CALL FOR EXPRESSIONS OF INTEREST – Validation of solutions developed in the ONCOVALUE project

The ONCOVALUE project is offering an opportunity to start working with Electronic Health Records (EHRs) based Real-World Evidence (RWE). We are looking for additional OECI cancer hospitals to participate in the validation of the solutions developed within the project.

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 clinics to collect, harmonize and analyse high-quality Real-World Data (RWD) in real-time, supporting cost-effectiveness evaluation of novel cancer therapies.

The project duration is from December 2022 to November 2026 with a total budget of 7M€. The project is funded by the European Union under the call 'HORIZON-HLTH-2022-TOOL-11-02: 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 ONCOVALUE project is currently looking for additional OECI cancer centres to participate in the validation of the solutions developed within the project. The selected centres will receive some financial support from ONCOVALUE for work that will take place during 2025 and 2026. The validation aims to demonstrate the validity of the solutions developed in the project in different European cancer centres.

1.1 PROJECT SUMMARY

ONCOVALUE aims to unlock the full potential of digital sources for RWD collected in European cancer hospitals to ease health regulatory and health technology assessment (HTA) decision-making on cost-effectiveness of novel cancer therapies. To achieve this, we build up data collection and processing capabilities of leading European cancer hospitals to create high-quality clinical, quality of life, and adverse events data-sources. With the use of powerful Artificial Intelligence (AI) technologies, we will transform unstructured data originating from medical notes and medical images into structured data to enable analytics and RWE. By opening the door to widespread regulatory and HTA integration of hospital RWD, ONCOVALUE could lead to safer, more efficient, and affordable therapies, technologies, and digital solutions for cancer care. As such, ONCOVALUE is positioned to contribute to increased cost-effectiveness and subsequent sustainability of cancer care.

More information can be found through the following links: ONCOVALUE website and ONCOVALUE LinkedIn.

Project partners

HUS Helsinki University Hospital (FI), Stichting Het Nederlands Kanker Instituut-Antoni van Leeuwenhoek (NKI-AVL) (NL), Rigshospitalet Copenhagen University Hospital (DK), Istituto Romagnolo per lo Studio deiTumori "Dino Amadori" (IT), Instituto Português de Oncologia do Porto (PT), STICHTING RIJNSTATE ZIEKENHUIS (NL), Siemens Healthineers AG (GER), IQVIA Solutions BV (NL), BC Platforms LTD OY (FI), CIAOTech Srl (IT), TTOPSTART BV (NL) and Elevate BV (NL)

1.2 WHAT WE ARE LOOKING FOR

The ONCOVALUE project is looking for additional OECI cancer hospitals to participate in the validation of (at least one of) the following solutions developed within the project:

1) Guidelines and standard operating procedures (SOPs) developed for the collection and processing of structured RWD.
2) Testing the various steps/elements in the Hybrid RWD-based HTA framework to assess effectiveness and cost-effectiveness of new interventions in the real world.
3) AI-tools for automatic extraction of structured information from unstructured data, specifically from medical images and text from medical reports.

Validation is conducted by pilot studies in the breast cancer setting or in the non-small cell lung cancer (NSCLC) setting. The breast cancer study aims to validate the hybrid RWD-based HTA-framework to estimate the cost-effectiveness of immunotherapy (pembrolizumab) compared to the standard of care as neoadjuvant treatment in patients diagnosed with early-stage triple-negative breast cancer (TNBC). The applicant-centre could either apply only for the standard of care arm or immunotherapy or both. The study also aims to apply the AI-tool developed for medical images to follow the progression of the disease to metastatic stage in a sub cohort of this group of patients.

The lung cancer study, using the guidelines and SOPs developed for the collection and processing of structured RWD, and the AI-tool for text from medical reports, primarily aims at replicating a clinical trial setting that includes patients with mutation-positive advanced NSCLC and who were treated with TKIs with those obtained in a real-world setting similar to that of the clinical trial.

Not all validation objectives are required to be met by all participating hospitals. The level of validation depends on the interests, capacity and capabilities of the applicant cancer centre**.** For example, participation in the proposed validation of the developed AI-tools is optional. However, each new participating centre is expected to provide either aggregated analysis results or anonymized/pseudo-anonymised patient-level data according to provided study protocols. The specific level of anonymity for shared data will be determined individually with each selected centre.

