BD2Decide

Big Data and models for personalized Head and Neck Cancer Decision support

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This document is addressed to the BD2Decide Consortium and provides an initial version of the user interface sketches for the BD2Decide components. More specifically, it summarises on the user centric approach for the development of the BD2Decide environment and emphasises on the usability design issues. It, then, presents the user needs for the three main components, namely the Clinical Decision Support System, the Interactive Patients' co-Decision Aid tool and the Visual Analytics Tool. The deliverable bases the analysis on the user requirements in Deliverable D2.1 and describes the user functionalities, along the steps defined for each target stakeholder in the head and neck cancer processes.

The main result of this deliverable is an initial design of the user interface sketches for these components, which aim to provide the clinical partners with a perception of how the BD2Decide environment will facilitate their needs for managing a head and neck cancer patient for efficient personalised decisions.

This document will be delivered to the European Commission.

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Abbreviations and definitions

CDSS	Clinical Decision Support System
DPEE	Digital Patient Exploration Environment
e-CRF	Electronic Clinical Record Format
EHR	Electronic Health Record
HN	Head and Neck
HNC	Head and Neck Cancer
IPDA	Interactive Patient Decision Aid
IPDAS Collaboration	International Patient Decision Aid Standards Collaboration
PDS	Patient Documentation System
QoL	Quality of Life
TBCE	Tumor Board Collaboration Environment
UCD	User Centric Design
UI	User Interface(s)

Abstract

In modern software development, usability is a key parameter for the acceptance of the software solution by the target end users. Thus, the adoption of a human (or user) centric design approach is considered a key success factor for the commercialisation of the software. In that respect, BD2Decide is widely supporting the engagement of the end users in the development process, not in an isolated way, but in a fully interactive approach. Thus, in the BD2Decide project, which integrates a multidisciplinary group of clinical researchers, health professionals and diverse technical teams, we emphasise on the interactive development of the BD2Decide components, by employing a user centric design approach across all the phases of the BD2Decide implementation plan to make these components being usable for the target end users.

Within the BD2Decide implementation process, usability is highlighted in the user centric design process and a three phases approach is followed to address usability, along the implementation plan of the BD2Decide software environment. These phases include the analysis of usability aspects, the design of the usability as part of the overall BD2Decide specifications and the usability evaluation of the BD2Decide environment, as it has been implemented in software implementation phases of the various individual BD2Decide components and the integrated view.

To this end, this deliverable is part of the usability design phase and elaborates on the visual representation of the BD2Decicde concepts and the expected wireframes that should eventually constitute the user interface components of the BD2Decice environment. The wireframes sketch a provisional view on how the defined end users will interact with the BD2Decide environment in order to manage the patients' data and clinical status, along a head and neck cancer workflow. The sketches of the user interaction design are grouped, according to the primary BD2Decide actor(s) that these interactions refer to, and are connected with the user needs and the respective requirements presented in Deliverable D2.1.

More specifically, the document analyses the interactions of the target stakeholders, namely the patients, the professionals (clinicians), and the researchers, with the BD2Decide components. For the patients, the deliverable sketches the interactions that allow them to be made aware of the candidate treatment methods proposed by their physicians (and the tumor board), and the impact of these treatments in their life and survival conditions. For the clinicians, we provide an initial design of the tools that allow them collect and manage their patients' data, in the context of assessing their clinical status, along the HNC treatment phases, assess the evolution of their patients' disease case, through personalised prediction, and collaborate with other professionals, in the context of the organization of tumor boards. Finally, this document delivers a first approach for the design sketches targeting the interaction activities of the clinical researchers with the BD2Decide environment, in order to query into big data sources and combine results from clinical studies, research activities and statistical bodies on HNC disease cases.

1 ABOUT THIS DOCUMENT

1.1 Introduction and scope

This document is the second deliverable of WP 2 and stands upon the user requirements to sketch the design of the interactions expected between the BD2Decide actors and the ICT environment. The work, which is presented in this deliverable, strongly relates to the user centric design process that the project follows in order to develop the BD2Decide components, in order to ensure that development is aligned to the user needs and the released software receives the acceptance of the stakeholder groups. As such, this deliverable establishes relationships with the work performed in WP 5 about the usability evaluation.

The user centric design process aims to achieve high degree of usability for the BD2Decide components. A principal requirement for this is to ensure the engagement of the BD2Decide end users in the implementation of the ICT environment early in advance in the project time plan. This must be done through a structured and systematic approach, which will enable us gather the all the information required for guiding the software development. The result of this process is the initial sketch of the user interaction design, as an effective approach for the initial conceptualisation of the functionalities expected from the BD2Decide software for each stakeholder group.

1.2 Structure of the deliverable

Following the objectives set for this deliverable, the document is structured as follows:

- Section 2 sets the scenes for this deliverable by placing the design of the user interface sketches in the whole software development process. As such, it makes an introduction to the user centric approach and describes how the design of sketches for the expected interactions of the BD2Decide actors with the envisaged ICT environment could establish a communication channel between the clinical and the technical partners of the project to come up with a highly creditable (from the perspective of the target users) and usable implementation.
- The following three Sections 3-5, approach the design of the user interfaces for the three main components targeting the three main stakeholder categories of the BD2Decide environment. Therefore, in Section 3 we provide the UI sketches for the Interactive Patient's co-Decision Aid tool, which targets physicians and their patients, in Section 4 we refer to the core component of the environment, which is the Clinical Decision Support System for allowing professionals in the HNC field to assess the clinical status of their patients, and in Section 5 we elaborate on the interactions of the clinical researchers with the BD2Decide environment.
- Finally, in Section 6 will provide concluding remarks for the work done in this deliverable and a roadmap on how the UI sketches will be exploited to guide the development of the BD2Decide components.

2 USER CENTRIC DESIGN

2.1 Introduction to a user centric design process

The development of a software system follows the software life cycle processes defined in the ISO/IEC 12207:2008 standard [1]. In this standard, software implementation is evolved into various processes, which refer to the software requirement analysis, the software architecture design, the software construction and integration, the software qualification testing and the software support and reuse processes. The support services include the software quality assurance and validation processes. Software validation is the confirmation that the software specifications conform to user needs and intended uses through examination and provision of objective evidence, and that the particular requirements implemented through software can be consistently fulfilled. Since software is usually part of a larger hardware system, the software validation typically includes evidence that all software requirements have been implemented correctly and completely.

Along the processes of a software implementation project, the level of the stakeholders' involvement in these processes defines whether a user centric design (UCD) approach is being adopted in the development of the software system. A UCD approach, which is, also, called human centric design, targets on the integration of a multidisciplinary group, which focuses on the interactive development of software solutions, with emphasis on making them being usable. As mentioned in ISO 9241-210:2010 [2], UCD is the *approach to systems design and development that aims to make interactive systems more usable by focusing on the use of the system and applying human factors/ergonomics and usability knowledge and techniques*. Thus, the scope of a UCD process is to achieve high degree of usability, which is introduced as an inherent measurable property for all interactive digital technologies and is defined in ISO 9241-11:1998 [3] as *the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use*. In order to meet this objective, the UCD process requires that the software end users and the solution domain stakeholders must be engaged with the implementation activities early in advance, through a structured and systematic approach for gathering all the necessary information, which will guide the software designers in making an effective first approach of the software sketch [4].

The UCD process is strongly dependable on user acceptance criteria, thus, it should approach usability from various perspectives and focus on aspects for the ease of use and the learning curve to adopt the solution in current business practices [5]. This can be measured by the envisaged users through empirical analysis of similar solutions and the actual testing of the software product, as it is progressively made available from a mock-up version, through functional prototyping and up to product testing. In this context, iterative design is a key function in the whole software development process for the continuous evaluation of usability aspects in the software solution.

The usability evaluation aims to assess the extent to which an interactive software solution is easy and pleasant to use. A lot of methods exist to measure the degree that is achieved in the development of a software interactive solution. These methods provide the theoretical background to apply specific robust, objective and reliable metrics that allow a quantifiable approach to

usability. The most well-known usability evaluation models are: i) quality in use model, which is used to asses to the use of the software product (effectiveness, efficiency and satisfaction in a particular context of use), and ii) the product quality model, which is used to assess the product user interface and interaction. These quality models are commonly included as part of the software validation process in the ISO/IEC 12207:2008 standard [1]. However, in a UCD process, these models should be employed across all the processes of the software implementation.

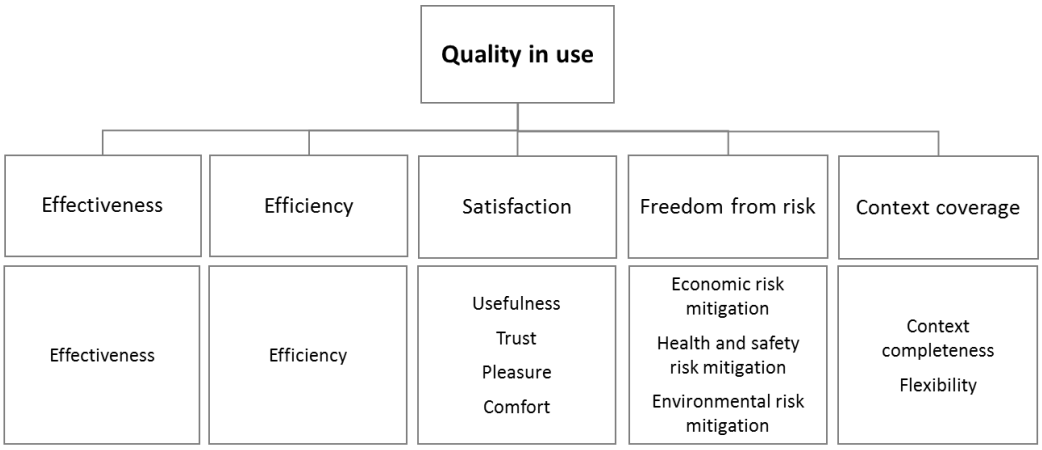


Figure 1: The quality in use model of the ISO/IEC 25010:2011 standard.

