Usage scenarios

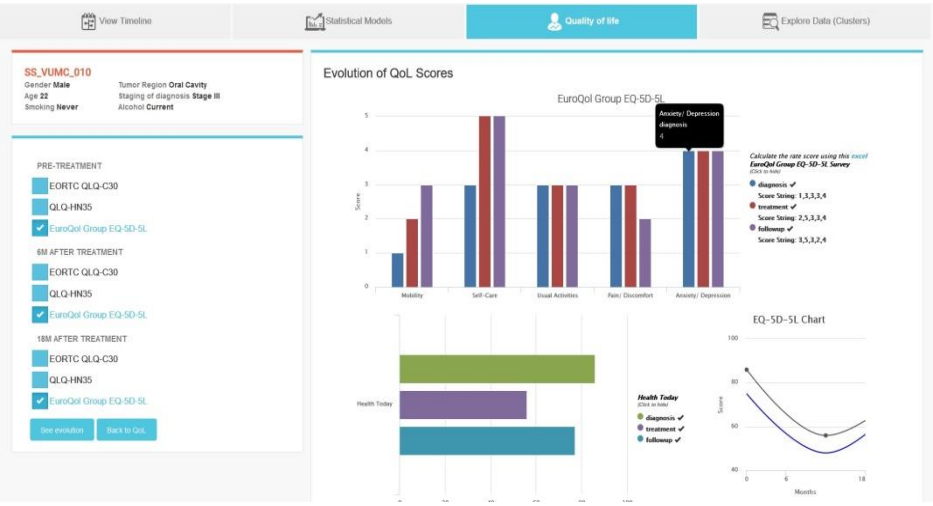
Who will benefit from BD2Decide, and how

BD2Decide will realize and validate an *Integrated Decision Support System*, providing clinicians with all the necessary tools and information to personalize treatment and care delivery to each and every head and neck cancer patient, in contrast to the current "one-size-fits-all" approach.

Several usage scenarios, presented below, may help to capture the actual benefits entailed by the Project, in addressing the needs of involved actors.

At diagnosis. BD2Decide collects all data from the patient's visit and radiological exam, as well as pathological tests when biopsies are taken. A dedicated Image Analysis software developed by Fraunhofer IGD will analyze CT and MRI scans, extract relevant tumor and lymph-nodes information and allow radiologists to identify affected areas. Radiomics features, i.e. information that characterize the tumor based on images, without the need of invasive inspections, will be extracted and recorded in the BD2Decide dataset by means of specialized tools developed by MAASTRO (Oncoradiomics®) and Milan Polytechnic. BD2Decide prognostic modelling immediately gives to the clinician a feedback regarding patient's prognosis in comparison to the standard staging system and to the average population survival curves and allows to compare outcomes probability of different treatments.

Treatment decision making. In current practice, patient's treatment options are discussed in a *Tumor Board session* involving different medical specialists. To facilitate multidisciplinary consultations BD2Decide provides tools for remote and asynchronous meetings through a "Virtual Tumor Board" based on videoconferencing. The system proposes an electronic



Big data for HNC

BD2Decide aims at providing solutions to a challenging clinical problem: personalizing treatment decisions for late stage head and neck cancer (HNC).

The strategy of the Project is to achieve such objective through the application of a "big data analytics" approach, that harnesses a large and diverse number of data sources, including population-specific epidemiology, behavioral and environmental data and patient-specific multiscale data from genomics, pathology, clinical and imaging repositories.

The system will integrate a number of software applications, to be used in daily clinical practice, from the first visit, to the evaluation of disease evolution, to the determination of the most effective therapeutic approach, throughout all the care path, up to the last follow-up visit.

After 24 months of work, the overall analysis of requirements and system specifications have been completed, and implementation has been started.

This Newsletter provides a view on the status of work and on expected benefits, building on information available from the Project's public deliverables.

The reader who is interested in obtaining more information is invited to contact us with no hesitation, at the coordinates given overleaf.

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agenda to define date, time, location and participants. Participants receive an automatic invitation. During the video-conference (or asynchronously, in case a specialist is not available at the time) all Tumor Board members access and share the patient's data, diagnostic images, radiomics and genomic profiles. They may run and evaluate the results of several BD2Decide prognostic models, as necessary to discuss the case. The results of the Tumor Board session (treatment decisions) are automatically recorded and digitally signed by the participants. A co-decision aid, available on tablet or PC will support the communications of treatment options to the patient and the explanation of reasons for treatment selection.

During follow-up. After therapy, BD2Decide supports the definition of a schedule for follow up care and generates a plan that can be printed out, for clinicians as well as for the patient. This plan integrates clinical investigations as well as laboratory and imaging investigations. The plan is changeable: suppose, for instance, that a lymph node metastasis has appeared in 8 weeks despite a low reoccurrence prediction by BD2Decide models. The software automatically "reacts" and intensifies the follow up schedule, suggesting new relevant imaging exams. Based on the new data, the clinician runs again the BD2Decide prognostic models and verifies how the prediction is changed.