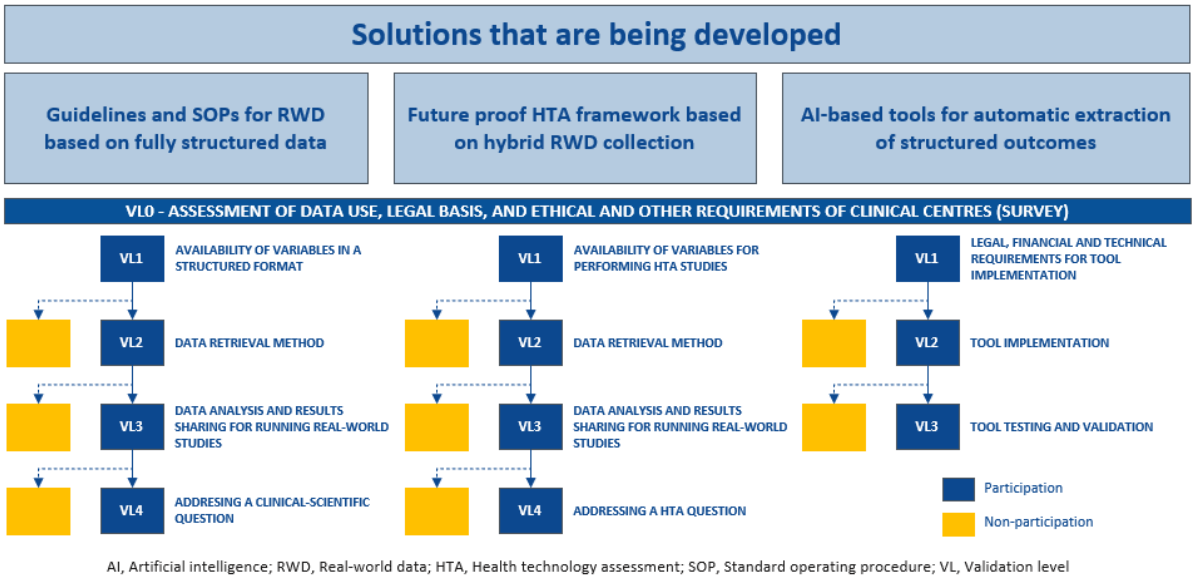

Figure 1. Developed solutions and levels of validation

Each new centre may be involved in

- **The lung cancer pilot study,** after obtaining required approvals (e.g. ethical committee (EC) approval), providing following results:
  - Identification of key structured data (inclusion/exclusion (I/E) criteria, baseline characteristics, treatment information and longitudinal outcome data)
  - Data extraction and Data Quality Control (DQC) activities
  - Analysis and sharing of aggregated or anonymised/pseudo-anonymised results
- **The breast cancer pilot study,** after obtaining required approvals (e.g. EC approval), providing following results:
  - Identification of key structured data (I/E criteria, baseline characteristics, treatment information and longitudinal outcome data and cost data)
  - Data extraction and DQC activities
  - Analysis and sharing of aggregated or anonymised/pseudo-anonymised results
  - Providing experts' opinions for AdViSHE framework validation purposes through interviews. Foreseen expert roles include clinician/oncologist, health economist and/or IT expert

The specific activities the selected centres will participate in will be defined in collaboration with them in the contract preparation phase.

1.3 CRITERIA FOR PARTICIPATING SITES

Criteria for participation are listed below. Please note that the required criteria are linked to the extent of activities performed by the hospital, which will be separately agreed upon (see section 1.2). **The first three requirements are to be met by all applicants**. The rest of the criteria are optional and fulfilling them is considered to the applicant's advantage. Applicants are requested to confirm that the listed criteria are met during the application process.