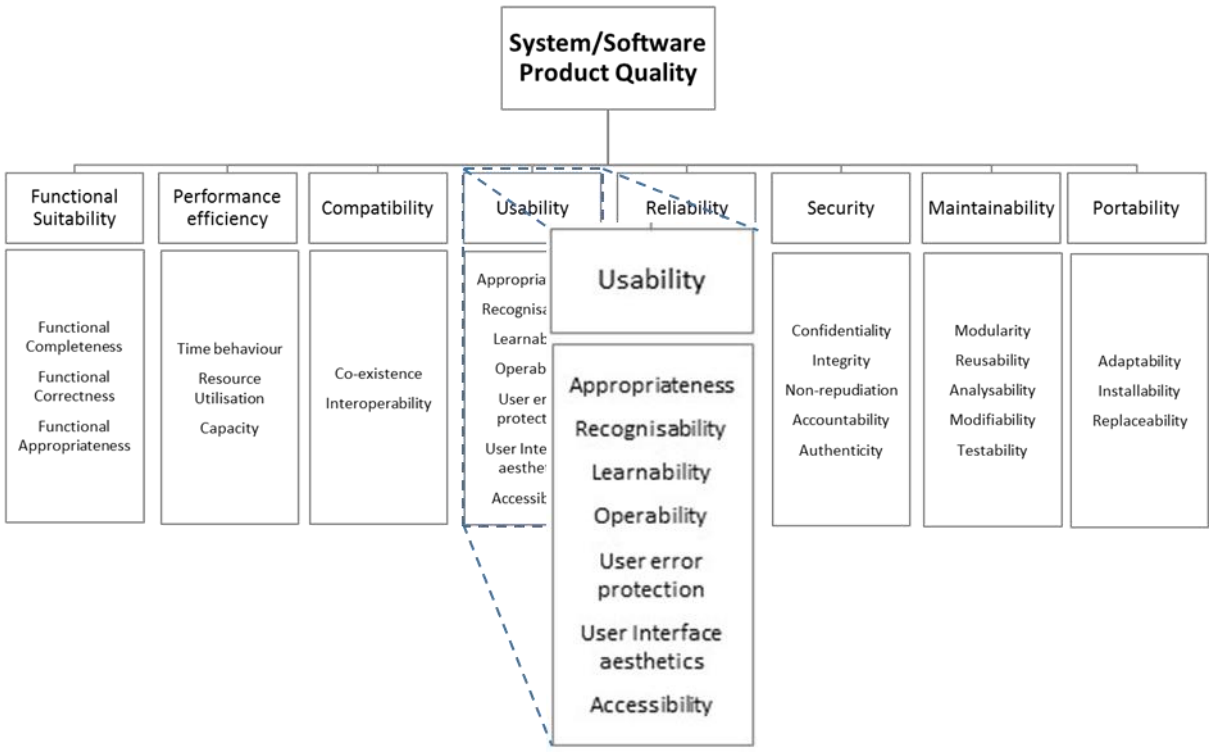


Figure 2: The product quality model of the ISO/IEC 25010:2011 standard.

The ISO/IEC 25010:2011 standard [6] is the most widespread reference model for software assurance and it includes eight software quality characteristics, across which the software solution can be assessed. This standard introduces the above mentioned quality models providing a

consistent terminology for specifying, measuring and evaluating system and software product quality. Thus, in ISO/IEC 25010:2011 standard:

- The quality in use model is composed of five characteristics that relate to the outcome of the interaction with the system and characterises the impact that the product can have on the stakeholders. In this model, usability is in the forefront and is realised through the characteristics shown in Figure 1.
- The product quality model is composed of eight characteristics that relate to static properties of software and dynamic properties of the computer system. In these model, the eight characteristics can be further divided into sub-characteristics, are shown in Figure 2.

The software quality model of the ISO/IEC 25010:2011 standard is adapted on a case by case basis, in order to define appropriate metrics and to be able to evaluate the software capabilities. These metrics need to reflect the characteristics that they represent. They also need to allow appropriate measurements to be obtained, either through quantitative methods (e.g. by software tests/simulations, usability tests) or qualitative methods (e.g. through user observations).

Three types of classes of metrics are defined in this standard:

- Internal metrics associated with static internal properties of a system such as number of function calls, number of rules.
- External metrics associated with dynamic external properties. These are metrics that are observable when the user interacts with the system (i.e. the user performs a task/function/operation and observes the response in the sense of time required, results obtained etc.).
- Quality-in-use metrics, which refer to metrics that evaluate the extent to which a system meets the needs of the user.

Focusing on the usability requirements, various standardisation bodies have defined common formats to allow usability professionals, end users and software development teams to create usability requirements. Such kind of common formats are published by ISO in the ISO 25062:2006 standard for Common Industry Format for Usability Test Reports [7] and NIST in the NISTIR 7432: Common Industry Specification for Usability – Requirements (CIRU-R) [8].

2.2 The BD2Decide User Centric Design process

Taking into account the overview of a UCD process, in this section, we present the approach that BD2Decide follows, in order to develop the big data environment and the interfaces that are accessed by the envisaged stakeholders. The overall UCD process is presented in Figure 3.

As shown in Figure 3, the three main steps for the end user involvement in the BD2Decide implementation processes, include the analysis of usability aspects, the design of the usability as part of the overall BD2Decide specifications and the usability evaluation of the BD2Decide environment, as it has been implemented in software implementation phases of the various

individual BD2Decide components and the integrated view. In Figure 3, we have highlighted the main tasks involved in the BD2Decide UCD process, while we have used a coloured scheme to place the respective activities in the contractual deliverables of the project. Thus, the analysis of the BD2Decide personas, their needs, the subsequent requirements for the definition of the BD2Decide functionalities and the context of use of these functions by the target end users has already been presented in Deliverable D2.1 [9].

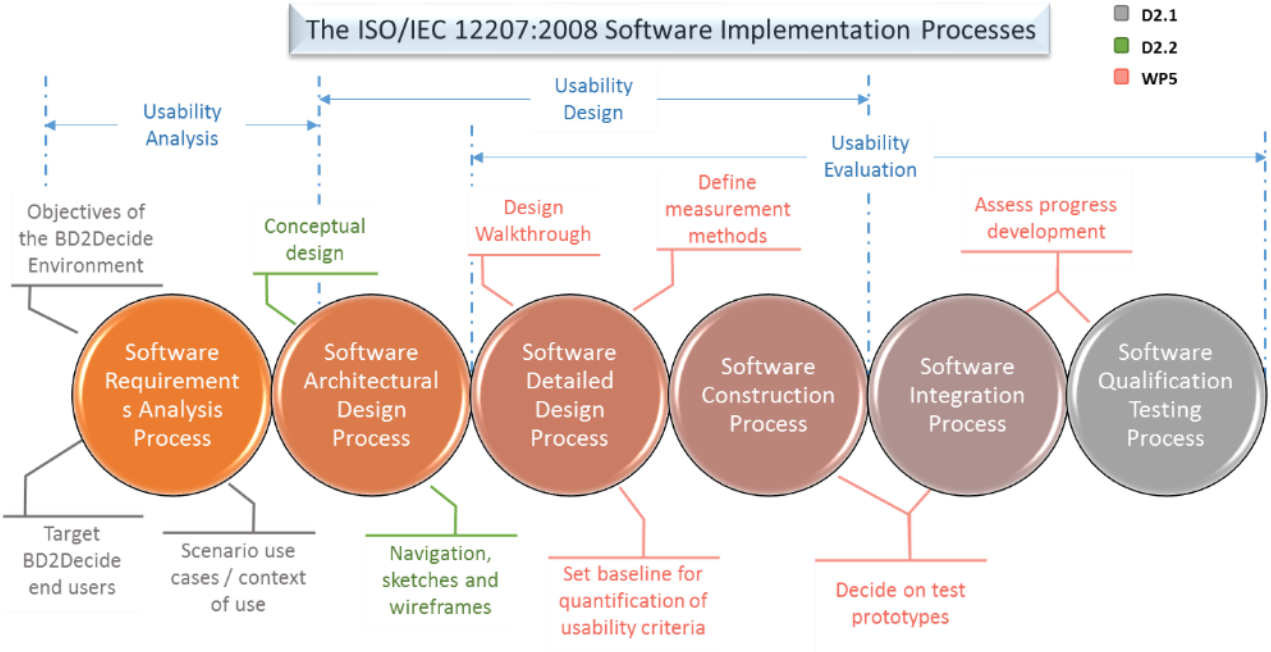


Figure 3: The User Centric Design approach of the BD2Decide project.

In this Deliverable, we touch the issues related to the design of the BD2Decide usability. Namely, we emphasise on the visual representation of the BD2Decicde concepts and the expected wireframes that should eventually constitute the user interface components of the BD2Decice platform. The wireframes sketch a provisional view on how the defined end users will interact with the BD2Decide environment in order to manage the patients' data and clinical status, along the HNC workflow. Therefore, taking into account the list of end users, the scenarios that each user group is to accomplish through BD2Decice, the type of data to be collected, processed and visualised within the BD2Decide environment (as reported in Deliverable D5.1 [10]) and expected user requirements to be fulfilled by the BD2Decide environment, we evolve the design of the user interface sketches around the following principles:

- *Suitability*: the sketches should reflect the suitability of the interfaces to enable the interaction of the specific target end user groups (i.e. physicians, clinicians, researchers, etc.) with the BD2Decide environment.
- *Familiarity*: the sketches must learn from best practices in the look and feel of tools for oncologists and other health professionals in the clinical domain.

