contribution of partners.....	25
4	Governance of the NoE	26
5	Dissemination activities.....	27
6	Synergies with the NoE	28
6.1	Synergies with other NoEs and EUnetCCC	28
6.2	Synergies with the ERNs	28
7	Collaborating stakeholders of the NoE	29
8	Sustainability.....	30
	Annex 1 – Full list of partner contributions	31
	Annex 2 – Poster to present the Omics NoE at BE-Precise, Brussels.....	32



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1 EXECUTIVE SUMMARY

Reporting Period: 1 November 2024 – 31 October 2025

The initial period of the Omics Network of Expertise (NoE) within JANE-2 focused on establishing a solid foundation for its activities, identifying the precise partners within each institution and better defining their contributions.

Milestone activities were streamlined by incorporating the mapping of the inequities across Europe (regarding omics implementation into the SOC, access to innovative technologies, reimbursement, emerging omics competence centres...) (T9.2), the mapping of training needs (T9.4) and the mapping of synergies, collaborations and funding opportunities (T9.5) into a comprehensive **survey** to be conducted among relevant experts, with results due by the end of year 2. Task 9.3 developed a **Legal Watch and Tracker** applicable to Omics Technologies to monitor the evolving regulatory and ELSI landscape. The Omics NoE also provided 3 joint statements and detailed recommendations to the **European Commission's public consultations on the IVD and HTA Regulations**.

Challenges included slow activation and low interest from some high-contributing partners, as well as administrative hurdles. Proactive one-on-one engagements and focused meetings were initiated to align expectations and accelerate sub-tasks.

Plans in the near future include finalizing the surveys, organizing the first **expert consultation event on 4 December 2025**, and initiating the development of the **ELSI Navigator tool** and a **beta version of the matchmaker platform**. These were thoroughly discussed during the first General Assembly on 24 November 2025.

2 INTRODUCTION

Omics technologies regarded in this network consist of large-scale sequencing of biomolecules and high-throughput computational analyses for comprehending biological processes, which are key to the development of **precision oncology**.

Objectives of the NoE

The NoE on omics aims to support the integration of omics technologies into cancer research and care at all stages of the patient journey, striving for equitable access to high-quality healthcare for all European citizens. It will provide services to address challenges related to the implementation of omics in clinical practice and in research. The network will follow a *network of networks* approach, relying on national/regional networks to cascade the resources and activities. In addition, it will foster the exchange of knowledge and best practices, with the aim of harmonizing approaches and learning collectively to drive continuous improvements at the overall EU level.

Thematic Areas

Task 9.1 is responsible for the governance of the NoE, as well as the organisation of pluriannual expert consultations which serve to build the NoE's community and maintain its relevance. Four thematic areas were devised to ensure adequate representation of omics technologies at different stages of clinical readiness:

1. Established omics in the standard of care
2. Omics in clinical research
3. Omics in translational research
4. Integrated Omics

The expert consultations aim to define needs within the expert community, and prioritise the NoEs services which will be developed in four cross-cutting tasks.

Cross-Cutting Tasks

The cross-cutting tasks will develop the services which will be provided by the network long-term.

- Task 9.2 : Omics technical and clinical support
- Task 9.3 : Ethical, legal and social implications (ELSI)
- Task 9.4 : Training Centre
- Task 9.5 : Synergies, collaborations and funding opportunities



3 TASKS

The WP coordinators and task leaders identified partners' expertise and appointed sub-task leaders, establishing a practical roadmap and defining the WP coordination. The first major goal for each cross-cutting task was to conduct **mapping exercises** to establish the current state of the field and prioritise activities. Work focused on defining topics for a **survey** to be conducted among relevant experts, with task-specific meetings held to define key subjects of interest.

3.1 Task 9.1: NoE Governance, Dissemination and Sustainability

3.1.1 Achievements

Milestone: Creation of a core board – 30 April 2025

The proposed governance model produced during JANE1 underwent several iterations, incorporating feedback gathered during the WP9 kick-off meeting and subsequent JANE2 consortium discussions, before reaching the beta version which will be implemented and tested during the project (see 4. *Governance of the NoE*). The key executive governance will be ensured by a steering committee ('core board') consisting of the WP9 coordinators, task leaders and thematic area leaders. Both groups (task leaders and thematic area leaders) convene monthly, and the full steering committee will be meeting every 2 or 3 months depending on the needs.

Milestone: Creation of expert working groups by domains – 30 June 2025

The four originally planned priority domains have been reframed as 'Thematic Areas' to ensure greater clarity and to avoid overlap with the term 'domains,' which in other WPs is used to denote fully independent NoEs. At the WP9 kick-off meeting, stakeholders agreed that activities would not be strictly separated by thematic areas, as these are inherently dynamic and often overlap, making an integrated approach more effective. It was therefore decided to establish one sole working group of thematic area leaders, where each leader ensures adequate representation of their area in the expert consultation activities. This working group has launched an external contact database of omics experts and other relevant stakeholders to be considered for the pluriannual expert consultations.

3.1.2 Challenges encountered

Our core board of task and thematic area leaders, along with most sub-task leads, demonstrated strong engagement and motivation, laying a solid foundation for WP9's progress. Nonetheless, activation of all high contributing beneficiaries has been slow due to:

- Seeming low interest of several partners, some of them considered high contributors & sub-task leads
- Administrative hurdles related to funding for specific partners.

To further harness the potential of all high-contributing partners, we recognized the opportunity to clarify expectations and align contributions more effectively. In response, the WP coordination initiated targeted one-on-one engagements with key partners to better understand their expertise and interests.



Task leads were also encouraged to organize independent focused meetings to accelerate the initiation of the expected sub-tasks. This proactive approach has enabled us to match individuals with specific (sub-)tasks and activities, fostering deeper collaboration and ensuring that each partner's strengths are meaningfully integrated into the WP.

3.1.3 Deviations in activities and justifications

Creation of expert working groups by domains was reframed. The four priority domains became "**Thematic Areas**", and it was decided to establish **one sole working group** to ensure an integrated, effective approach due to the dynamic and overlapping nature of the areas.

3.1.4 Use of resources

Financial resources: The envelope for engagement of collaborative stakeholders will be transferred to Sciensano. This budget (€100k) allows us as NoE coordinators to directly engage with stakeholders through sub-contracting or outsourcing relationships. Priority is given to patient representatives as their point of view is least adequately provided by the beneficiaries already granted in our WP. Task 9.5.4 (Patient engagement) will liaise between the Omics NoE and patient organisations, to align between our tasks and their activities. We have selected two patient associations -WECAN and Data 4 patients- with task 9.5.4 leaders, and their role in the WP9 is being defined based on their possibilities.

Centralized services: The Omics NoE will conduct a survey to map the current state of the field as relevant to all of our tasks. We recognised a risk of overlap with other NoE's surveys and of overwhelming stakeholders with an avalanche of survey requests. We therefore opted to request a streamlined approach, which will be facilitated by Triangulate Health Ltd. We are consolidating the proposed questions from each task and will deliver them to Triangulate by the end of November. Our proposal is to wield a granular approach to maintain a manageable number of questions for each participant, while allowing us to target three different target audiences; (future)healthcare professionals and academics, biotech and medtech industry representatives, and patient advocates. Contact persons by each country are being identified with task partners.