- **Member of the Organization of European Cancer Institutes (OECI) offering treatment for breast cancer and/or lung cancer patients**
- **Electronic Health Records (EHRs), preferably from at least 2015 onwards**
- **Ability to dedicate or consult a data analyst and/or expert for data curation and running R analysis scripts (if needed) as well as a clinician for participation duration**
- Expertise in participating in multicentric and/or international RWD studies
- Presence of and possibility to link and analyse data on costs of the total patient trajectory in the hospital
- Expertise in ETL (Extract, transform, and load)
- Use of quality of life questionnaires in standard clinical practice or data available from previous studies, preferably EQ-5D, 15D or EORTC-C30
- **Optional:** ability to adopt and utilize AI tools for images and/or text
  - **Availability of multiple longitudinal CT images** from breast cancer patients with metastases in lung and/or liver (preferably full body CT scans, minimum requirement is that the lung and liver are visible). The number of images is to be negotiated, the amount needed is in the hundreds. Availability of a powerful GPU workstation with capabilities to run AI tools on exported images via Docker or Python (hardware requirements to be further discussed), or the possibility to transfer images (data transfer agreement required).
  - **Variety of clinical notes** for text AI tool validation in Dutch or in Finnish. Availability of an inference server (hardware requirements to be further discussed) where the AI can be run on exported texts. The possibility of transferring texts could be discussed (data transfer agreement required).

1.4 WHAT WE CAN OFFER

The selected hospitals will join our pioneering research. They will develop their own RWE production and HTA capabilities as well as gain experience about novel AI tools being developed in the project. Participation offers a unique opportunity to engage with the ONCOVALUE consortium with learnings after exploring the processing and utilisation of real-world hospital data for over two years. The new sites may benefit from the consortium's expertise and experience while contributing to further research. Additionally, participation provides potential scientific co-author opportunities for interested parties.

The project will fund the validation activities based on the level/extent of validation and the income level of the participating hospital. ONCOVALUE is looking to acquire 3-5 additional clinical sites with approximately 30.000 – 60.000 € validation budget per site. The exact budget will be negotiated with the selected hospitals.

1.5 HOW TO APPLY/CONTACT US

Interested cancer centres can apply by following the below steps:

1. Express interest by contacting ONCOVALUE Project Manager Nea Hellman via email at nea.hellman@hus.fi while the call is open.
2. Accept terms for application*.
3. Fill in the provided survey by March 9th, 2025 (a link will be shared via email).
4. The survey results are analysed by the project and potential centres are selected based on the results.
5. Selected centres are contacted, and exact extent and terms of participation are agreed upon.
6. Studies are initiated in the selected centres.

**Completion of the survey (step 3) does not guarantee participation in the ONCOVALUE project as centres will be selected based on the analysis of the survey results. Filling in the survey is a requirement for consideration. The estimated time to complete the survey is 20 minutes. The ONCOVALUE project reserves the right to utilize the survey responses in an aggregated format also for centres that are not selected for further participation.*

The call for expressions of interest is open from February 10th, 2025, until March 9th, 2025, during which time interested centres will be granted access to fill in the application survey which is a requirement for participation. Survey results are to be submitted before the call closes. The selected centres will be contacted by approximately end of March 2025, and the first studies will be initiated in the selected centres around May 2025.

Before applying, please ensure support from the appropriate level of management to be able to enter contract preparations if selected.

With any additional questions or requests for clarification, please contact nea.hellman@hus.fi.

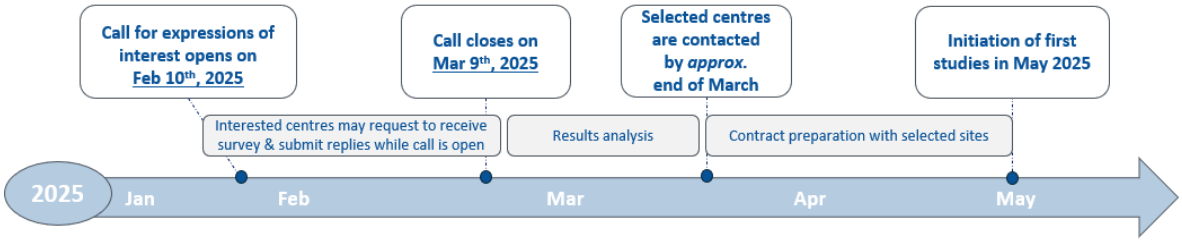

Figure 2. Planned timeline for expressions of interest and study initiation