Head and Neck Cancer: a brief intro

According to GLOBOCAN 2012 (http://globocan.iarc.fr), cancers of the head and neck region (*Head and neck cancer* – HNC) are the 6th most deadly tumors worldwide, with around 630.000 newly detected cases (of which 150.000 in Europe) and around 350.000 deaths every year (of which 70,000 in Europe).

HNC develops in the mucosal linings of the upper aero-digestive tract (oral cavity, larynx, oropharynx, hypopharynx). Over 90% are squamous cell carcinomas (*Head and neck squamous cell carcinoma* – HNSCC), arising from the epithelial cells on the mucosal surfaces of the head and neck.

HNCs are classically divided, according to their site of origin, in oral, oropharyngeal and laryngeal tumors, that differ widely considering risk factors and biological behavior, hampering the development of general prognostic models.

Risk factors for HNC are smoking, excessive alcohol consumption, and (more recently discovered) infection with the human papillomavirus (HPV).

Architecture

How the system is built

BD2Decide builds on emerging technologies for big data analysis and virtual representation of patients health data, that facilitate collaborative, objective, best informed and personalized decision-making.

The overall system architecture is composed of three layers: a *User Interfaces* layer, a *Models and Service* layer and a *Data layer*.

The **User Interfaces layer** enables end-user interactions with the BD2Decide system. It includes the following modules:

- A *Clinical Decision Support System*, comprising the Patient Documentation System and the Digital Patient Exploration Environment, that allow to access and interpret all patients' data in a comprehensive and consistent way. It also includes the Tumor Board Collaboration Environment, supporting the Tumor Board's multi-disciplinary decision making process, through remote interaction
- An *Imaging Visualization and Analysis Tool*, for image segmentation and radiomic features extraction
- A *Visual Analytic Tool*, that assists the work of clinical researchers active in HNC investigation, through query and aggregation of data, identification of trends, patients' clusters, etc.
- An *Interactive Patient's co-Decision Aid*, that presents patient's treatment alternatives, as identified by the physician, along with estimates of curative effectiveness and

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impacts/side effects, in order to support clinicians and patients in their co-decision process

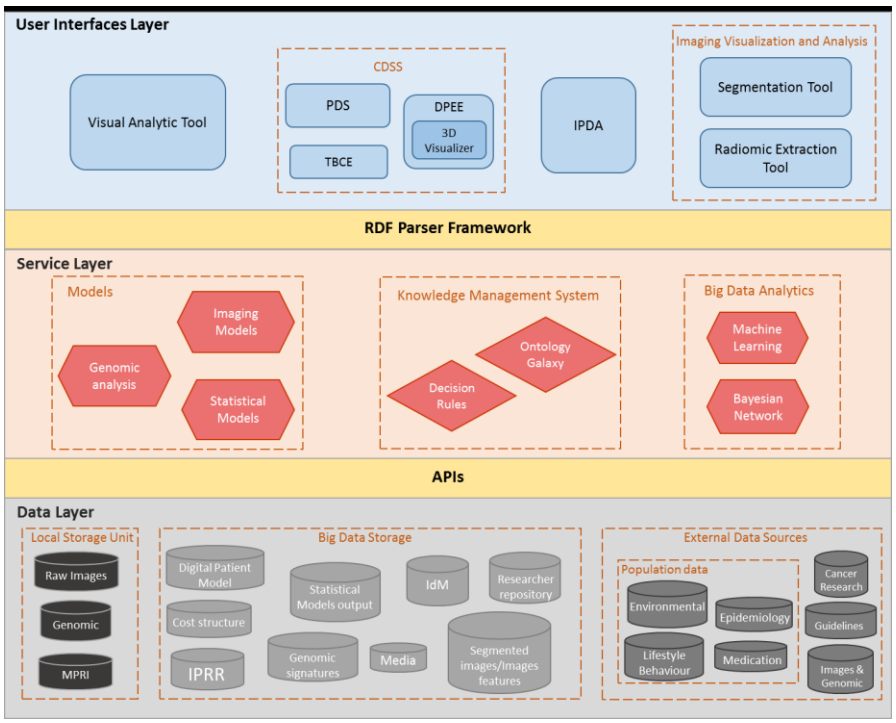
The **Models and Service Layer** gathers together the models to be used for data analysis, such as:

- a library of statistical prognostic models
- the module for image enhancement (segmentation and radiomics feature extraction)
- the module to support genomic analysis and identify genomic signatures
- the knowledge management system
- the big data analytics module

In particular, the big data analytics module includes functions for uncovering hidden patterns, unknown correlations, medical treatments trends, clinical preferences and other useful information to support clinical decisions.