JANE2 Teams Platform: The WP9 coordination, which was also housed at Sciensano during JANE1, already utilized a SharePoint platform that was subsequently carried over to JANE2. Due to a number of limitations, migration to the centralized JANE2 Teams platform was not completed. These limitations include technical barriers preventing many participants from accessing Teams, and the complicated and time-consuming process required to gain access (involving a partner survey and unfamiliar emails from Euroservis), which is difficult for partners with already full schedules who are spending a relatively small portion of their time on JANE2 (and as a reminder, some partners have not yet received any subsidies). It is significantly easier to manage accounts and access via the Sciensano-hosted SharePoint platform without dependency on a third party. The WP9 coordination will nonetheless continue to use the JANE2 SharePoint (but not the Teams channels due to a lack of access which cannot currently be solved by Euroservis) and will ensure that all relevant documents are uploaded both to the WP9 group and to the transversal groups (Coordination, Dissemination, Evaluation, and Sustainability).



3.1.5 Activities planned moving forward

Milestone: Organisation of the first pluriannual expert consultation for the 4 identified domains Thematic Areas – 31 December 2025

The first **expert consultation** event is scheduled on 4 December 2025 and will be an online workshop focused on innovative omics technologies and their transition towards the clinic (areas on Translational research and Integrative omics): spatial and single cell omics as well as integrative omics. The goal is to propose a roadmap on the way to from the current situation to the future vision in about ten years.

Topics more related to the use of Omics technologies in the clinical setting have already been addressed in two of our earlier activities, where we responded to the European Commission's public consultations on IVD and HTA regulations, so we have opted to address the more innovation-oriented thematic areas in this first NoE-organised consultation. Standard of care and clinical research are furthermore covered in our survey activity. Future consultations will build on the results of the tasks' surveys and the output of the upcoming 2025 workshop.

Dissemination. We are launching an Omics NoE newsletter at the end of 2025 (after our first General Assembly on 24 November) to enhance awareness of our activities among the Omics NoE community, especially towards lower contributors and observers. This newsletter will appear roughly every 3 or 4 months depending on the need, and will be targetted towards WP9 beneficiaries as well as external contacts who are invited to sign up when they participate in our expert consultation, or when we meet them at networking events. The newsletter will serve to give general progress updates, promote relevant events, engage *ad hoc* participation in specific activities, report on news from the Legal Watch and Tracker (as described in Task 9.3), etc.

Evaluation. In collaboration with WP3, we will begin to design impact indicators for a long term evaluation framework (EF) for the NoE. This effort will closely relate to establishing a sustainability plan, as the impact indicators will have to reflect the long-term structures set in place during the project.

3.2 Task 9.2 : Technical & clinical support

3.2.1 Achievements

1. Successful division of the work of T9.2 into four subtasks and attribution of subtask leads:

- T9.2.1: Mapping of the inequities across Europe (implementation of the standard of care, access to innovative Omics, reimbursement/funding, emerging omics competence centres...): UGent (Belgium) – Katleen de Preter & Kathleen Claes
- T9.2.2: Facilitation of Omics integration into the healthcare system via elaboration of practical guidelines and development of test bed concepts: Central Denmark Region - Aarhus University Hospital (Denmark) – Britt Elmedal Laursen & National Hellenic Research Foundation (Greece) – Colead Alexander Pintzas & Alexandra Voutsina
- T9.2.3: Validation procedures for innovative Omics implementation via optimal clinical trials' design: University Hospital Würzburg (Germany) – Anke Bergmann, Matt McCrary & Annalisa Musola



- T9.2.4: Harmonization of assessment methodologies to the definition of common indicators for omics technologies: Oslo University Hospital-OUS (Norway) – Ingrid Jenny Guldvik, Live Farengeng & Hege Russnes

- 2. **Development of survey on the implementation and harmonisation of omics-technologies:**
 - Purpose: map how omics-based diagnostic methods are available, implemented, and harmonised across European hospitals.
 - Scope: includes use in standard-of-care diagnostics, eligibility assessment for experimental treatments (clinical trials, off-label therapies), and translational research.
 - Survey content: covers access to omics technologies, decision-making workflows, reimbursement mechanisms, and development of SOPs.
 - Target respondents: key opinion leaders such as heads of pathology, hospital administrators, and clinical directors in EU hospitals.
 - Outcome: analyse responses to identify and understand geographical differences in omics implementation across the EU

- 3. **Mapping validation procedures for omics tests across Europe:**
 - T9.2.3 has mapped relevant EU legislation and regulations/guidelines which impact or have the potential to influence how novel -omics technologies are validated for use in oncology clinical trials.
 - In order to fulfil this work, they are reaching out to national contact points to inquire about the application of EU rules and guidelines, presence of additional relevant legislation/regulations/guidelines at the national level, and also specific ‘use cases’ of successful -omics validation (where possible, in the cancer context).
 - So far, subtask leaders have reached out to 29 national contact points, received responses from 8, and are in the process of following up with the remaining 21.
 - The next steps of this subtask include finalizing the mapping exercise by the end of February, and then use the mapping results to define best practice validation procedures (through focus groups) and a plan for the integration of these procedures into JANE-2 pilot(s)(anticipated in collaboration with WP5).

- 4. Successful **organisation of monthly T9.2 meetings** by T9.2 leadership team.
- 5. Successful **collaboration** with other WP9 tasks and **contribution** to overall WP9 work.

3.2.2 Challenges encountered

French affiliated entities and other partners are still awaiting their grant, which is delaying the hiring of a dedicated staff member to contribute to the work of T9.2, thereby trickling down to slightly delay the activities of task 9.2 as a whole.



Risk of delay due to a near-exclusive focus on the **survey development** in the first year, as well as a dependence on results of the survey (expected end of August 2026) to guide future activities.

3.2.3 Deviations in activities and justifications

Major focus on survey development work, T9.2.4 team (OUS) making major contributions to this work, on top of what was expected from T9.2.1. The team from OUS had the resources and expertise to contribute majorly to this work.

Milestone : Mapping the gaps in existing guidelines – 31 May 2025

Rather than being addressed separately, this milestone will be incorporated into the survey now in preparation, allowing for a more comprehensive and streamlined approach. Analysis of the survey results is expected to be finalized in August 2026 (M22) according to the expected timeline of *Triangulate Health Ltd*, the company that will support survey development and data analysis.

3.2.4 Use of resources

Use of all resources available to the group (WP9 SharePoint).

3.2.5 Activities planned moving forward

The survey will be finalized and disseminated in collaboration with *Triangulate Health Ltd*. Analysis results are expected to be received by the end of August 2026. These results will guide the production of (technical & clinical) **guidelines and validation procedures** tailored to (innovative) omics technologies.

Future steps include:

- Interaction with WP10 for the mapping of omics and high-tech medical resources used in clinical and translational research
- Capitalising on other WPs as use cases: Interaction with **WP5** (poor prognosis cancers) and **WP11** (AYA) for the identification of a pilot for the study protocol synopsis
- Mapping validation procedures for omics tests across Europe is ongoing → Development of one recommendation for validation procedures
- T9.2.3 (facilitation of Omics integration into the healthcare system via elaboration of practical guidelines and development of test bed concepts) to begin conducting literature review.

