



CARDIOVASCULAR Risk Assessment via multimodal data analysis enabling personalised prevention strategies targeting MENOPAUSAL women

CAMEL 2nd Project Brief

One year after its official launch in December 2024, the CAMEL project has made significant strides toward its objectives. This document provides a concise overview of the main achievements delivered by each Work Package (WP) during the first project year. It also outlines the strategic goals set for the upcoming six months, paving the way for continued innovation, validation, and impact across CAMEL's multi-disciplinary framework.



WP1 - Project management & coordination

2nd semester achievements

- Full operationalization of the governance framework: Steering Committee (SC), External Advisory Board (EAB), Gender, Legal, Ethical and Data Committee (GLED), Technical Management Team (TMT);
- Finalisation of essential data protection documentation, specifically the Data Protection Impact Assessment (DPIA) and the Joint Controllership Arrangement (JCA);
- Continued operationalisation of the GLED Committee, ensuring ongoing oversight of gender, legal, ethical, and data protection dimensions;
- Publication and internal dissemination of the project's Authorship Guidelines, promoting transparency and proper attribution in collaborative outputs;
- Roll-out of the tailored Gender in Research Training Programme, now available to all partners;
- Enhanced engagement with the External Advisory Board, with structured inputs contributing to project direction and scientific validation;
- Progress towards formal collaboration with CoroPrevention, with a Memorandum of Understanding (MoU) currently in preparation;
- Successful implementation of the 3rd Project Meeting, held in Sevilla, Spain, fostering strategic alignment and operational planning for the next semester.



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Goals for the next 6 months

- Implementation of the Semester 3 Work Plan as agreed during the Sevilla meeting, ensuring alignment across all WPs;
- Continuation of EAB engagement, with an updated interaction plan to extend into 2026;
- Finalisation and formal signing of the MoU with CoroPrevention, enabling structured collaboration on common goals;
- Initiation of the preparation process for the 1st Periodic Report (PR1), covering project activities and results from M01 to M20, in alignment with Horizon Europe reporting standards.

WP4 - Lived experience, requirements, co-creation and design

2nd semester achievements

- The CAMEL-WOMEN Survey was successfully completed, collecting responses from 7,470 women across clinical sites. A preliminary quantitative analysis has been conducted. Additionally, 122 women and healthcare professionals (HCPs) have participated in qualitative interviews; while analysis is still pending, interviews with clinical experts are currently in progress;
- Two Systematic Reviews are underway, focused respectively on: cardiovascular risk factors in women aged 40–60, and self-assessment methods for cardiovascular disease risk;
- The Patient and Public Involvement (PPI) Committees have been activated in most clinical sites, supported by newly developed co-creation guidelines;
- Guidelines for the first round of co-creation workshops have been finalised to guide the upcoming participatory design phase of the CAMEL digital tools.

Goals for the next 6 months

- Complete the quantitative analysis of the merged data from the CAMEL-WOMEN Survey and prepare findings for publication;
- Finalise the qualitative data collection with clinical experts and initiate analysis of interview content;
- Continue PPI Committee meetings across clinical sites and organise the first Network Committee Meeting to enhance cross-site exchange;
- Launch the 1st round of 4 co-creation workshops involving women and healthcare professionals to inform the design of the CAMEL digital tools;
- Ensure inclusive design practices throughout the co-creation process, with special focus on addressing the needs of women with intellectual disabilities;



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- Finalise and publish the 2 ongoing Systematic Reviews, contributing to the evidence base on cardiovascular risk factors and self-assessment in women aged 40–60.

WP5 - Multi-source data capture

2nd semester achievements

- The Data Capture Pilot was successfully implemented, validating the data collection workflows and tools;
- Technical setup and integration of wearables, skin patch devices, and eye fundus imaging were finalised across clinical sites;
- Retrospective studies have been initiated, with data collection and processing underway;
- Key themes and domains for the lifestyle questionnaires were identified, paving the way for harmonised data collection on behavioural risk factors;
- Patch devices have been delivered to all clinical sites, accompanied by secure access credentials and detailed usage guidance;
- An experience sampling methodology was designed to capture real-time self-reported data on lifestyle and behavioural patterns;
- A complete suite of user manuals and training videos was developed and disseminated to ensure consistent procedures for device usage and data collection across all sites.



Goals for the next 6 months

- Ensure delivery of the full quantity of patch devices to all clinical sites;
- Launch the measurement phase across all sites using the finalised skin patch and the



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dedicated patch app;

- Provide continuous technical support and troubleshooting to clinical sites throughout the measurement campaigns;
- Expand and test the data ingestion pipelines and initiate the first secure data transfers to the centralised CAMEL platform.