- *Simplicity*: the sketches should allow the end users to interact in an almost autonomous way, through self-explained interactive ways.
- *Flexibility*: the sketches should enable end users take the control of the workflow execution, through comprehensive navigation.
- *Awareness*: the sketches should reflect the capability of the BD2Decide platform to allow the end users realise the status of the workflow and the consistency of the information offered through the interface functionalities.
- *Efficiency*: the sketches should provide clarity on which is the primary action of each sketch that should be accomplished by the end user.
- *Presentation*: the sketches should be customised to the behaviour and philosophy of the end users, so that they are visually pleasant and attractive for use.
- *Accessibility*: the sketches must consider that UI development will be based on international standards and will target for specific access channels (end user devices).

2.3 Overview of the BD2Decide Environment

The BD2Decide Environment consists of a platform that supports the clinicians in making decisions along the various processes followed to treat patients with Head and Neck cancer (HNC). The platform integrates functionalities for collecting the patients' electronic health record from the clinical centres within the Patient Documentation System (PDS), organizing the professionals' interaction to discuss on the clinical status of a patient through scheduled tumor boards, exploring the details of the patient's health record and the results from the radiological imaging analysis and genomics extraction processes, applying big data processing prognostic prediction analysis models to follow the impact of the treatment on the patient's health status and assessing their long term quality of life.

The Clinical Decision Support System (CDSS) is accompanied by a tool, which aims to enhance the patients' awareness on the disease effects and implications, as well as to enlighten their ability on making informed choices on which treatment must be followed upon the diagnosis of an HNC situation. The Interactive Patients co-Decision Aid (IPDA) tool interfaces with the prognostic prediction analysis to personalize the treatment choices that are presented to the patient prior to the final decision, which is made in collaboration with the assigned physician.

Furthermore, the BD2Decide Environment integrates the view for the researchers, who access the data being collected and processed within the CDSS to allow researchers expand their capabilities for conducting their analysis on statistical and sample data sets. This view runs in parallel to the CDSS, through a Visual Analytics Tool, which enables advanced big data visualisations, according to the complex queries built by the researchers.

In each of these tools of the BD2Decide Environment, we define the relevant User Interface components, which are responsible for the interaction of the target end users with the BD2Decide platform. These users can be (as extracted from D2.1):

- Health professionals taking the specialty of a surgeon, a medical oncologist or a radiation oncologist. These are the main users of the BD2Decide environment and, as being the clinicians, they are responsible for the diagnosis, treatment and follow-up processes of the patient. They, also, have full access to the patients' health record data. To these specialties, we add the radiologists, who perform radiological image analysis and radiomics feature extraction, the pathologists, who are responsible for the pathology data management of the patients' health record, and the biomolecular analysts, who perform genomic feature extraction.
- Clinical researchers, who have access to HNC data stored in the CDSS for research purposes only and subject to the national and international laws and the data privacy policies of the associated clinical / research centre.
- To some extent, the patients themselves, who are involved in the treatment decision making process by running the IPDA tool (jointly with their physicians) and assessing the expected impact from the adoption of a specific treatment method in their overall life and survival conditions.

In order to summarise the involvement of the BD2Decide environment in this deliverable, we present the perspective of the BD2Decide logical architecture for the user interface (UI) components. This is depicted in Figure 4.

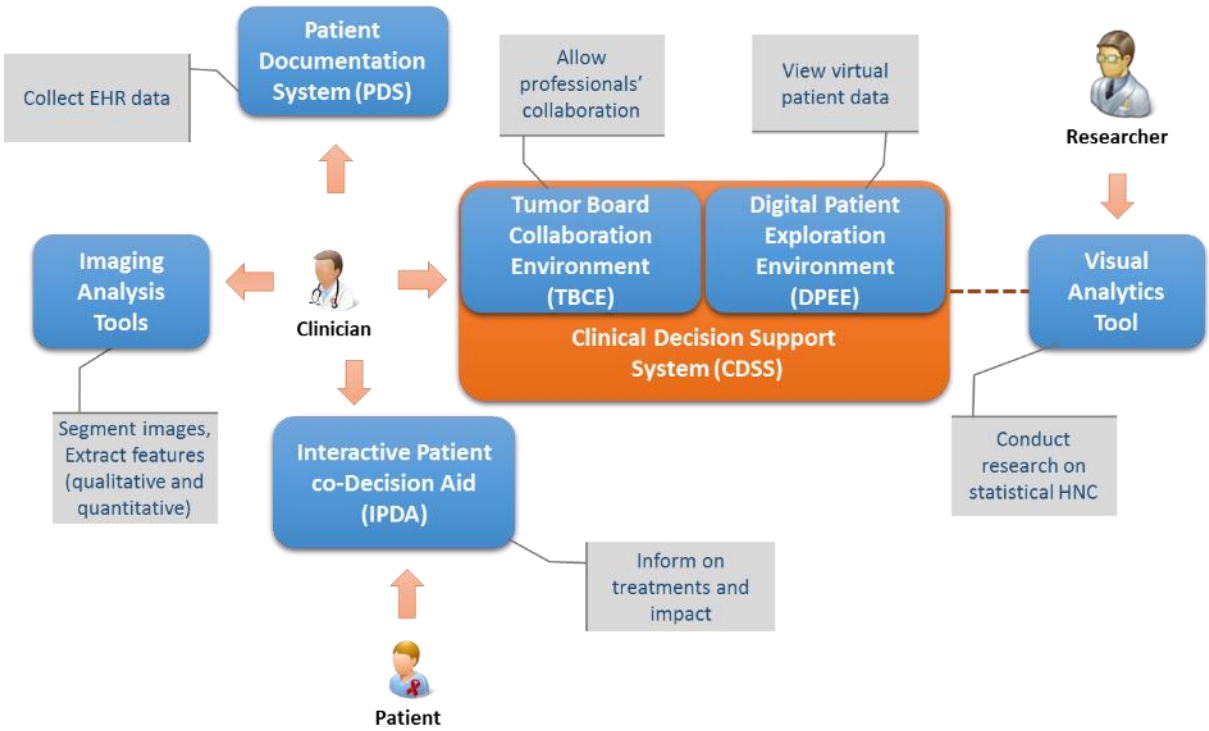


Figure 4: The User Interface components of the BD2Decide environment.

As shown in Figure 4, the BD2Decide environment offers the following tools to allow interactions with the envisaged end users:

- For the *clinicians*:
  - The CDSS, which hosts the main BD2Decide environment, including the prognostic prediction models. The UI of the CDSS acts as the UI container for the clinicians to: i) collaborate with each other in the context of the tumor board organization (through the Tumor Board Collaboration Environment – TBCE) and ii) to visualize the patients' data in the context of assessing their clinical status, along the HNC treatment phases (through the Digital Patient Exploration Environment (DPEE).
  - The PDS, which allows the development of the patient's electronic health record, based on the collection of the relevant data from the information systems of the clinical centres.
  - The Imaging Analysis Tools, which is a set of tools for the processing of radiological images. Namely, three separate tools are offered through the BD2Decide environment, which maintain their own distinct user interfaces. These tools allow the clinicians segment the radiological images, which may be provided in various formats, and generate the relevant radiomics features.
  - The IPDA tool, which is personalised for each patient, based on the treatment decision making process run by the clinicians. This tool, also, interfaces with the CDSS to invoke prognostic prediction for the selected treatment processes relevant to the disease case of the patient.
- For the *patients*:
  - The IPDA tool, which is used as an informative interface for the patients to be made aware of their HNC case, the treatment methods proposed by their physicians (and the tumor board), and the impact of these treatments in their life and survival conditions.
- For the *researchers*:
  - The Visual Analytics Tool, which assists them in managing the plethora of data made available in the Big Data infrastructure from clinical studies, research activities and statistical bodies on HNC disease cases.

The remaining of this deliverable is dedicated to the analysis of the interaction components of the BD2Decide environment by presenting an initial sketching of the screens expected for each end user. The analysis includes the functionalities that these sketches depict, as well as the flow of the sketches that should be followed by the end users.

3 INTERACTIVE PATIENT'S CO-DECISION AID

Interactive Patient's co-Decision Aids (IPDA's) are tools that help patients to become involved in Shared Decision Making by clarifying the treatment or medical decision that needs to be taken [11]. These tools provide information about the options and outcomes, and clarify personal values. To this end, IPDA's should:

- Help patients to decide the treatment option that fits better their preferences and circumstances;
- Support clinicians during consultation by providing information about patient's preferences.

In the rest of this section, we describe the user requirements of HNC patients and specialists. Then we present a first IPDA prototype we have created considering these requirements, as well as the processes described in Deliverable D2.1 [9].

3.1 User Needs

The International Patient Decision Aid Standards Collaboration (IPDAS Collaboration)[2] recommends that IPDAs: "*should be carefully developed, user-tested and open to scrutiny, with a well-documented and systematically applied development*" [12]. Figure 5 shows the development process recommended by the IPDAS Collaboration.

Following this recommendation, we identified patients and clinician user needs. We interviewed Dutch larynx cancer patients and their clinicians (Section 8.1 includes the interview schema used during the interviews, which is only available in Dutch).

From larynx cancer patients (Stage T3 or T4; N=14), who were treated at MAASTRO or in the Dutch Cancer Institute (NKI) between 2012-2015, the following user needs regarding IPDA's were identified:

- Easy to use;
- Reliable information and free of medical jargon;
- Treatment information related to implications in daily life, overview of side effects as well as information regarding to patient's own specific situation (doctor, hospital, physiological support);
- Minimal textual information: Animations and videos to make treatment options clearer; preference of spoken information, rather than text.