The **Data Layer** is composed of three databases groups:

- *Local Storage Units*, that represent storage placed at each clinical center instance. This contains data that is not shared across the system's modules and is only accessed internally from each center. The local storage is used by the imaging processing and genomic processing tools, installed locally
- *Big Data Storage*, that contains the large and varied datasets necessary for the discovery and validation of personalized prognostic patterns. Examples are: data related to statistical prognostic modelling, anonymized clinical data collected from patients EHRs, genomic signatures, segmented images and results of radiomics features extraction
- *External Data Sources*, that represent repositories on useful population data or scientific information, such as cancer registries, environmental or epidemiology repositories, and literature databases



Population data

A glimpse into a class of BD2Decide data

One of the pillars of the BD2Decide approach to big data analytics is the inclusion of population-related epidemiology and risk factors data, that will be used in order to complement patients' longitudinal data collected from retrospective an prospective cohorts, with a wider picture of HNC epidemiology information in European populations.

Population data in BD2Decide will be collected at different levels:

- Aggregated population data i.e. data not directly linked to individuals but linked to clusters of populations (e.g. by territory, gender, localization of disease, census etc.)
- High-resolution population data i.e. data linked to specific individuals. A small cohort of patients enrolled for BD2Decide (who have provided consent) will be selected to collect several of their health data from

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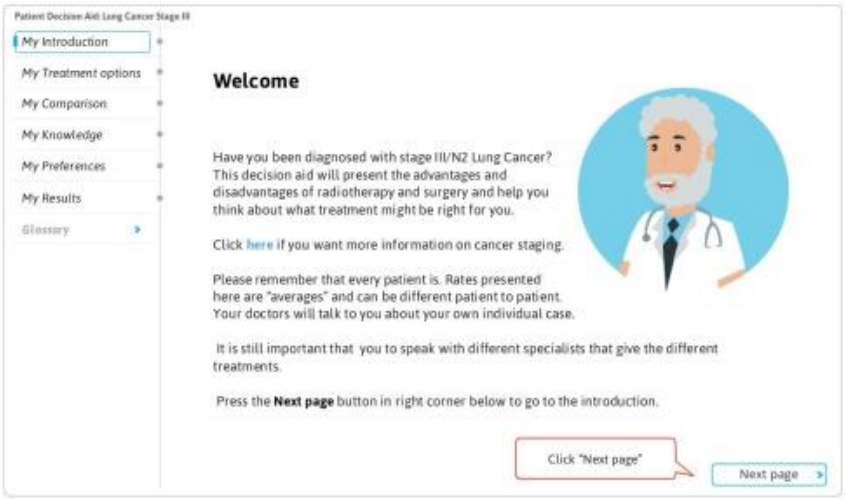

territorial health agencies (e.g. medications, visits to specialized physicians, comorbidities, visits to GPs) when available. This high-resolution data will allow to investigate how additional patient's data, not normally collected during HNC treatment, may increase population and patient's profiling and improve the accuracy of prognostic models

- Cancer Registries data, collected in collaboration with the RARECAREnet EU project. Data at individual level will be extracted from two different database: (a) the database of a pilot study on centers of treatment for rare cancers: (b) the database of a high-resolution study on head and neck cancers
- External data from other sources relevant to BD2Decide. This includes, for example, data from the International Agency for Research on Cancer (IARC) repositories, data from the World Health Organization (WHO) repositories, EUROSTAT aggregated data on health determinants that might be of use to correlate populations lifestyle behaviors with disease prognosis, etc.

Interactive Patient co-Decision Aids

The patient is involved in the decision process

Patients with advanced larynx cancer may be eligible for more than one treatment: laryngectomy, radiotherapy, chemo-radiation, or combinations of these treatments. These treatments have a distinct impact on the outcomes and quality of life of the patients. To empower the patient and enable a shared decision making process we have developed a web-based Patient Decision Aid tool specifically for larynx patients. Complex medical information is transformed into easy to understand animations and the patient can assess the consequences of each treatment available. The tool generates a report giving insights into the preferences of the patient, and structures the shared decision making conversation between doctor and patient.
A prototype, currently in Dutch language, is available at: http://www.treatmentchoice.info.

BD2Decide in the scientific community

BD2Decide has started disseminating its initial findings within the scientific community, through papers that have been accepted for publication at international journals and conferences, such as:

- Journal for Oto-Rhino-Laryngology and its Related Specialties
- Oncotarget
- Current Treatment Options in Oncology
- 39th Annual International Conference of the IEEE Engineering in Medicine and Biology Society

For a full list of BD2Decide publications, consult the Project website at the URL http://www.bd2decide.eu/publications

You are welcome to contact us:

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Provide your comments and opinions on our online channels indicated below.

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