Establishment of ctDNA as a biomarker in melanoma follow-up

Project Start: January 1st, 2026

Enrollment: at least 200 patients

Duration: 1 year

Objective

- Evaluate the value of circulating tumor DNA (ctDNA) by as a biomarker for detection and relapse
- Replace or complement other monitoring methods (e.g., S100)
- Establish a standardized approach for ctDNA assessment

Project Design

Type: multi-center EADO–EUMelaReg project

Site inclusion criteria:

- BioRad QX200™ or QX600™ infrastructure
- Accredited medical laboratory according to local standards e.g., ISO15189
- Access to EUMelareg (can be granted for this specific project only)

Patient inclusion criteria:

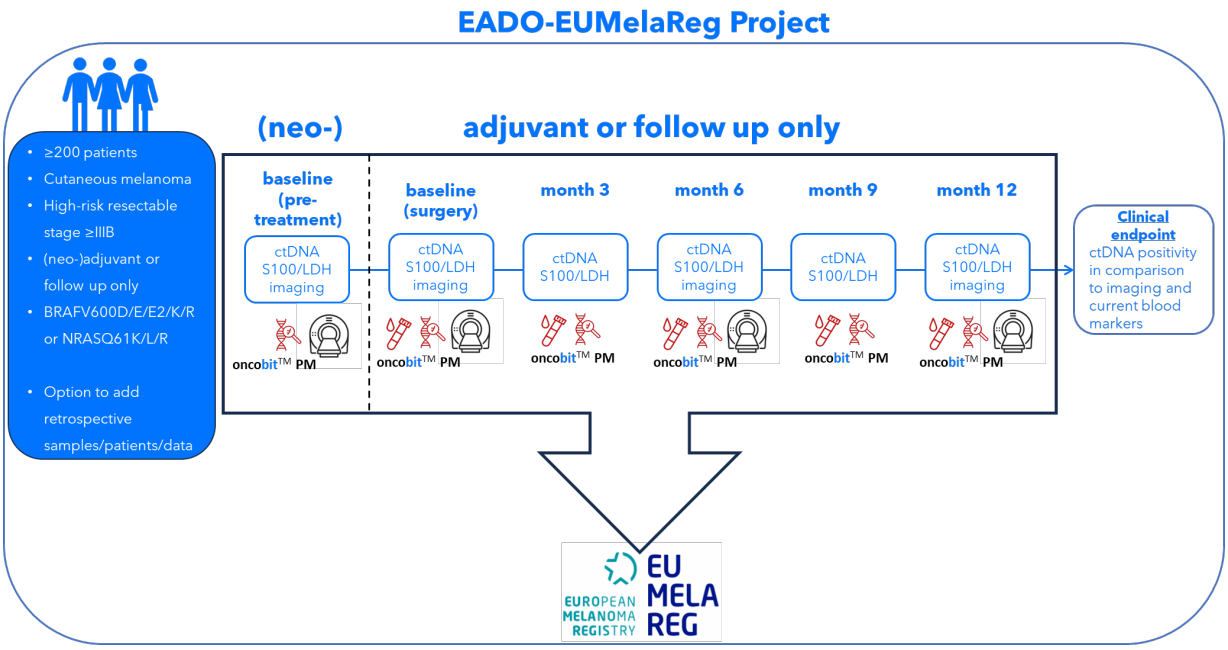
- High-risk resectable cutaneous melanoma, AJCC stage IIIB or higher
- Confirmed mutations that are covered with Oncobit™ PM (BRAFV600D/E/E2/K/R or NRASQ61K/L/R)
- Signed consent to provide routine clinical data (according to local ethical standards)

Sampling time points (as part of clinical routine):

- Quarterly plasma collection for ctDNA analysis (or more frequently if patients are seen according to local standards and if feasible to do within the local routine clinical setting)
- S100/LDH and other markers if performed according to local standards
- Imaging according to local standards every 6 months
- Collection of clinical information including treatment information

Clinical Endpoints:

- % ctDNA positive in comparison to imaging, S100, LDH or other markers



Funding

Oncobit Contribution
Oncobit will provide centralized support for the ctDNA assessment of the project. Specifically, Oncobit will fund:

- **Oncobit™ PM kits and cloud-based analysis software**: Provided together as a **CE-IVDR certified system**
    - **Digital PCR kits**, including positive controls, are optimized and designed for mutation-specific detection
    - The **software platform** enables secure upload, standardized analysis of digital PCR data, and automated reporting with mutation allele frequency (MAF), variant calls, and quality metrics

Participating Site Contributions
Each participating clinical site is responsible for the operational aspects of patient management and sample processing. Specifically, sites will fund:

- **Sample collection**: Blood draw and plasma separation.
- **DNA extraction**: Using site-validated methods suitable for circulating free DNA (cfDNA).
- **Execution of digital PCR**: Running Oncobit™ PM assays on BioRad QX200™ or QX600™ platforms.
- **Clinical data collection and management**: Data regarding clinical routine needs to be added to the EuMelaReg database (treatment documentation, imaging results, blood biomarker results). Sites are responsible for internal project protocol/IRB approval if needed according to their local standards.

Contact

For further information regarding this clinical project or interest in participation, please contact Prof. Dr. Reinhard Dummer or Dr. Claudia Scheckel, or complete the feasibility form.