[2] http://ipdas.ohri.ca/

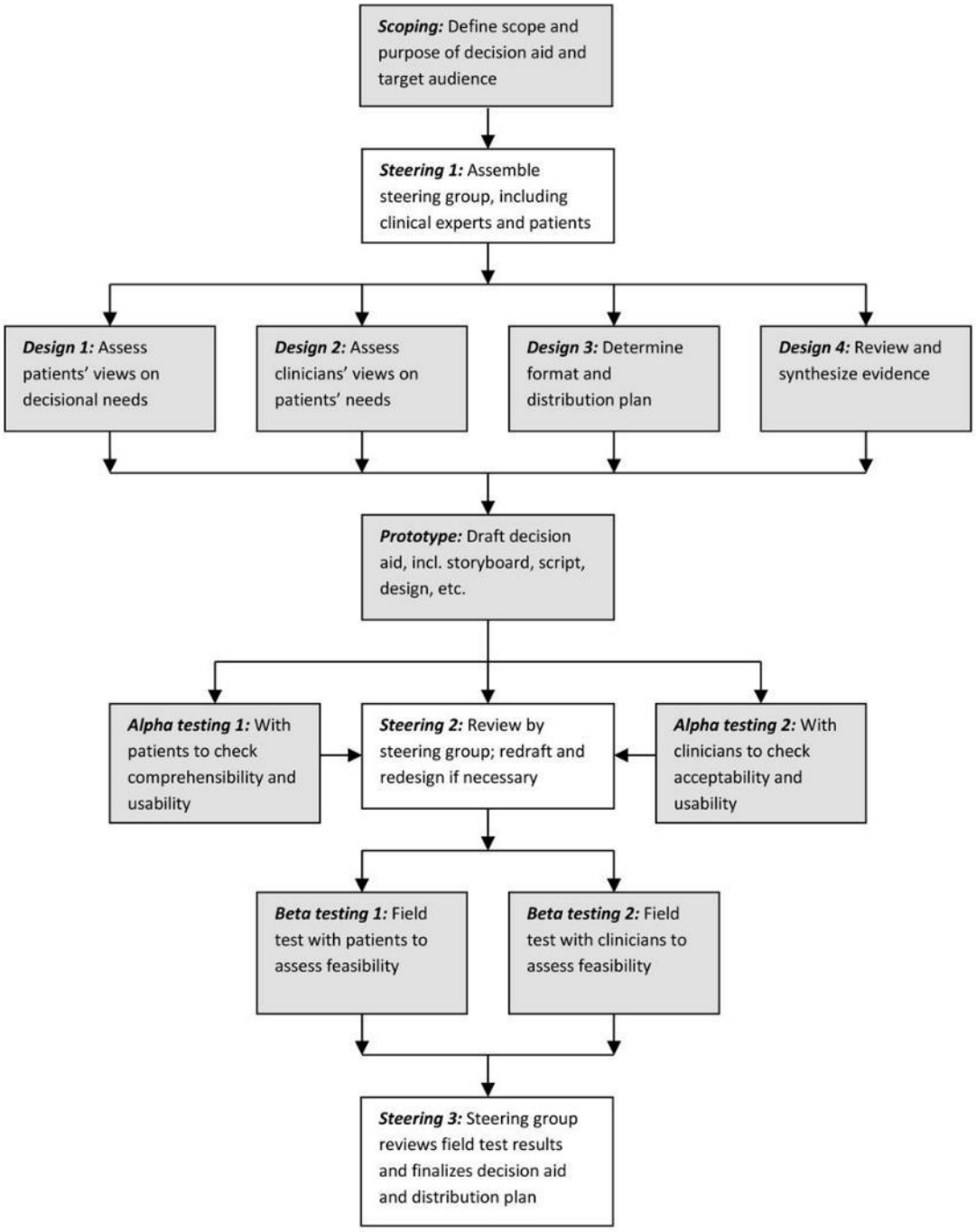


Figure 5: International Patient Decision Aid Standards Collaboration - Developing process.

From HNC clinicians (N=8: Radiotherapists, Ear Nose and Throat (ENT) physicians and Head and Neck Surgeon), the following user needs regarding PDA's were identified:

- Easy to use for people with low literacy and basic computer skills;
- Include mainly visual an interactive information;

- Provide a way to check if the patient understood the information about the treatment options and side effects, (self-tests);
- Information regarding survival rate, differences between treatment, side effects of the treatment, and treatment experience aspects, particularly treatment and hospitalization, follow up consultations, as well as Quality of Life aspects, such as swallowing, voice quality and odor and how these aspects will impact in their social life.
- Provide a way to understand how their lives after the treatments would be like, especially after surgery (an option could be using virtual reality);
- Help the clinician to understand what are the most important aspects for the patient;
- Guide the patient to understand her preferences, giving the possibility to score the most important aspects. This will minimise the error of choice and uncertainty.
- Facilitate the understanding of probabilities and percentages;
- Include psychosocial aspects, sexuality, marriage, and social life after treatments;
- Information of the IPDA should be equal to the one provided by the clinician, to avoid confusion;
- Include references to scientific literature.

Other aspects mentioned by clinicians were:

- In the literature the existing evidence of treatment is only available as average, and to provide advice to an individual patient was not always possible;
- Psychosocial aspects are very important;
- Considering to evaluate the cognition level of the patient before using IPDAs (as patients may have Korsakoff's syndrome or other mental illness).

3.2 Sketches design

As mentioned before, based on the user's needs and the functionality described earlier, we created an initial prototype for larynx cancer patients T3/T4 (in Dutch). In this section we describe first the main characteristics and functionalities of the IPDAs. Thereafter, we present how the interface looks.

3.2.1 User functionalities and workflow

We defined IPDA should be personalized, informative, provide guidance, interactive and user-friendly, reproducible and cost-efficient. An overview of the main characteristics of IPDAs is presented in Table 1.

Table 1: The main characteristics of IPDAs.

Characteristic	Description
Informative	For the *patient*, information should be: • Reliable, based on scientific evidence; • Based mainly on video and short animations, use of short phases; • Minimal use of text; • Preference for voice over; • Explain probabilities in a graphical way, not as percentages. For the patient and the clinician: • Printed report of the preferences of the patient, which includes patient's answers, questions and notes (to be used during consultation).
Personalized	• Personalize information about treatments; • Based on patient's disease, the PDA present only the information that is relevant to each patient (e.g. T3 vs. T4 patients may get different treatment options).
Provide guidance for value clarification	Guide patients to identify their preferences. To this end, the approach of values prompting questions regarding QoL and treatment experience is used (value clarification, from the Eisenberg Center for the Agency for Healthcare Research and Quality USA [13]: Question: *If you have to pee more often for a period of 2 months, this will affect your quality of life* Choose an answer: (A) Hardly, it is unpleasant but I can handle (B) Some but I would be able to adjust (C) Greatly, I would not be able to adjust
User friendly & interactive	• Easy to use, clear and close navigation; • Provide a structured way to understand and compare treatment choices; • Using attractive, interactive, "game-like" interface; • Patient can review the information as many times as she/he wants; • Available 24/7. Web-based tool, available for tablets.
Reproducible & Cost efficient	• Easy to adequate for other (HNC) diseases, and easy to translate into other languages; • Definition of a design framework that can be reused for different diseases and languages; • Animations created in a way that only by translating the voice over, the animation will be ready in other languages.

Based on the main characteristics presented above, the user's needs, and the literature in this area as well [14][15][16], we have described the workflow of the IPDAs in Figure 6.

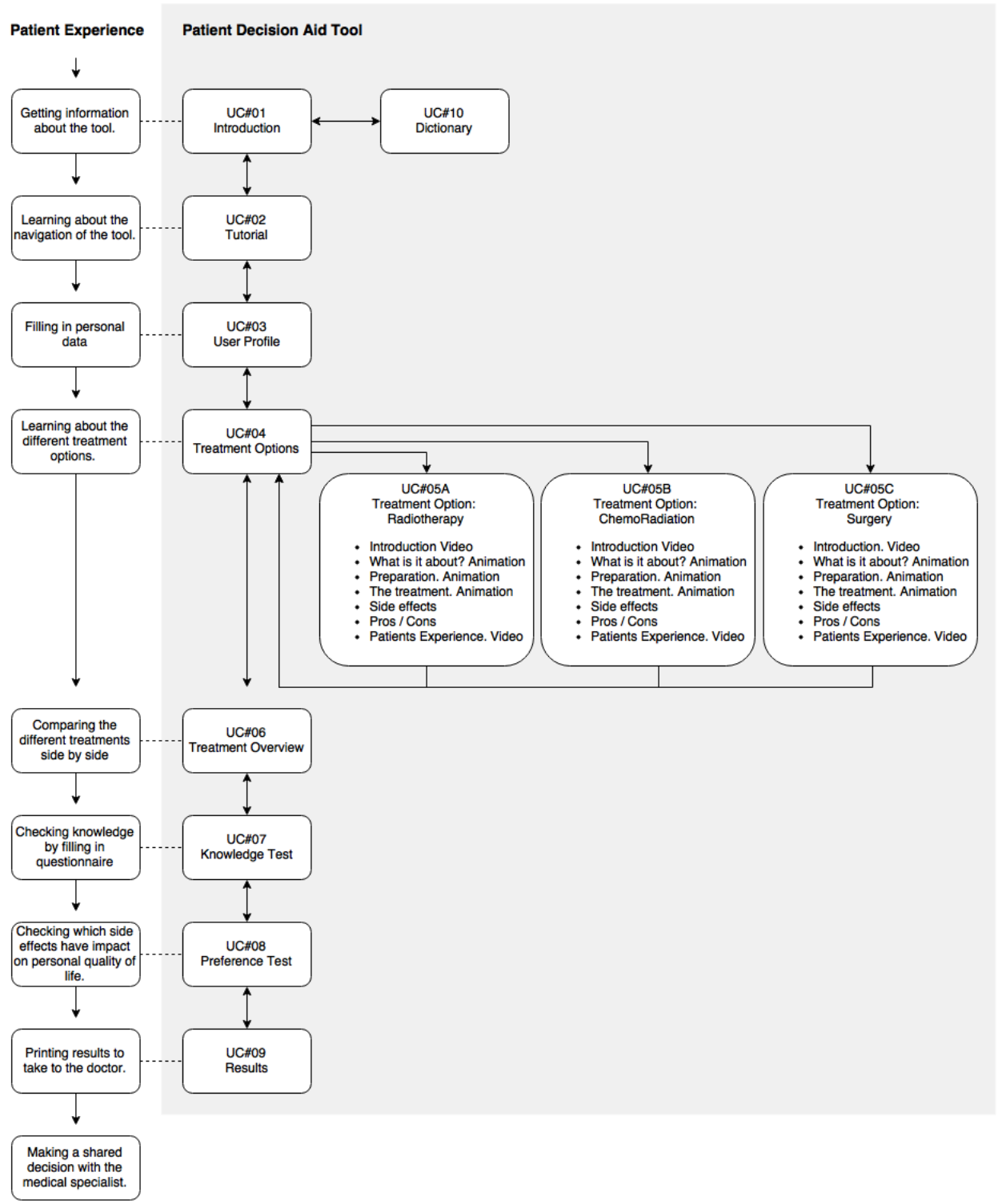


Figure 6: Workflow IPDAs.