3.3 Task 9.3 : Ethical, legal & societal implications

3.3.1 Achievements

Task 9.3 has coordinated responses to several **public consultations of the European Commission** by assembling joint statements from the Omics NoE partners. These responses, one addressing the HTA regulation and two addressing the IVDR, include detailed recommendations aimed at fostering more innovative and adaptive legal and regulatory frameworks.

A living document has been prepared to launch the development of the **ELSI Navigator Tool for Omics Technologies**, a use-case driven, multi-module framework designed to integrate laws, regulations, and guidelines into cancer care and research across Europe, laying the foundation for holistic and responsible omics governance.

Milestone: Mapping of relevant legal and ethical directives, rules and/or laws – 30 June 2025

To foster knowledge, awareness, and training on the evolving regulatory and broader ELSI landscape applicable to Omics, Task 9.3 is developing a Legal Watch and Tracker. This resource is envisioned as a centralized platform that systematically gathers, organizes, and contextualizes regulatory and legal frameworks developments, ensuring that the Network of Excellence (NoE) has timely access to relevant information through the interactive support tool (see Milestone below).

The Legal Watch and Tracker is a living tool, updated on a monthly basis and continuously enriched through stakeholder input. It monitors laws, guidelines, and policy publications across the entire omics lifecycle, from early-stage research and clinical trials to translation into standard of care. Each entry is linked to official sources and complemented by concise annotations that highlight lessons learned from practical application, thereby bridging the gap between abstract regulation and real-world implementation.

While currently internal, the platform is designed with a **progressive roadmap**:

- Short term: serve as a structured internal reference for WP9 contributors, supporting alignment and consistency across work packages.
- Medium term: expand coverage with cross-country inputs, ensuring inclusivity of diverse regulatory perspectives and practices.
- Long term: transition into a publicly accessible, regularly updated resource that strengthens transparency, supports training, and fosters dialogue between regulators, researchers, and patient communities.

3.3.2 Challenges encountered

The development of the Legal Watch and Tracker faces several interconnected challenges:

- Regulatory fragmentation across Member States, combined with frequent updates and amendments, requires constant monitoring to prevent outdated or conflicting entries.
- The impressive volume and complexity of regulations, guidance documents, and scientific publications risk overwhelming contributors, while distilling this information into concise, actionable insights without oversimplification is resource-intensive.
- Gathering stakeholder input can be slow and uneven, and balancing inclusivity with efficiency demands careful coordination.
- Translating abstract legal texts into practical lessons and collecting use cases remains difficult given diverse interpretations, with rigorous validation needed to ensure annotations reflect real-world application without bias.
- At the same time, designing the Tracker to be intuitive for both legal experts and non-specialists requires thoughtful visual structuring and modular navigation.



- Sustaining monthly updates alongside other WP9.3 tasks poses resource constraints, and building a robust, secure, and scalable infrastructure for a future public-facing platform adds further complexity.
- Finally, care must be taken to ensure the Tracker complements rather than duplicates existing EU or national initiatives, reinforcing its added value.

3.3.3 Deviations in activities and justifications

Not applicable.

3.3.4 Use of resources

SharePoint of Sciensano is used as the central platform for collaboration. It enables:

- Document sharing & version control, ensuring contributors access the latest drafts and edits.
- Community engagement, allowing stakeholders to review, comment, and exchange perspectives.
- Accessibility, providing secure, structured access for internal teams and selected partners.

It directly supports WP9.3 activities by serving as the repository for toolkit drafts, public consultations drafts and feedback, and references, keeping the process transparent and collaborative.

Webex Sciensano used for interactive meetings, workshops, and stakeholder consultations. It facilitates real-time dialogue, supports inclusive participation across institutions, and complements document sharing by enabling direct discussion and decision-making.

3.3.5 Activities planned moving forward

Milestone: Creation of an interactive support tool for the NoE – 28 February 2026

A living document has been prepared to initiate the development of an **ELSI Navigator Tool for Omics Technologies**, which will be a use-case driven framework for holistic and responsible Omics Technologies integration. The toolkit will focus on laws, regulations, and guidelines relevant to omics in cancer care and research across Europe and will contain 4 modules:

- **Module 1** (EU Regulatory Interplay Navigator) provides a visual guide to how key EU regulations, such as but not limited to GDPR, IVDR, CTR, AI Act, and EHDS, intersect in omics-related cancer care and research. It aims to help stakeholders identify applicable legal frameworks, resolve overlaps or conflicts, and choose the right regulatory path. By clarifying the relationships between these regulatory frameworks, it serves as an ELSI compass, guiding stakeholders toward the most appropriate EU legal pathway for their specific activities.
- **Module 2** (National Regulatory & Legal Heatmap) is a heatmap that visualizes national regulatory, ethical, and legal differences across Europe. It supports the identification of key areas for harmonization by highlighting overlaps and gaps, such as those between ISO standards and IVDR requirements, ultimately guiding the development of an optimal checklist for standardization.
- **Module 3** (Proportionality-Based Governance Grid) is a governance grid based on the principle of proportionality. It provides a structured approach to evaluating data governance, GDPR



compliance, and technical and organizational measures for (gen)omic data, helping stakeholders identify an appropriate and balanced response tailored to the level of risk and sensitivity involved.

- **Module 4** (Cross-Border Contract Toolkit) offers practical contractual frameworks to support cross-border collaboration, covering key areas such as Data Processing Agreements (DPA), Intellectual Property (IP), and data access. It helps stakeholders pinpoint the essential components of a robust and effective agreement, ensuring legal clarity and mutual understanding across jurisdictions.

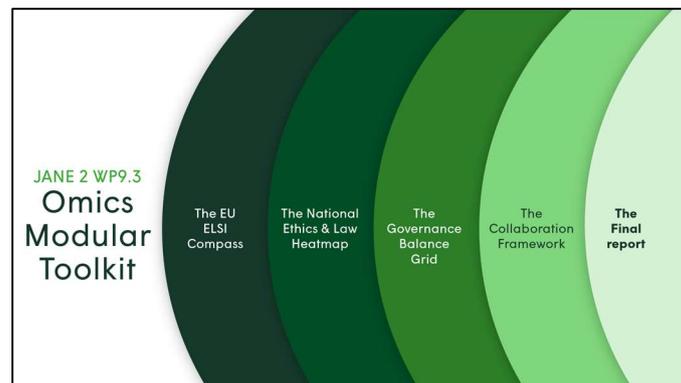
This work builds on early consultations with contributors and is continuously refined to reflect both real-world conditions and the expertise of those involved.

The tool will be developed in two stages:

- Phase 1: initial design based on mock use cases.
- Phase 2: iterative refinement through partner testing and integration of real-world use cases.

Ultimately, it aims to be adaptable to the interests and levels of knowledge of diverse stakeholders, including patients and citizens, clinicians, study sponsors, ethics oversight bodies, and regulatory authorities.

A current risk for the timely completion of this milestone is that somebody has yet to be appointed for the technical development and online hosting of this tool. We are first evaluating whether this can be handled internally by Sciensano, as was the case for the patient involvement tool developed during JANE1.



