

NeoMark

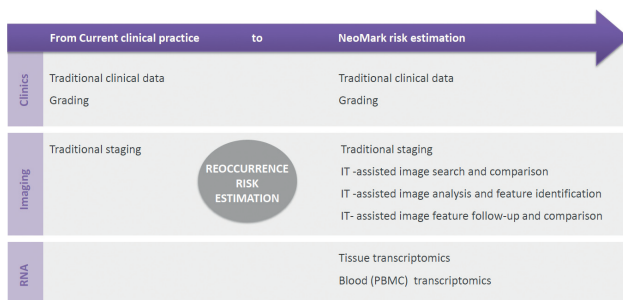
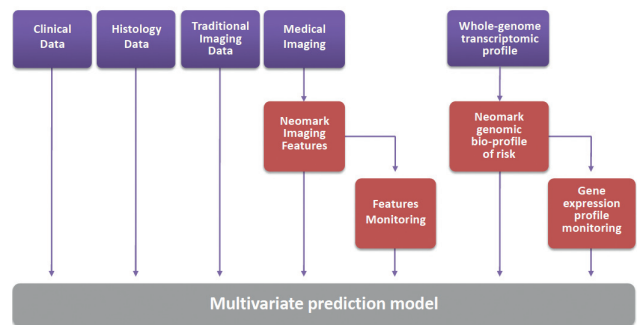
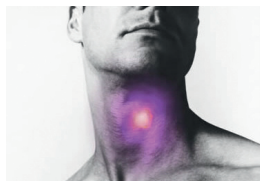
ICT Enabled Prediction of Cancer Reoccurrence

Improve management of highly invasive and recurring cancers through a computer-assisted risk stratification and disease evolution prediction system

NeoMark Virtual Physiological Human (VPH) approach integrating heterogeneous data collected with different techniques and in-silico representation, modelling and prediction of biological phenomena linked to the disease evolution, will improve significantly the management of oral cancers.

Clinical Problems

Oral Squamous Cancer Carcinoma (OSCC) holds the eight position in the cancer incidence ranking worldwide (World Health Organization mortality data), and is increasing among young citizens, with relevant social costs. Locoregional recurrence rates following treatment (ranging 25-48%) represent the most common cause of death for patients with oral cancer, and 95% of cases occur within 24 months from remission. Several factors correlate with the disease reoccurrence (e.g. age, sex, Human Papillomavirus infection, site and stage of primary tumour) but they have not been studied all together.



Neomark Scenario

A patient is diagnosed with an oral cavity cancer. His data are collected, blood and tissue samples processed to extract RNA genomic data, and diagnostic images are evaluated by NeoMark system. After the adequate treatment (surgery, chemotherapy, radiotherapy), NeoMark model compares pre- and post-treatment patient's data and identifies the relevant biological signature. For high-risk patient a chip is prepared and is used on a periodic basis to re-evaluate the presence of the disease signature in blood RNA, so anticipating the diagnosis of a possible reoccurrence even before any visible signs or symptoms appear.

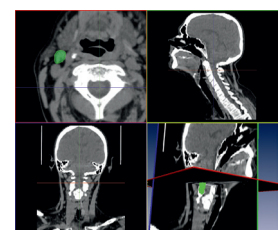
Neomark Approach

Analysing oral cancer patients' data (clinical, biomedical, genomic, histological, from digital imaging, from surgery evidence) before treatment and at the time of remission, NeoMark will extract the disease bio-profile. During patient's follow-up visits their bio-profile is compared with the bio-profile of the disease and to the bio-profiles associated with a high risk of reoccurrence. Patient's reoccurrence risk is determined or on-setting reoccurrence is detected even when diagnostic methods do not give evidence of it.

Neomark Innovation

NeoMark will consider the multiscale and multivariate data from clinical examinations, diagnostic images, genomic i.e. Ribonucleic acid (RNA) biomarkers extracted from both tissues and blood circulating cells at different times (follow-up visits) to assess the presence/absence of the disease bio-profile also before any visible signs of reoccurrence are detected.

NeoMark will also identify a limited subset of most relevant factors characteriz-

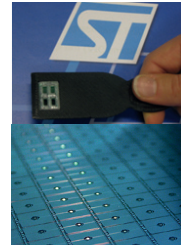


ing the disease. They will be included into a RT-PCR (Real Time Polymerase Chain Reaction) portable diagnostic device, usable for oral cancer recurrence screening purposes, so implementing the disease prevention strategies of European Health Systems.

INSTRUMENT

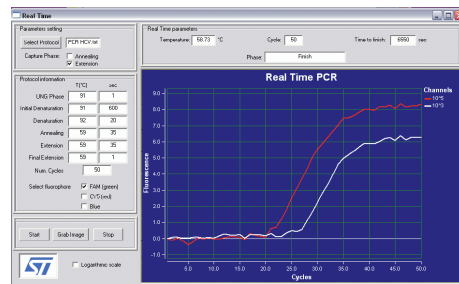


CARTRIDGE



BIOLOGICAL CONTENT

- ✓ Enzymes
- ✓ Primers
- ✓ Targets
 - Nucleic acid type: DNA/RNA
- ✓ Protocols
- ✓ Labeling dye: commercial FAM/TM or VIC® fluorophores

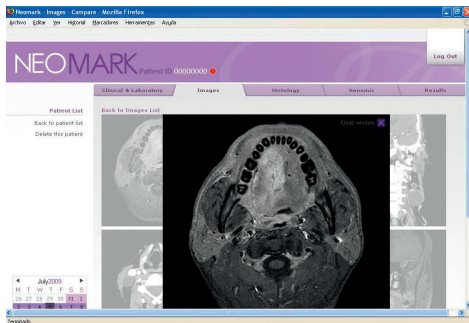


Pilot Study

The NeoMark approach is currently validated in an ad-hoc longitudinal clinical study with 18-month follow-up, in about 150 patients with complete disease remission after treatment. By comparing a sub-set of early relapsers and non-relapsers, bio-profiles associated with reoccurrence risk and current reoccurrence will be identified and then validated in the rest of the cohort.

Achievements

At present stage the NeoMark system is being trained with complete follow-up data from 56 patients and additional 30 with baseline data. The diagnostic image analysis tool is able to automatically evaluate the tumor volume and infiltration levels for both primary tumors and lymph-nodes. The RT-PCR chip is ready to test the RNA samples. The next step, for the end of the project, is a look-out on the possibility to identify a “patient-specific bio-profile” for oral cancer.



NeoMark contributes to Virtual Physiological Human (VPH) paradigm

NeoMark is the first attempt to develop a multifactor prediction system and methodology, based on gene expression from circulating cells, which can be analysed by a new portable and easily usable Real-Time PCR chip early detecting reoccurrence risk from blood RNA.

NeoMark provides a complete digital patients' dataset including: research and clinical database; image repository for image annotation, search, comparison; transcriptomic profiles of tumor and circulating cells.



NeoMark

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Partners:

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- Fraunhofer - Institut Graphische Datenverarbeitung (Germany)
- Link Consulting (Portugal)
- M.D. Anderson International España (Spain)
- MultiMed (Italy)
- Planet (Greece)
- STMicroelectronics (Italy)
- University of Ioannina (Greece)
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Timetable: from June 2008 to December 2010

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Instrument: STREP

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KEYWORDS

Oral Cancer, Reoccurrence prediction, Multifactor prediction, Disease bio-profile, Patients' data, Diagnostic device, Virtual Physiological Human (VPH)