3.2.2 User Interfaces - Initial prototype example

Following the workflow presented in Figure 6, in the rest of this section we describe the initial prototype and provide some examples. The tool was created in Storyline Articulate[3], which is a software to create interactive content.

1. Introducing the patient to the tool

Flow ID	**UC#01**
Title	**Introduction**
Actor	**Patients**
Description	Introducing the patient to the concept of the tool and its purpose.
Steps **1** **Example**	Introduce the purpose of the tool, give access to glossary ("woordenboek") and help  *Menu is presented on the lift-side of the screen with the following options: Mijn introductie ("My introduction"); "Mijn Behandelopties" ("My treatments); "Vergelijken" (Comparison); "Mijn Kenis" ("My knowledge" (regarding the treatment options), "Mijn voorkeuren (My preferences); "Mijn resultaten" (My results); "Woordenboek" (Glossary).*
Precondition	PR.0
Description	None
PostCondition	PO.0

[3] https://www.articulate.com/

Description	The user will be able to follow a tutorial about the tool.
Alternative flow	Close the application

2. Making the patient comfortable with the tool

Flow ID	**UC#02**
Title	**Tutorial**
Actor	**Patients**
Description	Tutorial to explain to the user how to navigate through the tool
Steps **1** **2** **Example**	Follow the tutorial. Tutorial animation explains the tool navigation. Or skip the tutorial.  *UC#02 Introduction to the tool ("Introducie van de tool")*
Precondition	PR.0
Description	Introducing the patient to the concept of the tool and its purpose.
PostCondition	PO.0
Description	Patient profile. It allows to customize the information about treatment options presented to the patient.
Alternative flow	Close the application or go back to any of the previous pages.

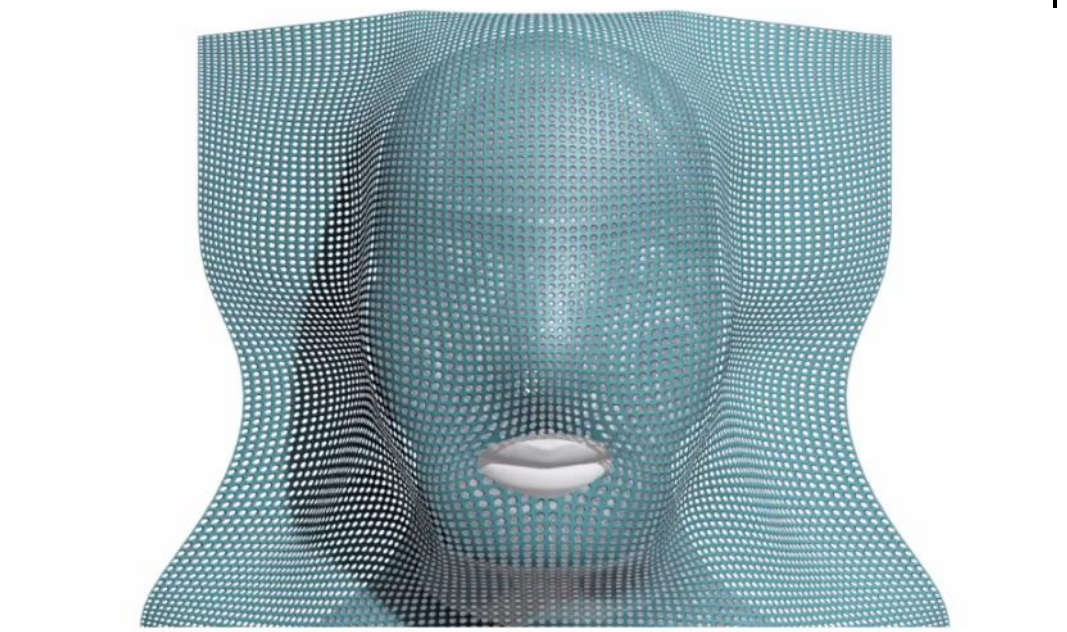
3. Knowing the patient, get the profile of the patient

Flow ID	UC#03
Title	**User's profile**
Actor	**Patients**
Description	Patient profile. It allows to customize the information about treatment options presented to the patient.
Steps **1** **2** **Example**	Select age, type of tumor and institution Save user's profile  *Patient's profile ("Profile")*
Precondition	PR.0
Description	When the user opens the application, he or she must select her profile: age, type of tumor, and hospital
PostCondition	PO.0
Description	The user is able to access the information about treatments
Alternative flow	Close the application or change the user's profile

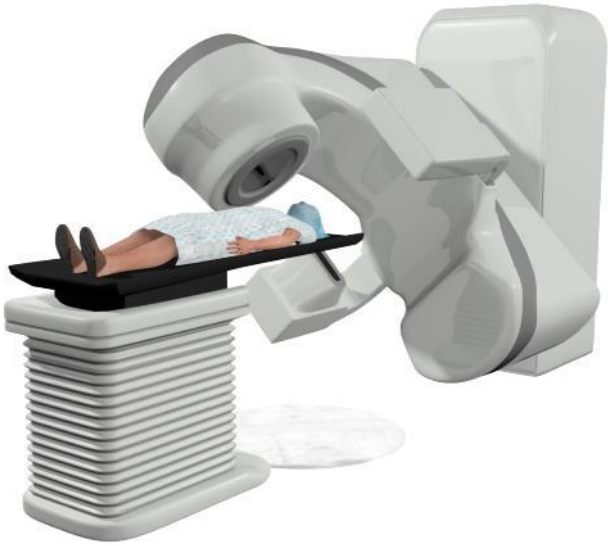
4. Provide information about treatment options, side effects, risks and benefits

Flow ID	UC#04, UC#05A, UC#05B, UC#05C
Title	**Treatment options (“Mijn behandelingopties”)**
Actor	**Patients**
Description	Treatment options. Explains the treatment options regarding: Characteristics; Pros, side-effects; evidence of treatment (survival rate, tumor control) User must first see all information about a treatment, so the next treatment becomes active
Steps **1** **2** **3** **Examples**	Select “Watch” in each one of the treatments (sequential navigation) Watch the videos and animations on the topics Read more information by clicking the red buttons  *UC#05A Radiotherapy – Introduction(Video)*

Flow ID	UC#04, UC#05A, UC#05B, UC#05C



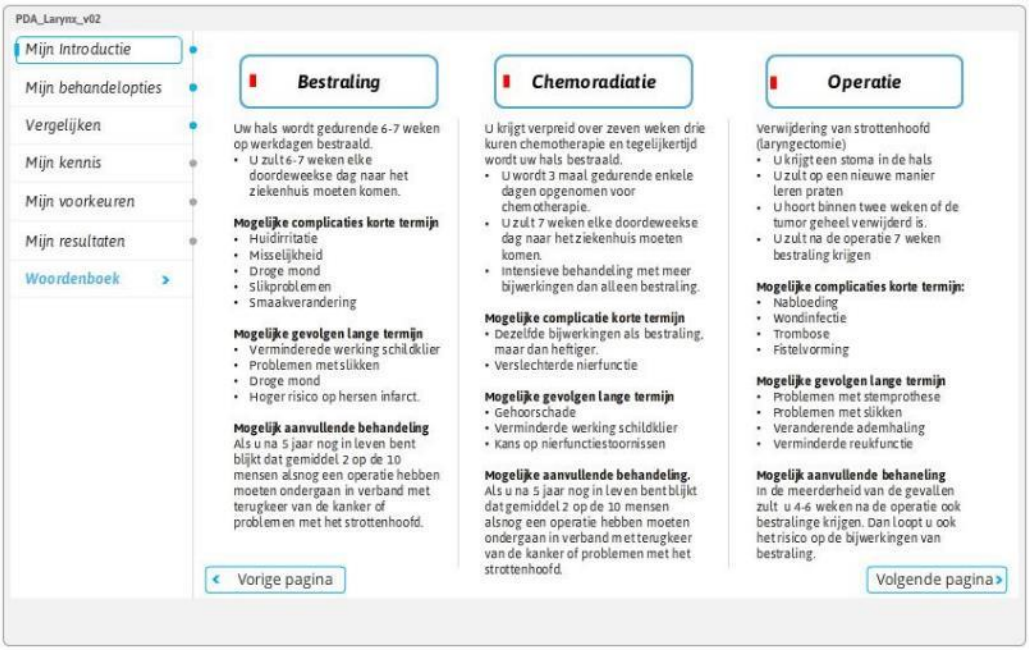
UC#05A Radiotherapy – Preparation (Animation)