Milestone: Identification of gaps/discrepancies in the application of directives, rules and/or laws
– 31 August 2026

This milestone focuses on systematically identifying and documenting gaps, inconsistencies, and discrepancies in the application of relevant directives, rules, and laws across Member States and stakeholder groups. Building on the preparatory work already underway in 2025, including early consultations, draft analyses, and the Legal Watch and Tracker, the process will:

- Map regulatory frameworks across the omics lifecycle, from research to clinical implementation.
- Compare national practices to highlight divergences in interpretation and enforcement.

- Collect stakeholder input (patients, clinicians, sponsors, ethics committees, and authorities) to capture practical challenges and lessons learned.
- Integrate findings into the ELSI Navigator, ensuring they are accessible, transparent, and usable for training and awareness.
- Feed into recommendations for harmonization and improved guidance, supporting both policy development and operational practice.

3.4 Task 9.4 : Training Centre

3.4.1 Achievements

The execution of this Task was led by the Institute of Biochemistry and Biophysics Polish Academy of Sciences (IBB PAS) in Warsaw. During the reporting period, the primary focus was to advance efforts to strengthen omics-related knowledge and training across Europe, with the overarching objective of gathering information serving as foundation to establishing a dedicated Training Centre. Work progressed toward achieving the following internal deliverables:

- **List of needs and gaps in the training (T9.4.1, M12)**
- **List of training possibilities (T9.4.2, M12)**
- **List of advanced and developing member states regarding Omics technology(T9.4.3, M12)**

To address these deliverables, collaboration activities were expanded. Engagement with EUnetCCC intensified, and initial discussions with DKFZ opened new avenues for coordinated work on identifying existing gaps, unmet needs, and emerging priorities in omics training. In parallel, a structured mapping exercise was launched to assess how omics concepts are currently represented in European and national medical curricula—covering general medical and nursing education as well as selected specialist pathways such as oncology and general practice. The initial mapping also considered the perspectives of patients and their families to identify gaps in understanding and support for omics-related information. These analyses will form the basis for forthcoming workshops and focus groups aimed at defining the most urgent educational priorities.

As part of the mapping process, we identified **key survey audiences**—patients and their families (Group 1) and healthcare professionals together with early-stage professionals (including medical and life science students) (Group 2). Background information was collected from diverse sources to ensure broad and representative insights. The **proposed key survey topics and survey questions** addressed recurrent challenges such as limited familiarity with omics terminology, insufficient access to clear and trustworthy information, low confidence in advanced diagnostics, and limited interpretive support for omics-based results.

In addition, the Working Group developed an initial conceptual framework to improve patient and public literacy related to personalized medicine and advanced diagnostics. Early methodological criteria were drafted to support a systematic assessment of knowledge gaps, information needs, and barriers across patient groups, the general public, and healthcare professionals.

A preliminary analysis of **training possibilities** was also conducted, focusing on potential target audiences for omics training and the types of content to be included, covering both established and emerging omics methods, the initial **training possibilities list** has been established .



Preparatory work has also progressed toward national-level capacity building. This included an initial analysis of EU Member States based on their level of advancement in omics technologies, resulting in a construction of the **list of advanced and developing member states regarding Omics technology** containing two groups: advanced and developing countries regarding omics. Further options under consideration include cascading stakeholder engagement strategies, closer collaboration with national and regional networks, and the establishment of mission hubs and mirror groups to support coordinated activities at the local level.

Through these coordinated efforts, T9.4 is laying a solid foundation for enhancing training, increasing awareness, and supporting the effective integration of omics technologies into healthcare practice and education across Europe.

3.4.2 Challenges encountered

Risk of delay for activities in Tasks 9.2 and 9.4 due to a near-exclusive focus on the **survey development** in the first year, as well as a dependence on results of the survey (expected end of August 2026) to guide future activities.

3.4.3 Deviations in activities and justifications

Milestone: Mapping the needs for training and education – 31 July 2025

Rather than being addressed separately, this milestone will be incorporated into the survey now in preparation, allowing for a more comprehensive and streamlined approach. Analysis of the survey results is expected to be finalized in August 2026 (M22) according to the expected timeline of *Triangulate Health Ltd*, the company that will support survey development and data analysis.

3.4.4 Use of resources

The resources have been used according to the initial plan.

3.4.5 Activities planned moving forward

The survey will be finalized and disseminated in collaboration with *Triangulate Health Ltd*. Analysis results are expected to be received by the end of August 2026. These results will guide the production of **training materials** tailored to omics technologies.

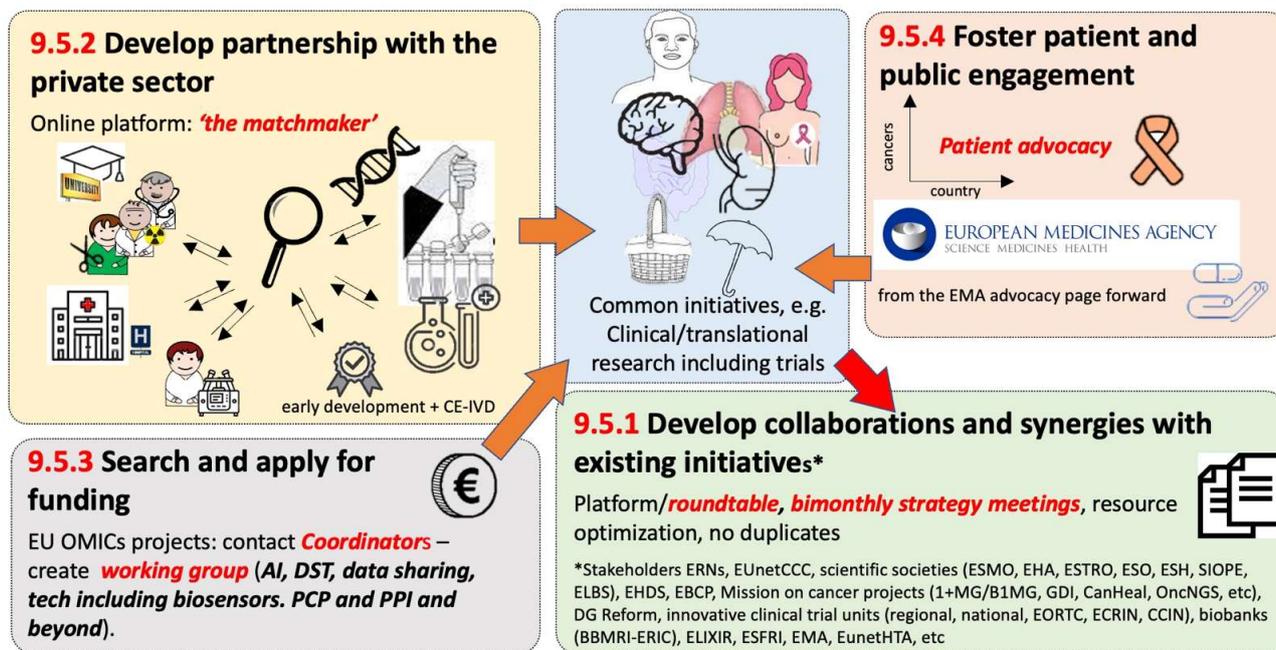
Milestone: Activation of bi-monthly meetings for preparation of training courses – 31 August 2026

Bi-monthly coordination meetings will be launched to support the development of training courses on omics technologies within the frame of T9.4. These meetings will bring together partners to plan course content, align training priorities, coordinate expert input, and ensure steady progress toward building a comprehensive and high-quality omics training programme.