WP6 - Retrospective AI modelling

2nd semester achievements

- The initial modelling pipeline integrating multimodal data sources was defined, setting the stage for structured AI development across the project;
- Access to multiple cohort studies advanced, enabling preparation for data-driven model training and validation;
- Retrospective data auditing activities progressed, and guidelines for data extraction were formalised to ensure methodological consistency;
- First data outputs from the CAMEL Retrospective Study will soon be available via the CAMEL platform;
- The preliminary risk stratification framework was reviewed and refined, with prioritisation of key multimodal data inputs, including biomarkers, imaging, wearable data, and psychological assessments;
- A dedicated workshop was held in Sevilla, engaging the consortium in the co-design of a Personalised Prevention Program (PPP) tailored to menopausal women aged 40–60;
- A second internal workshop in Sevilla explored how AI models could support both opportunistic and proactive screening approaches, including self-assessment tools.





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Goals for the next 6 months

- Conduct data preparation, harmonisation and curation of retrospective datasets, including EHR and external cohorts;
- Initiate first AI model prototypes using data from external cohorts or biobanks;
- Identify relevant features and train baseline AI models on time-series data, particularly ECG data from implantable devices;
- Advance image data collection and standardisation, and develop an initial predictive model based on imaging;
- Perform exploratory analysis, anomaly detection and stress indicators extraction using the AllofUs dataset; finalise the anomaly detection model;
- Integrate iBreve wearable data into the modelling pipeline;
- Begin ingestion of real-world data from WP5, testing the full modelling pipeline on retrospective EHR datasets;
- Assess model performance and fairness, evaluating potential biases and refining algorithms as needed to ensure equity and robustness.

WP9 - Digital platform & ecosystem

2nd semester achievements

- The baseline architecture was successfully deployed on the production server, establishing the core infrastructure of the digital platform;
- Foundational knowledge models and evidence-based approaches were defined to support intelligent data interpretation and personalised recommendations;
- Ingestion interfaces were implemented and the data lake is fully operational, ready to receive multimodal datasets from WP5 and WP6;
- The CAMEL Self-assessment App (asApp) is currently under design, including experience sampling elements and lifestyle questionnaires integrated with the CVD Prevention Portal;
- The App for data capture and lifestyle monitoring is undergoing testing in selected pilot sites, validating usability and data collection workflows.

Goals for the next six months

- Implement access control, data privacy, and cybersecurity mechanisms across all components of the platform;
- Deploy the CAMEL Research Environment to enable secure data analysis and model training by project partners;
- Finalise, test, and deploy the asApp on the Google Play Store, making it available for user interaction;
- Complete full integration of the Digital Platform components and conduct thorough verification and testing to ensure readiness for data-driven studies.



WP11 - Prospective clinical studies (CAMEL-OS)

2nd semester achievements

- The design and protocols of the Prospective Clinical Studies were finalised, aligning clinical, ethical and methodological requirements across participating sites;
- The CAMEL Observational Clinical Study I (CAMEL-OS) was officially launched, supported by the delivery of the full initiation package, including registration information, study protocol, and Ethics Committees approvals across all sites;
- The CAMEL biobank was set up, with procedures for sample management and analysis established to support biomarker identification and validation;
- A consortium workshop was held in Sevilla to explore key variables potentially influencing cardiovascular risk in women, and how these may be integrated into the CAMEL stratification framework.



Goals for the next 6 months

- Refine clinical Key Performance Indicators (KPIs) based on findings and inputs from WP4, WP5 and WP6;
- Continue the implementation of the CAMEL-OS study and begin continuous monitoring of clinical activities;
- Begin continuous monitoring of clinical activities and ensure alignment with relevant policy objectives and targeted clinical outcomes.



**CARDIOVASCULAR RISK ASSESSMENT VIA MULTIMODAL DATA ANALYSIS ENABLING
PERSONALISED PREVENTION STRATEGIES TARGETING MENOPAUSAL WOMEN**

WP14 - Communication, dissemination and exploitation

2nd semester achievements

- The Communication, Dissemination and Exploitation (CDE) Plan has been continuously implemented across all work packages and target audiences;
- Development of flyers for the CAMEL Observational Study (CAMEL-OS), targeting both women and HCPs, is ongoing;
- The first project newsletter was issued, highlighting early achievements and future milestones;
- The engagement strategy for the CAMEL-Women study was successfully executed, supporting wide outreach and participation;
- The first requirement analysis for the CAMEL CVD Prevention Portal was completed and analysed. The second requirement analysis is in progress, supported by the first session of co-creation workshops and two questionnaires shared with women and HCPs of the PPI committee. A first low-fidelity mockup of the Portal has been designed and approved;
- Awareness and training materials for the CVD Prevention Portal are currently under development.

Goals for the next 6 months

- Finalise the second requirement analysis for the CAMEL CVD Prevention Portal, analyse the results, and develop a high-fidelity mock-up for the next co-creation workshop; proceed with the implementation of the Portal;
- Develop and publish awareness and training materials on the Portal to support user engagement and adoption.
- Prepare communication assets and tools to support the dissemination of scientific results and policy-relevant findings, based on emerging needs identified during the semester;
- Continue clustering and networking activities with related EU projects and stakeholder networks, based on opportunities that arise.

