



ONCOVALUE is a consortium of cancer institutes and commercial businesses that is working together to implement value-based oncology care.

The project team will enable and guide cancer clinics to collect, harmonize and analyse high-quality Real-World Data (RWD) in real-time by developing an AI-based framework for assessing real-life effectiveness of novel cancer therapies in real-time.



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1. Describe your project through key words/key phrases that identify it.

ONCOVALUE is a consortium of cancer institutes and commercial businesses that is working together to implement value-based oncology care by enabling and guiding cancer hospitals to collect, harmonize and analyse high-quality Real-World Data (RWD) in real-time, supporting cost-effectiveness evaluation of novel cancer therapies. The project seeks to incorporate hospital Real-World Evidence (RWE) in Health Technology Assessment (HTA) and regulatory decision-making, enabling making decisions on medications and treatment based on information that considers e.g., clinical response, effect on quality of life of patients and costs of care, complementing knowledge derived from randomised clinical trials (RCTs).

2. In terms of impact, what will be the most tangible your project will achieve?

The ONCOVALUE project aims to achieve results that will have a significant impact on the future of oncology care. A key objective is to guide cancer hospitals in the collection and processing of RWD by introducing new methods and tools. The project will produce guidelines, standard operating procedures (SOPs), and educational materials on how to collect and process RWD, sharing insights on how to organise and build up structured collection of data as part of clinical routines, drawing from real-life use cases in various clinical settings, such as breast cancer and lung cancer.

Another key objective is to enable the inclusion of high-quality RWD in regulatory and reimbursement decision-making. If successful, this would have many

tangible impacts such as supporting the adoption of effective new medicines and reducing spending on drugs that yield little benefit to patients. However, there are several challenges in accomplishing this aim, such as the lack of a universal standardised common data model, difficulties in transforming abundant and diverse data from different sources into meaningful and harmonized data for analysis and the perplexities in ensuring that hospital-generated RWD is of high enough quality to be utilized for HTAs and regulatory purposes. ONCOVALUE is actively addressing these challenges by harmonising data to the Observational Medical Outcomes Partnership (OMOP) common data model, maintaining active discussions on data interpretation and assumptions within the consortium, while also focusing on data quality to ensure reliable and consistent assessments.

An additional challenge in utilising RWD is the large amounts of unstructured data in electronic health records (EHRs). ONCOVALUE is addressing this by developing and testing AI-based tools to support the effective use of unstructured data, such as text analytics to extract and structure clinical information from free text, and imaging tools for analysing treatment responses from CT scans. This data provides valuable insights into the assessment of cancer therapies' effectiveness in real-world settings.

Another key result will be the harmonization of clinical hospital data into the OMOP common data model, enabling the analysis of similar data between different hospitals without pooling patient-level data together in one central database. This federated

analysis will allow for larger sample sizes, more variation in patients, and variation across clinical centres and countries, which are essential for value-based HTA decisions, especially when locally available data sources include only small patient populations. It is worth noting that this development work is influenced by the evolving legal frameworks in Europe. The project is closely following the development of the European Health Data Space (EHDS) to ensure compliance.

The ultimate goal is that ONCOVALUE will lead to safer, more efficient, and affordable therapies, technologies, and digital solutions for cancer care.

3. Please describe your project's overall impact, if applicable, at the European level.

The overall aimed impact is to unlock the full potential of RWD and RWE in cancer hospitals. We remain convinced that the vast amounts of RWD stored in cancer hospitals can and will be better exploited in the future. The advantages and opportunities of hospital RWD are undeniable, such as the ability to evaluate treatment effectiveness for broader populations, including populations that are underrepresented in RCTs, enabling longer follow up periods and being able to view the entire patient trajectory. We see that in the long term, the implementation of value-based cancer care through RWE will aid in reducing the growing burden of cancer treatment in Europe and beyond.

4. As an applicant, what advice would you have wanted in the Horizon project design process? What support did you receive from National Contact point (NCP) and your organisation, and what improvement of support would you benefit from?

Pekka Kahri, ONCOVALUE Project coordinator, HUS, shares that Helsinki university hospital invited partners to the ONCOVALUE consortium and initiated the proposal preparation as the coordinator. Early identification of the potential Horizon call topic and an early start of the proposal preparation and discussion with key consortium partners was instrumental to success. At HUS, we got support from the dedicated EU Affairs Manager, who follows the Horizon work programme development, analyses draft call documents, and interacts with the NCPs to ensure that interested parties within organization can grasp potential opportunities. During proposal preparation, a multidisciplinary team with clinicians, IT experts, and project management professionals could dedicate time to prepare and develop the proposal. To support the proposal phase, we hired an

external consultant, whose role was important especially when the proposal deadline was approaching.

Difficult parts in the proposal preparation and later in project execution relate to e.g. best practises regarding data sharing and federated analytics, how to approach legal challenges in EU-funded projects, how to plan and integrate validation activities into the project, and how to collectively define measurable impact in the proposal. Also differences in organizational cultures, varying readiness to public-private collaboration, and difficulties in finding common language in multicultural and multidisciplinary consortium must be considered and managed both during proposal preparation and project execution phase.

5. Please highlight aspects of your Horizon project's strengths that you consider important and that may constitute good practice for other applicants.

Executing the ONCOVALUE vision requires broad collaboration among all consortium partners and active engagement with important stakeholders to ensure relevance of project results. We see that a strength in our consortium is the collaborative spirit we have and the open policy we promote, which breaks down the tendency to work in silos. We believe that cultivating such an atmosphere is good practice already in the proposal phase, as it will then carry through to the implementation. Similar communication is also crucial in stakeholder engagement, which there cannot be too much of.

It is also important to engage with other initiatives with similar goals to learn from each other and avoid duplicating efforts. ONCOVALUE is actively engaging with the MetReal cluster, which includes six EU-funded projects funded under the same call: 'New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment'. The cluster is seeking for collaboration opportunities, utilising each other's knowledge and strengths. This is also good practise and encouraged by the EU.