3.5 Task 9.5 : Synergies, collaborations & funding opportunities

3.5.1 Achievements

Major achievements are listed by subtask (T9.5.1 to T0.5.4), according to the flowchart below that summarizes subtasks, their relationships, and the ultimate collaborative goal of T9 altogether.



T9.5.1: Coordination was secured through ISNB, which enables strong connection with a number of EU initiatives such as ERNs (in particular EURACAN), EUnetCCC, scientific societies, research infrastructures (e.g., BBMRI-ERIC, ELIXIR, ECHOs), patient organisations, national and regional authorities, and other EU-funded projects represent essential partners for strengthening coherence across initiatives, avoiding duplication, and enabling coordinated responses to emerging needs in precision oncology.

A strategy meeting has been planned to occur every 2 months, bringing together representatives from WP9 and the most relevant external initiatives that interact with JANE-2. First meeting planned Q1 2026.

The main focus will be to align ongoing activities across initiatives, ensure coherence with existing European networks, and avoid unnecessary duplication of efforts. These meetings will also help identify emerging needs, areas of overlap, and opportunities for coordinated action.

During each meeting, WP9 will summarize the progress and key findings of T9.5, including the development of the matchmaker platform, the mapping of stakeholder needs, and the updates from the interactions with other stakeholders. This structured exchange will allow partners to connect with complementary expertise, infrastructures, and resources, strengthening synergies both within JANE-2 and with the broader European ecosystem.

The meetings will also serve as a channel to gather feedback from external partners and to refine the functionalities of the matchmaker platform, ensuring that the tool responds effectively to scientific, organisational and patient-related priorities. In this way, the roundtable/strategy meetings will act as a bridge between JANE-2 and the wider community of initiatives working on omics, cancer care, data

infrastructures, and policy development, supporting a coordinated and transparent approach to collaboration.

T9.5.2: Matchmaker (MM) will be an online hub connecting the public and private sector. It will be a virtual place to launch requests for collaboration and offer expertise. It will focus on the implementation of clinical Omics platforms and will be open to both for-profit and non-profit clinical-translational studies. It will be aimed at a pragmatic use of the available tools, e.g. at clinical and translational Investigators having ongoing Omics trials, sample collections, and specific questions that may benefit from quick, larger corroboration through improved recruitment, better Omics application, scale economy, or any other tool/measure that cannot be easily gathered in single-center studies. Conversely, the biotech world may be interested in launching pre-commercial beta testing of prototypes and Omics platforms at relatively early TRL maturation stages.

MM will multiply collaboration opportunities and will shorten time to implementation. MM has been the focus of a very intense exchange of opinions and many specific suggestions. Its design must be foresighted, since duplications must be avoided with several platforms that are already available, and functions to be implemented must be carefully prioritized. Superficially it may bear some resemblance with LinkedIn and EU partnership tools (and possibly other online collaboration tools), but effort will be devoted to introduce unique features (see below).

IT and bioinformatic expertise has been gathered, mainly through the Maria Sklodowska-Curie National Research Institute of Oncology (Gliwice Branch, PL), Department of Biostatistics and Bioinformatics. They have been appointed as the major contributors in this task. This is an outline of foreseen initial actions and strategy to create a beta-testable MMv0 version.

- Decide on hosting the platform. Possible routes – create the platform de novo OR present a document with recommendations to the European Commission to improve their platform. This may ensure that MM survives in the JANE2 ‘afterlife’. This determines the choice to develop an advanced beta version.
- Define target audience (public and private sectors).
- Contact other NoEs. Matchmaker would be beneficial to all, so everyone should be able to participate in designing – possibly via survey.
- Specify functionalities. The most intuitive way is through user stories – scenarios on the desired use of the tool (see below).
- Propose metadata standard. For efficient searching, participants would need to input information about themselves and/or the project.
- Prepare a ToR document for the contractors. JANE 2 Partners will develop a functional beta platform incorporating main functionalities although devoid of fully implemented cybersecurity and online meeting features, but from this point on the platform will be maintained and further developed through outsourcing. Whereas MMv0 will be an academic effort, platform maintenance requires dedicated facilities and workmanship.

Desired functionalities of the platform

Primary:



1. Create a profile of my own group, project portfolio ... (input)
2. Search/filter institutions, research groups etc. (output). Possible augmentation with Large Language Model (LLM) – search matching entities based on a short, natural language description of the needs.

Secondary/optional:

3. Collaboration - a communicator with a (limited) data sharing space to e.g. work on grant proposals. Increases need for data security and storage requirements.
4. Training – host workshops e.g. introducing new methods or tools developed by a group, or patient education. Increases GUI sophistication, storage requirements

User Story – Help wanted.

This is the MMv0 peculiarity. The tool is for those who have a specific clearly defined need. There will be a specification field where the prospective user can outline needs and find a group whose project needs match particular skills or equipment.

For instance: I am a PI in a group specialising in microCT tissue scanning and image analysis. I want to find groups who are looking for collaborators with my expertise or facilities; I am planning a multicenter OMICs trial and am interested in expanding the collaboration team (either recruiting sites or expertise needed); I have a new IVD: this is the patient population that may potentially benefit, need a quick validation timeline, budget is (is not) available etc.

Metadata

Metadata are crucial for efficient searching and filtering. A well-designed metadata standard, including comprehensive dictionaries, will also facilitate the introduction of intelligent searching. An example of a metadata standard (dedicated to health-related datasets) is HealthDCAT-Ap¹.

Designing the metadata standard will require:

- Identification of all possible entities in the database (Institution, group, project),
- Assigning required, recommended, and optional metadata tags for each entity type,
- Defining the format, dictionary, and cardinality for each tag.

Designing metadata is non-trivial and will require expert knowledge and public consultations. The most important aspect is to define the minimum required set of information (MRSI), which might be topic-specific. For example, aspects specific to medical imaging/radiomics:

- Imaging modality (MRI, PET, CT, ...)
- Resolution, voxel size
- Patient position/orientation
- Scanner parameters (e.g. for MRI the magnet strength)

¹ <https://www.healthinformationportal.eu/healthdcat-ap>



- Acquisition parameters (e.g. MRI sequence)

T9.5.3: Among several possibilities, the Partners have elected to focus their efforts toward a Public Procurement of Innovative solutions (PPI). Circulating tumor DNA (ctDNA) has been prioritized for the following reasons:

- a) Extreme fragmentation: many available platforms; different healthcare models (centralized vs de-centralized); heterogeneous business models (local deployment vs outsourcing), uneven access to ctDNA diagnostics across EU and within EU Member states.
- b) Too high burden on individual institution to meet IH-IVD requirements
- c) Dis-alignment between approval of ctDNA diagnostic assays and reimbursement
- d) Shortage of clinical and technical guidelines
- e) Lack of standardization in diagnostic reporting
- f) Cost

The OncNGS (www.oncnsgs.eu) precommercial procurement (involving many of JANE2 Partners, including Partners from WPs other than WP9) has shown that novel ctDNA solutions may be generated addressing in principle all the above challenges. The possibility to engage into a PPI is being discussed as an opportunity to strengthen ongoing JANE 2 synergies and widen collaborations whereby the agenda is set by the public sector and the technical high-quality implementation is curated by the private sector.