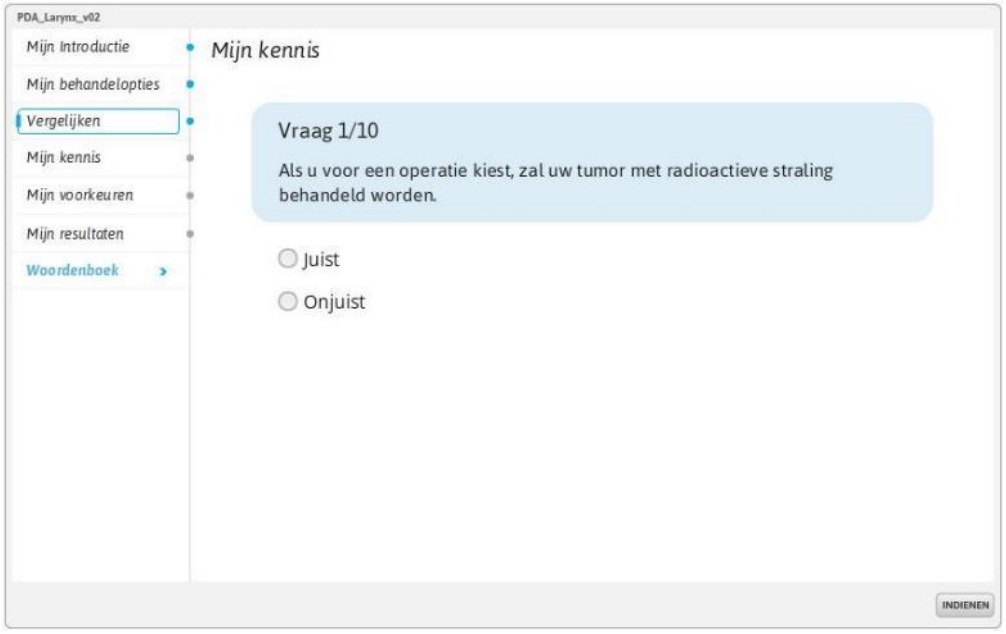
UC#05A Radiotherapy – The treatment (Animation)

Flow ID	UC#04, UC#05A, UC#05B, UC#05C
	 *UC#05B Surgery: What is it about? (Animation)*
Precondition	PR.0
Description	User profile must be completed. To watch each treatment, the last treatment needs to be seen by the user.
PostCondition	PO.0
Description	The user is able to access the information about the second treatment
Alternative flow	Return to user's profile, or select dictionary or return to an already seen treatment

5. Provide a way to directly compare the treatment options

Flow ID	UC#06
Title	**Treatment overview**
Actor	**Patients**
Description	Giving an overview of all the different treatments.
Steps **1** **2** **Example**	Watch a summary of the different treatments.  *UC#06 Treatment Overview ("Vergelijken")*
Precondition	PR.0
Description	All treatments must be watched in order to compare them.
PostCondition	PO.0
Description	The user is able to access the information about treatments
Alternative flow	Either: Go back to Treatment Options; change user's profile; Help; Glossary; close the application

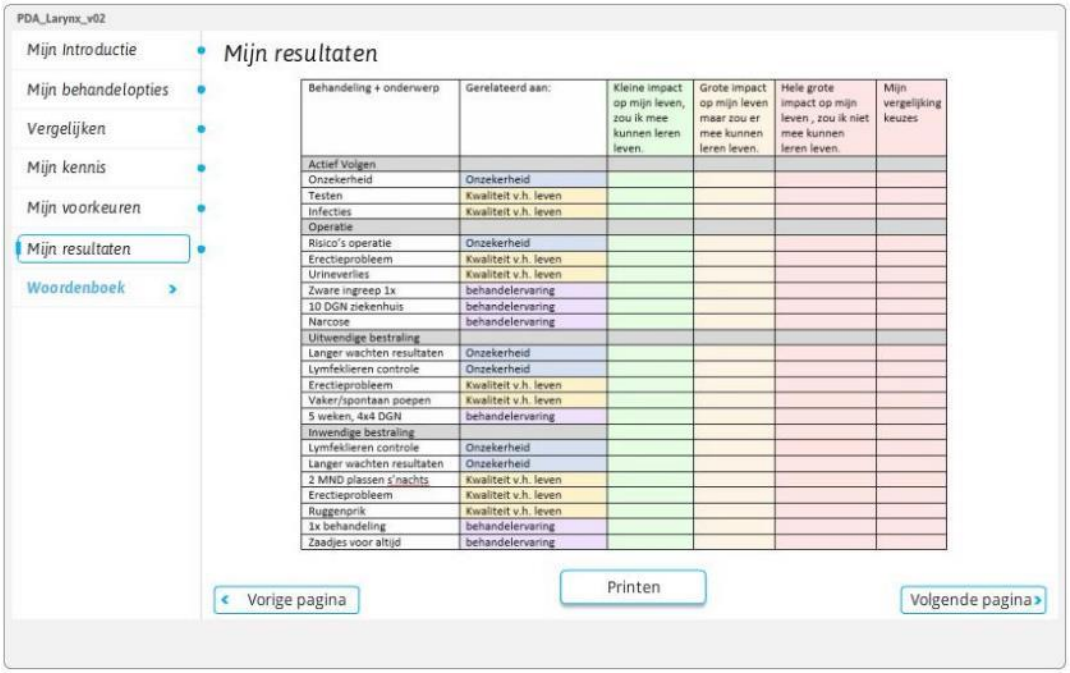
6. Check patient's understanding of treatments and side effects

Flow ID	UC#07
Title	**Knowledge Test**
Actor	**Patients**
Description	Testing the knowledge of patient via a questionnaire
Steps **1** **2** **Example**	Fill in the questionnaire  *UC#07 Knowledge Test ("Mijn Kennis")*
Precondition	PR.0
Description	The treatment overview (UC#06) must be seen by the user.
PostCondition	PO.0
Description	The user is able to access the treatment overview
Alternative flow	Either: Go back to Treatment Options; change user's profile; treatment overview, Help; Glossary; close the application

7. Help patient to clarify values and preferences

Flow ID	UC#07
Title	**Preference Test**
Actor	**Patients**
Description	Checking the preferences of quality of life and treatment experience of the user using questions `prompting value questions"
Steps **1** **2** **Example**	Select per question one option ("… how this will affect your quality of life.." Answers: (a) Hardly, It is unpleasant but I can handle; (b) some but I would be able to adjust; (c) Greatly, I would not be able to adjust" Get report over preferences  *UC#08 Preference question*
Precondition	PR.0
Description	The knowledge test must be finished in order to start the preference test
PostCondition	PO.0
Description	The user is able to access the information about treatments
Alternative flow	Either: Go back to Treatment Options; change user's profile; comparison, knowledge test, Help; Glossary; close the application

8. Provide a summary report to be used during consultation

Flow ID	UC#09
Title	**Resultslide**
Actor	**Patients**
Description	Providing a summary report to be used during consultation
Steps **1** **Example**	Print the report in the questionnaire  *UC#8 - Results*
Precondition	PR.0
Description	The knowledge and preference test must be finished in order to see the results page.
PostCondition	PO.0
Description	The user is able to access the information about treatments
Alternative flow	Either: Go back to Treatment Options; change user's profile; comparison; knowledge test; preferences; Help; Glossary; close the application

3.3 Interfaces and functionalities validation

In the context of this deliverable, a validation with Dutch patients and clinicians has been conducted, and an initial IPDAs prototype has been created (see previous section 3.2). Next step is to check comprehensibility and usability of the prototypical IPDA. To that end, we will use a revised version of the technology acceptance model formulated by Venkatesh et al. [17] and ask patients and clinicians.

Thereafter, the information will be translated in the languages of the clinical centres of the consortium (e.g. English, Italian, Dutch, and German) and IPDAs for at least larynx and oral cavity cancer cases will be created and validated with patients and clinicians, (following the IPDAS criteria). Additional inclusion of highly interactive content will be evaluated (e.g. virtual reality to help patients to experience the radiotherapy facility).

In parallel, the BD2Decide IPDAs will be enhanced with personalized information of survival, coming from the prediction models of the CDSS. A java script will be defined to connect the IPDA to the CDSS.

4 CLINICAL DSS TOOL SUITE

In this section, we emphasise on the tool used by the health professionals to manage the treatment process of the HNC patients, based on the processes that we have already defined in Deliverable D2.1 [9]. We first make an overview of the user requirements to set the context of use of the CDSS tool by these stakeholders and we then proceed with an initial approach for design of the user interfaces, through sketches and wireframes. These sketches aim to provide a first look and feel of the CDSS UI with the expected functionalities being invoked by the health professionals, along the phases of an HNC treatment process.

It must be noted that, since the CDSS is the main BD2Decide component, the interactions with the imaging analysis tools, from Fraunhofer, MAASTRO and POLIMI, and the PDS will be presented in this section, as well.

4.1 User Needs

The CDSS tool is used by the health professionals to manage the HNC processes. As presented in D2.1 [9] and was further elaborated in D5.1 [10], these processes are split into three main phases (namely diagnosis, treatment and follow-up), each of which is further divided into process steps. For each process step, one or more user interactions are involved, which reflect the necessary interactions of the health professionals with the BD2Decide environment. For most of these interactions, the CDSS UI is the main front end component, which these stakeholders need to access in order to benefit from the BD2Decide offered functionalities.

