

# Risk stratification and prediction of locoregional recurrence in OSCC: the OraMark project up-dates and refines the Neomark project results.

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## Background

In patients affected by oral squamous cell carcinoma (OSCC) locoregional recurrence following treatment (25-48%) represents the most common cause of death for patients and have an important impact on physical appearance and function.

## Aims

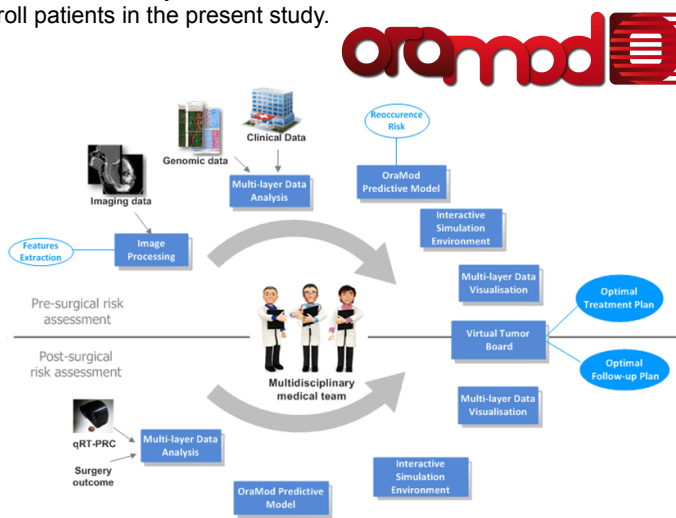
The OraMod project (ICT VPH based predictive model for oral cancer reoccurrence in the clinical practice, Seventh Framework Program, CE) focuses on the implementation of 'omics'-based predictive systems from the lab bench to the bed side using risk models on basis of clinical, histological, imaging and genomic markers to help clinicians to predict oral cancer reoccurrence. The project continues the research conducted by previous FP7-EC-funded NeoMark project, which produced a set of prognostic biomarkers and a gene expression signature significant for reoccurrence of oral cavity tumors, a disease more and more frequent and with a very high mortality rate. The OraMod project will ultimately result in a software tool based on the risk model for each individual patient to identify the patients at highest risk for disease reoccurrence at baseline, for whom personalized and specific therapeutic approaches could be adopted in a future scenario.

## Methods

Gene sets have been identified within the previous NeoMark project and will be updated and reanalyzed for OraMod. In this project the array technology will be replaced by an RT-PCR "lab-on-chip" system for most predicting genes. The RT-PCR set-up will be trained, verified in existing independent retrospective cohorts, and validated in a multicenter prospective trial. The validated gene sets will be combined with imaging predictors, histological and clinical parameters to build a risk model. Three university hospitals (VU University Medical Center in Amsterdam, Heinrich-Heine University Clinic in Dusseldorf and the Maxillofacial Surgery Unit of the University Hospital of Parma), will prospective enroll patients in the present study.

Partner name	Role
1- Maxillofacial Surgery Unit, University of Parma (HND), Italy	Project and scientific coordinator Clinical partner (Responsible for IPRs and Dissemination strategy, Clinical Assessment, Impacts assessment, Clinical study execution)
2-Stichting VU-VUmc, Amsterdam (VUMC), The Netherlands	Clinical partner (Developer of the Model, Responsible for Clinical Protocol and study design, Clinical study execution, Clinical Assessment, Impacts assessment)
3- Fraunhofer IGD, Department Cognitive Computing & Medical Imaging (Fraunhofer), Germany	Research partner (Technical R&D partner, responsible for the Image Analysis and features extraction)
4- STMicroelectronics s.r.l. (STItaly), Italy	Industry partner (Develops the qRT-PCR and lab-on-chip, Exploitation Manager and responsible for products certification roadmap)
5- Velti Kainotomes Epixeiriseis Anonimi Etaireia Kefalailou Epixeirimatikon Simmetoxon kai Ependiseon (VCI), Greece	Industry partner (development of the Knowledge-Assisted Visualization tools, the Simulation Environment and the Virtual Tumour Board tools)
6- OneToNet Srl (OneToNet), Italy	Industry partner (provision of the Platform infrastructure -ClinicalHub, Technical Manager, Responsible for the System Design and overall platform integratio)
7- Universitätsklinikum Dusseldorf - Department of Otorhinolaryngology (HNO), Germany	Clinical partner (Pilot Health Institution, Responsible for Ethical aspects, Clinical study, Clinical assessment, Impacts assessment)
8- Teknologian Tutkimuskeskus VTT (VTT), Finland	Research partner (Pilot Health Institution, Clinical assessment, Impacts assessment)

The OraMod Consortium: partners' involved and their role in the project.



Healthcare problem in OSCC: the future clinical solution proposed by OraMod.

## Discussion

OraMod will capitalise on and advance the research and development results of NeoMark on the areas of oral cancer modelling and medical image analysis in order to attain a restructured model fine-tuned to the reality of the clinical practice. This new model will be coupled with a novel environment and underlying services that will seamlessly integrate data coming from legacy systems while offering tailored visualisations and natural interaction methods. The project officially started in October 2013: gene selection, model building and new patients recruitment are proceeding fast so that we expect to have the final list of biomarkers by 2014.