T9.5.4: Within the subtask, a strategy was developed to structurally involve patients in the activities of the network of expertise on omics. The methods and activities are in line with the previously developed JANE patient involvement toolkit. Two partners (Data for Patients and WeCan) were approached and agreed to perform critical tasks in the execution of the patient involvement strategy.

WP9 Task / Subtask	Potential Area of Work	Potential Role for Patient Organisations	Potential Type of Contribution
T9.2.1 & 9.2.2	Reducing inequalities and integrating omics in care	Consultations: identify real-world patient needs and barriers to omics access across Member States	Testimonies, patient surveys, co-creation of case studies
T9.3.1 - T9.3.3	Legal & Ethical aspects: GDPR, IVDR, data ethics, AI	Review legal/ethical tools and provide patient-centered perspectives on consent, transparency, data rights; <ul style="list-style-type: none"> •Join ELSI expert panels or working groups on specific topics (e.g., data ethics, transparency, return of results, etc.) •Provide case-based insights or respond to targeted consultations •Validation of proposed ELSI frameworks and tools 	Expert review; scenario testing; participation in ethical deliberation groups
T9.4.1 - T9.4.4	Training and literacy (for professionals and public)	Co-develop or validate patient literacy materials; help design inclusive educational content <ul style="list-style-type: none"> •Review and test patient/public literacy materials •Advise on framing omics literacy for advocacy communities •Provide feedback on communication outputs for cancer patients 	Co-creation workshops; review of materials ; communication campaigns
T9.5.1 - T9.5.4	Synergies, collaborations, and engagement	Ensure meaningful patient and public engagement; build links with national networks <ul style="list-style-type: none"> •Co-develop stakeholder engagement methodology •Advise on recruitment and facilitation of patient involvement activities •Validate engagement protocol with cancer-focused patient networks 	Strategy input; engagement facilitation ; feedback collection and reporting
Cross-cutting	Data management and patient-centric design	Integrate patient and frontline worker perspectives into omics validation tools and platforms	Strategic advisory, content co-design, feedback loops

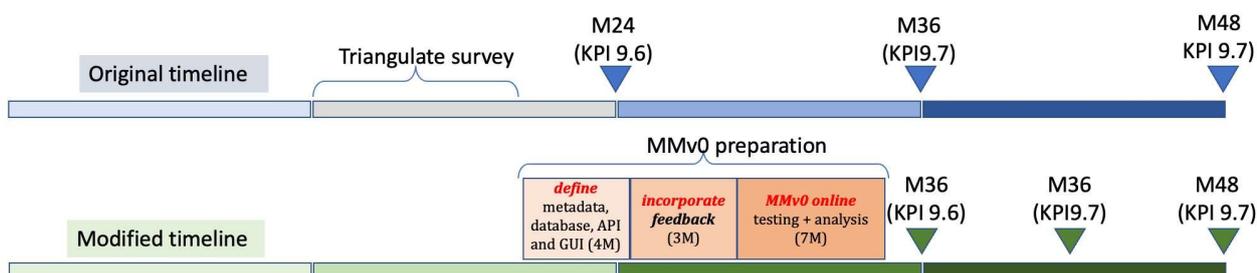
3.5.2 Challenges encountered

Whereas the technical definition of MMv0 was smooth, extensive discussions among the partners have highlighted the opportunity to leverage MM as an ‘unifying’ tool to foster collaboration not only with the private sector, but also with patient advocacies, as well as medical and clinical-pathological societies across EU. Going beyond scope and increasing expectations have raised the bar for economical support. This is being addressed by exploring the possibility to obtain extra support through JANE2 coordination and/or individual partners. Support is needed both for the IT backbone and labor. Budget re-modulation is being defined. In addition, the precise spectrum of desirable MMv0 features (crucial to develop MMv0) will be deduced from responses gathered through an online survey that will be carried out on behalf of the consortium by Triangulate. As per study plan, results are expected to be available by August 2026. This due date cannot be modified, since it is determined by the centralized JANE2 survey format. Hence, a delay is expected in MMv0 testing/delivery, specifically KPI milestones originally expected at M24 (October 2026) and M36 (October 2027), as shown by the modified Gantt chart below.

After the survey results are available (August 2026, M 10), we distinguish three phases: (a) definition of metadata and database structure, API and GUI, example data, prepare feedback form (4M); (b) Incorporate feedback (3 M); (c) MMv0 online testing + analysis (7Mo). Ultimately, M24 milestones (October 2026), are postponed by 12 months, and M36 milestones are postponed 6 months. Since MMv0 will be ready 12 months before the end of the project, it is estimated that the Partners will have anyway sufficient time to explore it and provide useful inputs for future improved versions.

MatchMaker: KPIs and Milestones revisited

	Type	Definition	Tasks	Justification	Type2	Methodology	Data source(s)	Data collection instrument	Periodicity of data collection	Completion criteria	Acceptance criteria	Observations
KPI9-6	Indicator	Beta version of JANE MMv0 available	T9.5	A beta version of the matchmaker web platform available to be tested	Output	Quantitative	Online tool/platform	JANE MMv0 platform	M24	1	1	A beta version of the JANE MMv0 tool needs to be available for successful completion.
KPI9-7	Indicator	Acceptance rate of invitations to use JANE MMv0	T9.5	The matchmaker web platform will gather information of interest for both stakeholders and/or professionals	Outcome	Quantitative	Online tool/platform	Number of users signed up in JANE MMv0	M36, M48	≥80% of MS participating in the JA and ≥50% of invited key stakeholders	≥50% of MS participating in the JA and ≥30% of invited key stakeholders	Rate of acceptance of invitations both from MS and key stakeholders to use the JANE MMv0 tool.



3.5.3 Deviations in activities and justifications

Milestone: Establishment of the matchmaker platform – 31 October 2025

This milestone is delayed as the first year was spent establishing a strategical approach and finding a leading partner to develop the platform. We are also still determining the required budget and exact funding sources for this effort. After discussing the practical approach for the matchmaker platform, it was concluded that (1) developing a fully fledged platform would be challenging within the scope of the joint action, and (2) such a platform would ideally be hosted by a « neutral » party (i.e. the EU) rather



than any particular institution. The decision was made, therefore, to produce a **beta version** of the platform to evaluate its potential and map the features that are most useful to our community. Eventually this beta version, along with a report including recommendations, can be delivered to the EC to launch a collaboration towards a mature platform, perhaps building on infrastructure that is already in place.

3.5.4 Use of resources

The main issue is related to the optimization of the IT workflow of MMv0. Through extensive discussions it was apparent that centralization of all MMv0 efforts was mandatory, to ensure smooth development and internal consistency of the platform. The necessary expertise was gathered at the Maria Skłodowska-Curie National Research Institute of Oncology (Gliwice Branch, PL), Department of Biostatistics and Bioinformatics. Whereas most of the resources were available locally and through JANE2 specific funding, the need emerged to hire a full time post-doctoral fellow who could technically implement the platform to meet the requirement pre-defined by the Consortium. It was estimated that a fellowship and associated support for travel and consumables (total €24.000) could cover these extra cost.