In the diagnosis phase, when a Head and Neck (HN) tumor is suspected by the physician, the relevant clinical personnel are collecting information about the patient's first visit, which information is used for the creation of the electronic health record (EHR). This information is locally collected and managed in the clinical information system, but it is also inserted into the BD2Decide environment. The information included in the EHR is progressively collected from the clinical personnel and the physician, while, depending on the data that needs to be collected, a number of health professional specialists are, also, involved. To this end, the PDS, which is the tool for the collection of the patients' data in the EHR, should allow the health professionals and the clinical personnel to perform the following user actions, once an HN tumor is suspected:

- The clinical personnel must be able to insert demographic data and record the patients' behaviour affecting the risk factors into the EHR maintained in the PDS.
- The clinical personnel must be able to record the clinical data into the EHR maintained in the PDS.
- The radiologists must be able to perform analysis of radiology images, including automatic segmentation and characterisation of the images.
- The clinical personnel must be able to record the radiomics data, produced from the imaging analysis performed by the radiologists, into the EHR maintained in the PDS.

- The radiologists must be able to manage the radiomics data and the segmented images produced from the imaging analysis process.
- The clinical personnel must be able to insert the genetic data from the biopsy/sample analysis into the EHR maintained in the PDS.
- The health professionals must be able to manage the genomic data produced from the biopsy/sample analysis.

Through CDSS, the health professionals require to support the process for managing the criteria for making decisions on the treatment that should be followed by a patient diagnosed with HNC. To this end, the CDSS must be used by the health professionals in order to perform the following:

- Associate the collected patients' clinical, radiological and genetic data with epidemiology and other population-based data to monitor the health status of an HNC patient with respect to the statistical population.
- Request for prognostic prediction analysis, which allows the different specialties to assess the impact of treatment decisions in the survival probability of the patient.
- Enable the physicians and the health professionals to select the prognostic model(s) to run.
- Offer comparison between the results produced from the selection of alternative models.
- Allow visualisation of the prognosis results both in a graphical and a textual way.
- Be able to monitor the impact of changing critical factors in the treatment on the prognosis results.

Following the physician's assessment on the status of their patients, a virtual tumor board can be organised, in which the assigned physician will analyse the disease case of the patient and the participating health professionals from various specialists will be able to explore the patients' data being exported by the PDS and provide their own assessment on the clinical status of the patient and the expected recovery period. Through the tumor board, the health professionals may examine the disease progress from their own angle and build consensus on which are the appropriate treatment options that should be proposed to the patient. This has to be implemented by the Tumor Board Collaboration Environment component of the CDSS, which must cover the following user needs:

- Allow multiple health professionals to join up remotely in virtual tumor boards, which can run either in a synchronous or an asynchronous mode.
- Allow the professionals exchange their views in an audio-visual way, while exploring the patients' data, as they have been collected and analysed.
- Allow the professionals to monitor the patient's recovery curve under different treatment scenarios.
- Give the option for inviting health professionals in a tumor board.

- Allow the tumor board chair to manage the virtual tumor board in a virtual space.
- Enable recording the meeting for future reference.
- Give the possibility for producing a consensus report on the treatment options to be proposed, along with the foreseen impact on the patient quality of life, as the result of a running tumor board.

During the treatment phase, the CDSS must allow the physicians to record the selected treatment option and update the patients' data in the PDS, according to the clinical status during this phase. Thus, clinical, pathological and potentially radiological data, also, collected at this phase, which have to be inserted into the PDS and the BD2Decid environment to facilitate personalised assessment of the treatment criteria to be examined by the physician and the other health professionals. In that respect, the CDSS must implement the following needs of the health professionals:

- Allow the collection of patients' clinical, radiological and (if needed) genetic data and associate them with epidemiology and other population-based data to monitor the health status of an HNC patient with respect to the statistical population.
- Allow the surgeon to insert into the PDS the treatment data, recording the surgery procedures.
- Reassess the prognosis on the survival probability through prognosis, which is performed using the patients' data collected at the treatment phase.
- Be able to analyse the impact of the treatment procedure on the patient's clinical status.

As the last phase in the HNC process is the follow-up phase. In this phase, the health professionals must be able to personalise the follow up schedule of their patient, based on the foreseen individual outcome. Subsequently, the CDSS should be able to:

Explore patients' data in a user friendly way, through the use of comprehensible images and graphics. The data exploration view should combine an overview of the main follow-up to present (such as the patient's demographic data, risk factor data and tumor characteristics.

- Visualise patient's risk assessment in the form of graphs.
- Compare the risk assessment of a patient with respect to the risk stratification for a group of patients with similar tumor disease cases. This should be accessible through interactive graphs, in which the health professionals can select the datasets to visualise for part or the whole group population.
- Suggest the patients an editable version of the follow-up schedule.
- Propose the health professionals to customise the follow-up schedule of a patient, if any additional data is made available for this patient, which affects the prognosis.
- Reassess the prognosis on the survival probability through running the respective prediction models, which is performed using the patients' data collected at the follow-up phase.

Across the three phases of the HNC treatment process, the CDSS should allow the health professionals to access the quality of life assessment score for their patients. This assessment is collected from the responses that the patients are requested to give in online questionnaires. As presented in D5.1 [10], for the BD2Decide project, we have selected the following quality of life assessment questionnaires (the implementation of which has been introduced in this deliverable):

- The EQ-5D-5L questionnaire developed by the EuroQol Group[4] for the measurement of health outcome;
- The QLQ-C30 from EORTC[5], which is a questionnaire developed to assess the quality of life of cancer patients;
- The QLQ - H&N35 from EORTC, which is a questionnaire developed to assess the symptoms or problems arisen from a treatment followed by cancer patients.

Through CDSS, the health professionals, and especially the physicians should be able to check the assessment score for their patients in the various phases of the treatment process. Typically, the patient is requested to fill in these questionnaires as follows: i) at least one time during the diagnosis, so that the physician has a baseline assessment of the patient's quality of life, ii) in frequent intervals during the treatment phase (and depending on the selected treatment option), so that the physician can monitor the impact of the treatment evolution in the quality of the patient's life, and iii) following the scheduled visits of the patient during the follow-up phase. Irrespective of the time that the questionnaires are filled in, the physicians must have access to the available quality of life data at all times.

4.2 Sketches design

As mentioned in Section 2.3 and shown in Figure 4, this section focuses on the user interfaces for the PDS, the CDSS, including the TBCE and the DPEE, and the imaging analysis tools.

Based on the user needs in section 0, we introduce in this section the general flows for the implementation of the expected functionalities for the CDSS, considering also the role of other components, such as the PDS and the imaging analysis tools. In that respect, Figure 7 presents the workflow for the diagnosis phase. As shown there, the main steps of the process include: i) accessing the PDS to collect patient's data and get a baseline quality of life assessment, ii) accessing the imaging analysis and radiomics tools to extract segmented volumes of the radiological images and their radiomics features, iii) accessing the DPEE of the CDSS to explore patient's data in the digital exploration environment, iv) accessing the CDSS to perform prognosis prediction analysis for the patient, and v) accessing the TBCE of the CDSS to organise virtual tumor boards.

In the same sense, Figure 8 presents the workflow for the treatment phase. As shown there, the main steps include: i) accessing the PDS to collect patient's data on the followed treatments and get the

[4] http://www.euroqol.org/eq-5d-products.html

[5] http://groups.eortc.be/qol/

quality of life assessment at scheduled time periods of the post-treatment phase, ii) accessing the DPEE of the CDSS to explore patient's data in the digital exploration environment, and iii) accessing the CDSS to perform prognosis prediction analysis for the patient.

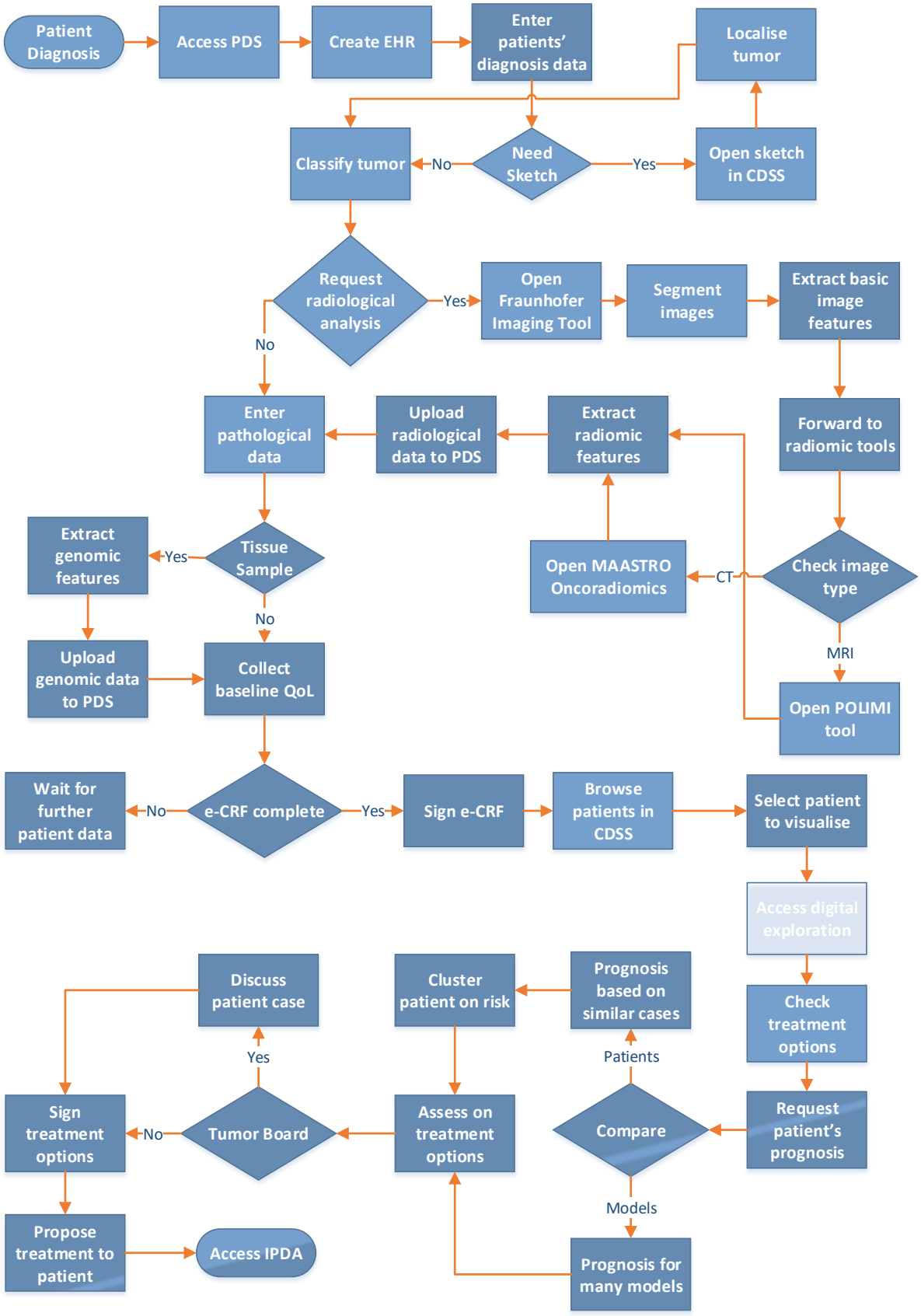


Figure 7: The general workflow for the CDSS, the PDS and the imaging analysis tools in the diagnosis phase.

