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ONCOVALUE Project Update

Progress Across Work Packages

ONCOVALUE has continued to make substantial progress toward its overarching goal: enabling value-based oncology care through high-quality real-world data (RWD), AI-supported analytics, and a future-proof HTA framework. Below is an overview of developments across the project's work packages.

Guidelines, standards, and SOPs for RWD collection based on fully structured data

WP1 continued strengthening the structured, real-time collection of oncology data using breast cancer and non-small cell lung cancer (NSCLC) as primary test cases. Validation work focused on concrete clinical use cases, including metastatic breast cancer and colorectal cancer, helping to test how structured data entry performs in real clinical settings. While some operational challenges have slightly delayed the final validation steps, the work has already generated valuable insights into what it takes to integrate structured RWD collection into daily hospital practice. The core achievement of WP1 remains the delivery of comprehensive guidelines and standard operating procedures (SOPs) that describe how structured oncology data can be collected, processed, and analyzed. These guidelines are designed as a practical blueprint for other cancer centres wishing to embed structured data practices into routine care. An exploratory effort to map quality-of-life instruments in breast cancer patients proved infeasible due to unavailable legacy datasets and methodological limitations. Importantly, this does not affect the broader objectives of the project.

Working towards a future proof HTA framework based on hybrid RWD collection

WP2 has made significant strides toward creating a European-oriented framework for RWD-based health technology assessment (HTA). A key milestone was the development of a structured approach to defining "Minimum Data Blocks" - the essential data elements required to perform robust HTA analyses using hospital-derived real-world data. This approach was tested in pilot contexts in lung and breast cancer and follows a clear logic: start by defining the decision problem, identify the necessary variables for comparability and validity, and validate the selection with clinical experts. The result is a more harmonized and transparent basis for RWD-informed HTA across institutions. At the same time, a broad expert consensus process helped shape the future-proof HTA framework itself. Structured around four pillars - real-world hospital data, methodology, advanced technology, and ethical/legal considerations - the framework reflects both technical requirements and organizational realities. Most consensus statements were validated through the Delphi process, with remaining elements being refined into practical tools such as data-quality checklists and decision flowcharts for AI use. Internal cost-effectiveness pilots are progressing, with cleaned datasets and modelling strategies in place.

External pilots are beginning to integrate data from multiple centres. Engagement with the European Medicines Agency (EMA) is planned once the framework is fully finalized and supported by concrete use cases.

AI tools for automatic extraction of structured outcomes

WP3 has delivered some of the project's most technically advanced progress, focusing on AI tools that transform unstructured clinical data - both medical images and free-text reports - into structured, analyzable information. On the imaging side, a high-quality annotated dataset of longitudinal CT scans in metastatic breast cancer was completed, enabling the development of an automated pipeline for disease progression assessment. The system integrates lesion detection, tracking, and classification aligned with RECIST principles, with methodological improvements that significantly enhance lesion matching across time. The work has expanded toward multi-organ analysis and has been presented at leading international conferences. On the text side, multilingual natural language processing (NLP) models are being trained to extract clinically relevant variables from medical reports. Annotation work in Finnish breast cancer reports has already supported the development of an initial NLP model, with promising early performance results, particularly in extracting measurements and contextual information. Work at additional sites is ongoing, supported by large-scale pseudonymization and structured annotation processes. Deployment planning has also begun, including the technical infrastructure and user interface concepts needed to bring these AI tools into clinical environments for validation.

Demonstrating the implementation and validity of developed solutions in different European cancer centres

WP4 is where ONCOVALUE's solutions come together in practice. Two pilot studies - one in breast cancer and one in lung cancer - were designed to test the full chain: structured data collection, hybrid HTA analysis, and AI-supported outcome extraction. A comprehensive feasibility assessment across participating centres revealed important heterogeneity in data availability, legal frameworks, ethical approvals, and data-sharing practices. Differences in access to cost data and patient-reported outcomes, in particular, highlight the complexity of conducting multinational RWD-based studies. To address this, the consortium developed a multi-level validation strategy built around four core dimensions: data availability, quality, usability, and usefulness. Rather than relying on a single definition of "validation," this approach recognizes technical, methodological, and process aspects. WP4 also refined its vision for advanced analytics. Instead of developing a standalone dashboard - which would have limited real-world integration potential - the project is moving toward publishing transparent, well-documented analytical workflows in a public code repository. This ensures reproducibility, scalability, and practical relevance for clinicians, researchers, and HTA bodies alike. Ethical approvals for the pilot studies have been secured at coordinating sites, and broader implementation is progressing.