3.5.5 Activities planned moving forward

Milestone: Establishment of the matchmaker platform – 31 October ~~2025~~ 2026

The **matchmaker platform** will connect academics, clinicians, industry partners and patient representatives. The beta platform development will be led by a team of computational biologists at MSCI (Poland) and users will include both WP9 partners as well as external invitees. A first concept was prepared of the general design and actions to be taken. We agreed to aim for a launch of the beta version by M24, and will measure a KPI of usage rate among member states and key stakeholders at M36 and M48.

3.6 Contribution of partners

The key collaborators in this WP are listed in the table below.

WP Coordination	Hélène Antoine Poirel, Inge Smeers	Sciensano, BE
Task Leads	Maud Kamal, Christophe Letourneau, Venice Hancock	Unicancer, FR
	Roxana Albu, Wannes Van Hoof	Sciensano, BE
	Tomasz Sarnowski	IBB-PAS, PL
	Patrizio Giacomini, Valentina Trapani	ACC, IT
Thematic Area Leads	Camilla Nero, Gloria Anderson	FPG, IT
	Luisa Pereira, Luis Filipe Silva	I3S, PT
	Antoine Italiano, Venice Hancock	Unicancer, FR
	Janne Lehtiö, Xenia Vilalobos	KI, SE
Sub-task leads	Wannes Van Hoof	Sciensano, BE
	Kathleen Claes	UGent, BE
	Katleen De Preter	VIB, BE
	Karen-Lise Garm Spindler	RM, DK
	Anke Bergmann, James McCrary, Annalisa Musola	UKW, DE
	Alex Pintzas, Alexandra Voutsina, Theodora Katsila	NHRF, GR
	Giovanni Roti, Elisa Iezzi	AOUPR, IT
	Enrico Francesci	ISNB, IT
	Rasa Ugenskiené	LSMUL KK, LT
	Gro-Live Fagereng, Ingrid Jenny Guldvik, Hege Russnes	OUS, NO

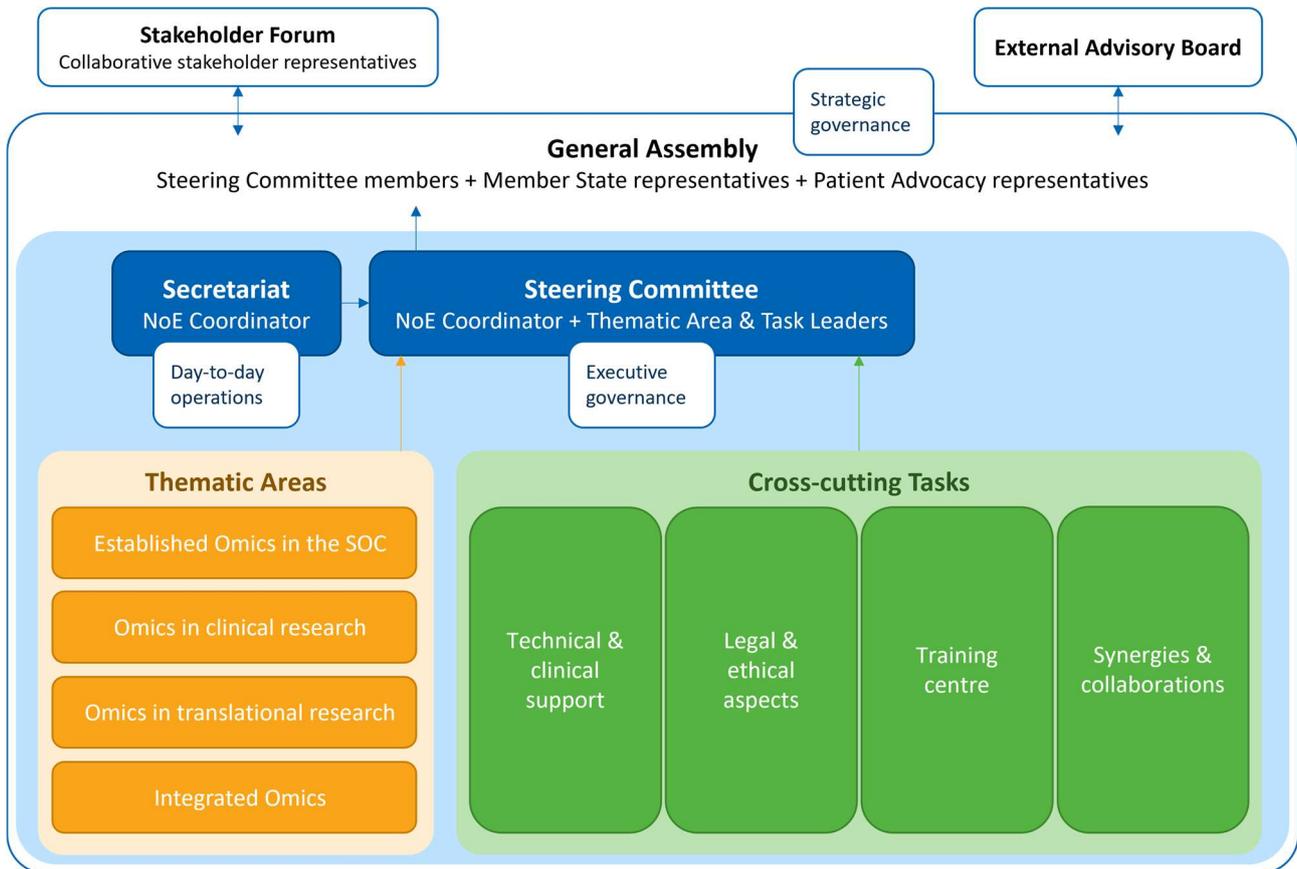
Other contributing institutions in year 1 were: CUSL (BE); HUB-IJB (BE); UZA (BE); MMCI (CZ); FICAN (FI); CHU CF (FR); UC-COL (FR); DKFZ (DE); HSE (IE); UCD (IE); UL (IE); CRO Aviano (IT); UNIMI (IT); PSCUH (LV); NVI (LT); SAM (LT); INC (LU); LIH (LU); MSCI (PL); OIL (SI); CNIO (ES); IDIVAL (ES); VGR (SE).

A detailed list of partner contributions is added in *Annex 1 – Full list of partner contributions*, which will be submitted in support of this document.



4 GOVERNANCE OF THE NOE

The (alpha) governance model produced during JANE1 underwent several iterations, incorporating feedback gathered during the WP9 kick-off meeting and subsequent JANE2 consortium discussions, before reaching the beta version which will be implemented and tested during the project and further amended if necessary.



Elements of the governance implemented during the first year :

- The **NoE Secretariat** convenes at least weekly.
- The two working groups of **Thematic Area** leaders and **Task** leaders convene monthly.
- The **Steering Committee** convenes circa every 2 or 3 months, depending on the needs and progress of the WP.



5 DISSEMINATION ACTIVITIES

- A hybrid kick-off meeting was held in Brussels on 9 December 2024
 - Purpose: Convivial event to thoroughly present the scope and planned activities of the WP as well as to meet WP9 partners.
 - Followed up by dissemination of a detailed WP overview, planned milestones and deliverables, and the DoA of WP9.
- Contribution to the JANE2 newsletter disseminated by WP2
- Social media posts on JANE2 pages, as well as by the Sciensano Cancer Centre
 - WP9 Kick-off meeting
 - Description of the NoE, recorded by WP2 partners
 - Responses to EC public consultations on IVD and HTA regulations
- Participation in the BE-Precise conference in Brussels on 25 September 2025
 - Promoting the Omics NoE to Belgian experts in precision and personalised oncology via a poster presentation (see *Annex 2 – Poster to present the Omics NoE at BE-Precise, Brussels*).

In year 2, we plan to continue establishing the NoE's presence at relevant events across Europe (e.g. EUnetCCC conference in Paris, HARPOON conference in Heidelberg, ...), to disseminate the NoE's outputs via the JANE2 website and social media profiles, and to improve communication to internal partners and interested external experts via a newsletter as described in Task 9.1.



6 SYNERGIES WITH THE NOE

6.1 Synergies with other NoEs and EUnetCCC

One-one-one meetings, as well as cross-participation in meetings, were held with synergistic networks, including;

- WP8 (Tasks considering omics)
- WP10 (Particularly domains on radiomics and *ex vivo* testing of agents)
- EUnetCCC (Particularly Task 8.4 on precision diagnostics)

WP9 is progressing an advanced manuscript on IVDR as it relates to omics technologies, building directly on the expert feedback gathered within the work package. Current discussions with WP10 focus on exploring how similar efforts and recommendations might be developed for MDR, under the remit and expertise of WP10. WP9 continues to provide guidance where relevant, while the scope and format of any MDR-related outputs are still being clarified.

In the second year we will also start to explore possible collaboration with **WP5 - Complex and Poor Prognosis Cancers**, and **WP11 - AYA with Cancers**, particularly to investigate their potential role as a use case provider for D9.3 *Synopsis of a study protocol implementing omics technologies*, where many services of the Omics NoE will be exemplified.

6.2 Synergies with the ERNs

Collaboration with the **European Reference Networks (ERNs)** is essential for the Omics NoE. The JANE2 NoEs aim to provide services transversally relevant to all types of cancer, whereas the ERNs focus on specific, rare cancer conditions. The NoE's services -such as guidelines, knowledge transfer, and recommendations for optimal clinical care- are designed to support caregivers with relevant expertise on every stage of the patient journey. To ensure that these services are relevant to the journeys of patients with rare cancers, we will interact with the ERNs to ensure adequate representation of fields such as haematological malignancies (EuroBloodNet: eg, adaptation of the current survey is under-going) and, in the future, paediatric cancers (PaedCan).



7 COLLABORATING STAKEHOLDERS OF THE NOE

Key stakeholders were invited to the WP9 kick-off meeting to present their organisations and explore synergies;

- ESMO
- ELIXIR

One-on-one meetings were held with stakeholders of interest to determine possible collaboration opportunities;

- ELIXIR
- EIT Health
- EUCOPE
- EAPM
- 1+MG Working Group on Cancer (WG9)
- WECAN
- Data For Patients



8 SUSTAINABILITY

We conducted an extensive stakeholder mapping of potential partners, users and customers of the future NoE, in collaboration with WP4. Subsequently we have contributed feedback on their needs assessment survey and provided suggestions on optimizing outreach to these stakeholders.

Besides stakeholder mapping and engagement, we consider it crucial to establish practical points of action that we can take to ensure post-project sustainability. We will therefore begin envisioning the long-term structures that can be put in place by each task (tools, working groups, educational materials, ...), designing a model for NoE membership, and exploring funding options.



ANNEX 1 – FULL LIST OF PARTNER CONTRIBUTIONS

Excel file will be submitted in support of this document.



ANNEX 2 – POSTER TO PRESENT THE OMICS NOE AT BE-PRECISE, BRUSSELS



The Network of Expertise on Omics in Cancer Supporting the implementation of omics technologies in cancer care across Europe through health networking



Inge Smeers¹, H el ene Antoine Poir el¹

On behalf of the Network of Expertise on Omics in Cancer

¹Cancer Centre, Department of Epidemiology and Public Health, Sciensano, Belgium

Background & rationale

Europe’s Beating Cancer Plan (EBCP) aims to improve the quality of care for cancer patients in the EU through increased cross-border cooperation. The **Joint Action on Networks of Expertise (JANE-2)** answers the call to address priority items within the EBCP through health networking. Seven Networks of Expertise (NoEs) will be conceived to tackle transversal issues in the cancer domain: complex and poor-prognosis cancers, palliative care, survivorship, personalised primary and secondary prevention, **omics technologies**, hi-tech medical resources, and cancers in adolescents and young adults.

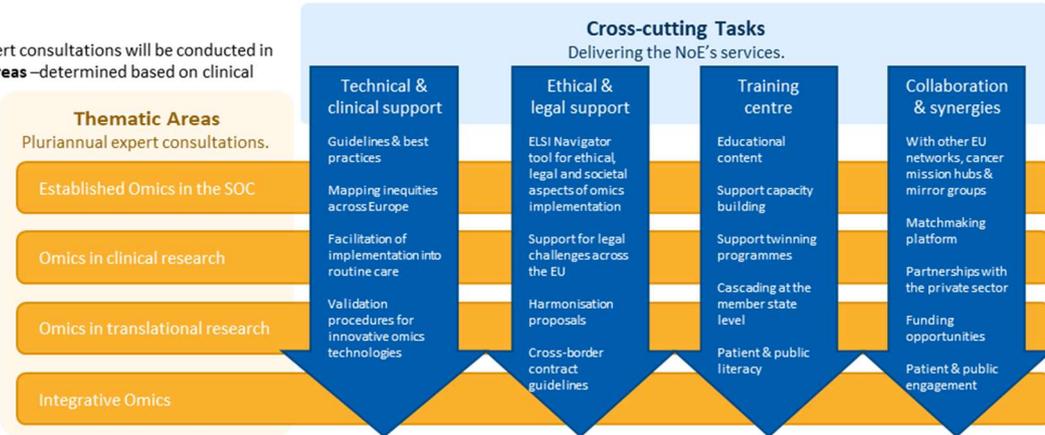
Objective

The NoE on Omics Technologies aims to support the **integration of innovative omics technologies into care** at the different steps of cancer management in a flexible and sustainable manner, promoting **equitable access to high-quality care** for all EU citizens.



Methods

Pluriannual expert consultations will be conducted in four **thematic areas**—determined based on clinical readiness—to define and prioritise the needs across Europe. These consultations will lead to consensus reports and will inform the activities conducted in the four **cross-cutting tasks**.



Network of networks

The Omics NoE will include key experts in the field across Europe, but will rely on national or regional networks to cascade its activities to the local level and ensure a broad reach.



Output

Expert consultations will lead to consensus guidelines, whitepapers, best practices, ...
💡 In 2025 the NoE has consulted its experts to evaluate the IVDR and HTA regulations, leading to reports that summarise key issues and recommendations.

A **matchmaking platform** will promote cross-border, transdisciplinary collaboration and public-private partnerships.

Guidelines and validation procedures to fill the gaps for omics technology implementation in routine care and clinical research.

Educational materials will be provided for healthcare professionals, students, patients and the public.

An **ELSI Navigator Tool** will address the European ethical and legal landscape.

Perspectives

Via synergies with the Joint Actions *EUnetCCC* and *Personalised Cancer Medicine*, the Omics NoE strives to improve **precision oncology** across Europe through cross-border collaboration and health networking in Europe.