Infrastructure for RWD reporting in regulatory/HTA decision-making

WP5 continued building the technical and governance backbone required for federated, standards-based RWD use in regulatory and HTA contexts. Progress on OMOP Common Data Model implementation varies across centres, reflecting different starting points, but steady advances have been made in oncology-specific mapping, ETL pipelines, and data quality validation. A federated data network has been successfully established and technically validated, demonstrating the feasibility of

harmonized querying across centres. Even though not all hospitals could be connected within the reporting period, the federated use case has been effectively proven using both real and harmonized mock datasets. Work on data quality has increasingly aligned with the evolving European Health Data Space (EHDS) landscape. The project is contributing to discussions on governance, interoperability, and secondary use, ensuring that ONCOVALUE's approach remains aligned with European regulatory developments.

Trainings and guidelines for the collection, management, and analysis of RWD by HTA/regulatory bodies

WP6 has taken an important turn during this reporting period. After the unexpected disruption caused by the bankruptcy of the original lead partner, the consortium paused to reflect not only on how to move forward, but also on what would truly work in everyday clinical settings. It became clear that traditional, full-scale online training programmes were unlikely to meet the needs of busy cancer centres and HTA professionals. Clinicians are working under significant time pressure, and long, formal courses are often difficult to integrate into routine practice. Instead, WP6 is now moving toward a more practical and flexible approach. The focus is shifting to raising awareness and providing short, easy-to-use materials that can genuinely support daily work. This includes concise guidance documents, practical example templates, and short video explainers tailored to both hospital staff and HTA bodies. The aim is to make the project's tools and frameworks understandable and usable without adding unnecessary burden. To ensure continuity and fresh momentum, the Netherlands Cancer Institute (NKI) has stepped in as the new WP6 lead. With this renewed leadership, the work package will continue developing and refining these materials, keeping the approach realistic, supportive, and aligned with the overall goals of ONCOVALUE.

Dissemination, exploitation, and sustainability of the project outcomes

Activities within WP7 have remained strong. ONCOVALUE results have been shared through newsletters, media outreach, conference presentations, cluster collaborations, and ongoing website and social media updates. The project has actively engaged with other EU-funded initiatives working on real-world data and regulatory innovation, contributing to joint workshops and guidance outputs. Market and technology monitoring activities have advanced, including structured evaluation of key exploitable results and preparation for a sustainable business model beyond the project's lifetime. Planning for the final symposium is underway, with major European congresses under consideration.

Project management and coordination

WP8 have remained steady throughout the reporting period, even during moments of change. In August 2025, the role of Project Manager transitioned to new leadership, marking an important shift within the coordination team. The updated structure has since stabilized well, and collaboration across work packages continues to function smoothly. Regular governance meetings and close communication between scientific, technical, and clinical teams have helped maintain alignment and momentum as the project moves into its later stages. In parallel, ONCOVALUE continues to follow developments at European level that are relevant to its objectives. Work under Task 8.6 focuses on monitoring progress related to the European Medicines Agency (EMA) and the European Health Data Space (EHDS), ensuring that the project remains aligned with evolving regulatory and data governance frameworks. While interaction is not continuous, the consortium maintains contact opportunities and participates in

relevant discussions where appropriate. This ongoing monitoring and occasional exchange help ensure that ONCOVALUE's frameworks, infrastructure, and governance approaches remain consistent with broader European policy and regulatory developments.

Ethics requirements

WP9 continues to be an integral part of ONCOVALUE. The project's Ethics Advisory Board meets annually in a joint session with the Scientific & Clinical Coordination Group, providing a structured opportunity to review progress, reflect on emerging challenges, and offer guidance. The resulting yearly ethics reports summarize the key observations and recommendations discussed during these meetings and support the project's continued ethical alignment as it evolves. Importantly, the reports do not focus solely on project-specific matters. They also address broader European-level considerations that shape real-world data use, AI development, and cross-border research. Recent reflections have highlighted issues such as potential selection bias arising from differences in consent procedures across countries and the impact of restricted access to training data on AI model development and validation. By placing ONCOVALUE's activities within this wider regulatory and ethical landscape, the Ethics Advisory Board helps ensure that the project remains not only compliant, but also responsive to ongoing developments in European data governance and responsible innovation.

ONCOVALUE Partners