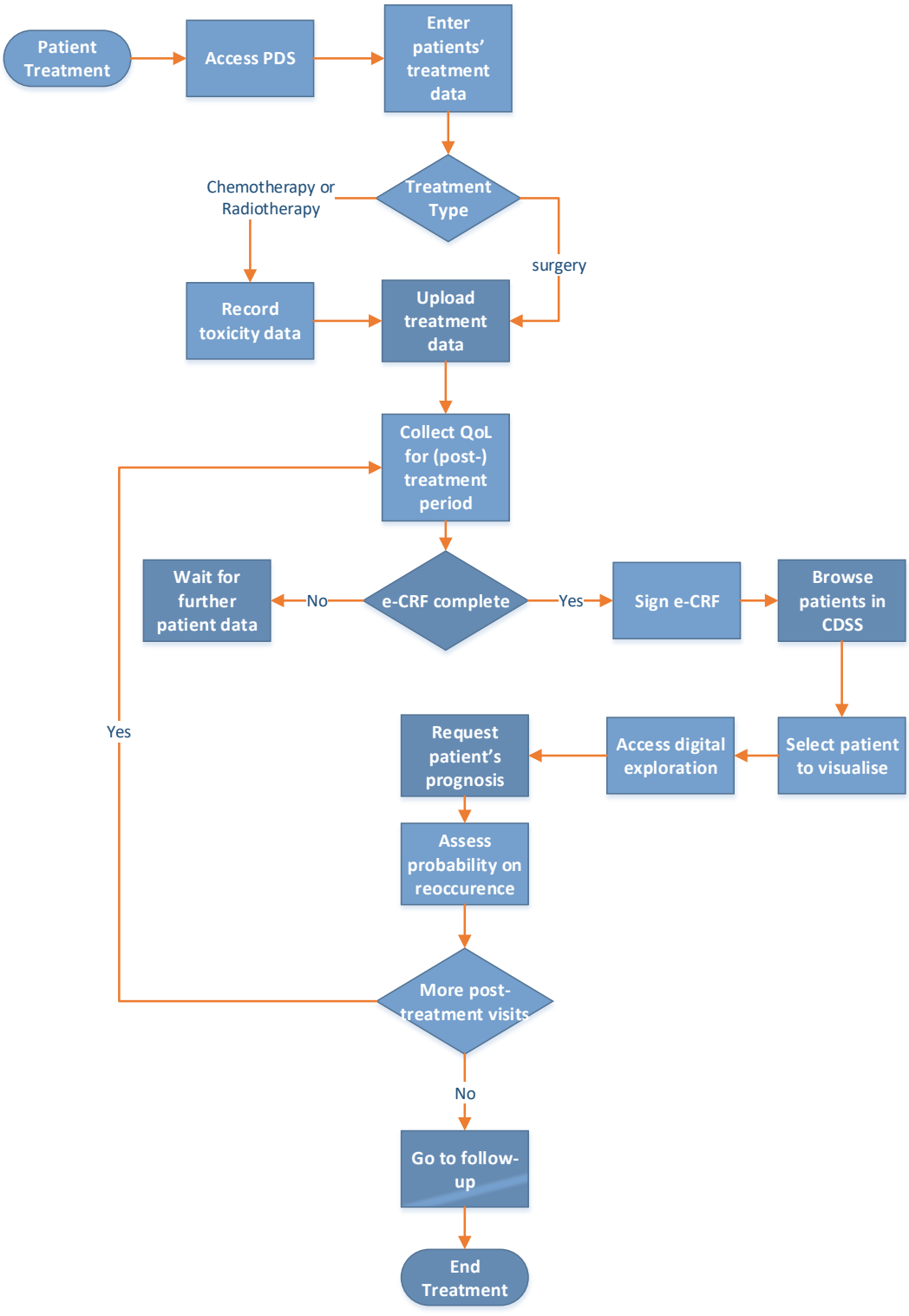


Figure 8: The general workflow for the CDSS and the PDS in the treatment phase.

Finally, Figure 9 presents the workflow for the follow-up phase. As shown there, the main steps of the process include: i) accessing the CDSS to manage the follow-up schedule, ii) accessing the PDS to assess the quality of life in the follow-up schedule, iii) accessing the DPEE of the CDSS to

explore patient's data in the digital exploration environment, and iv) accessing the CDSS to perform prognosis prediction analysis for the patient.

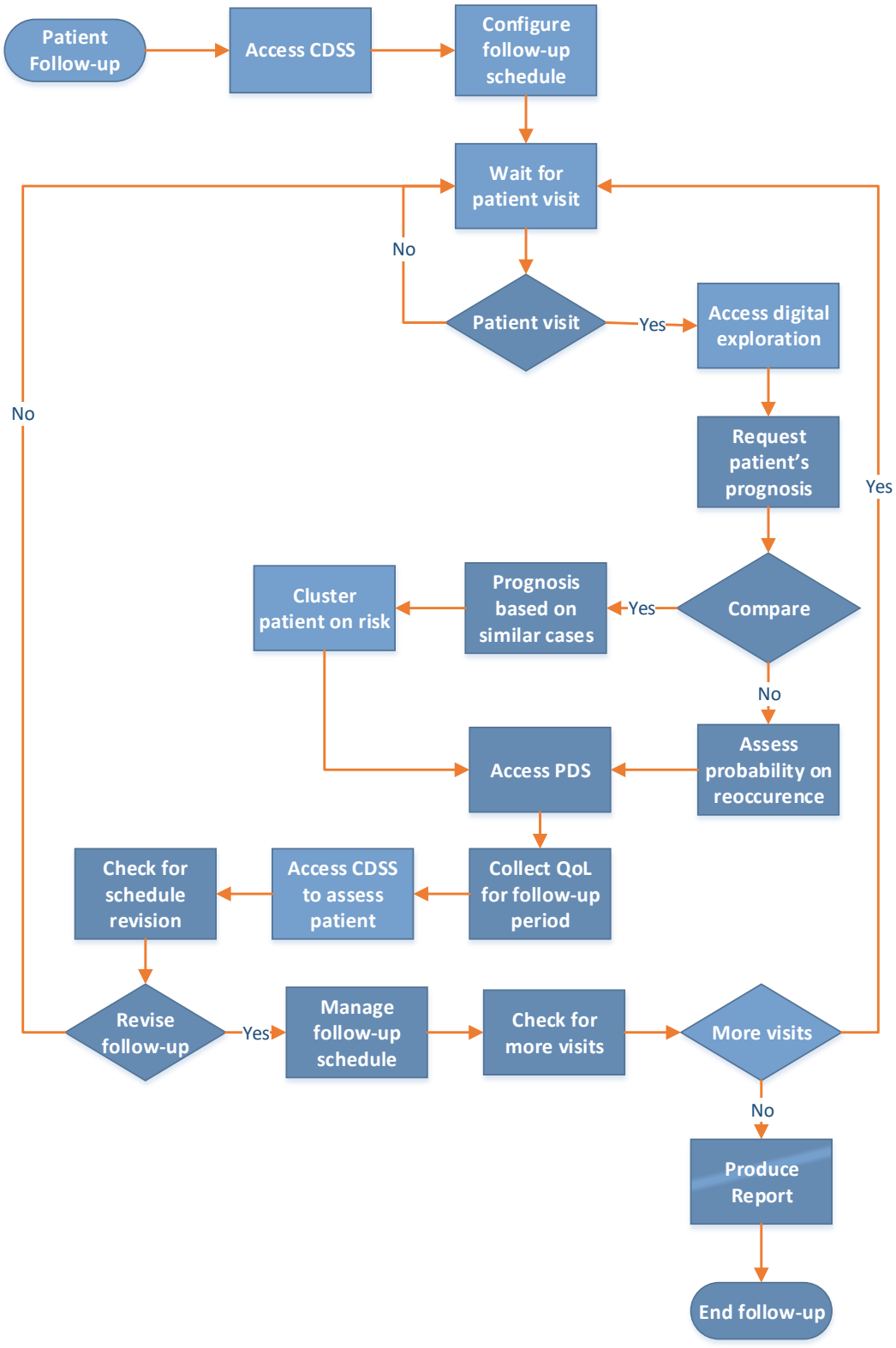


Figure 9: The general workflow for the CDSS and the PDS in the follow-up phase.

The above described flows are analysed to define user functionalities in the following section.

4.2.1 User functionalities

The functionalities defined for the CDSS tool target to allow the health professionals execute the HNC processes. As such, in this section, we define these functionalities, which have been initially identified in the description of the use cases and BD2Decide user needs in Deliverable D2.1.

Diagnosis Phase

At the diagnosis phase, once a patient first visits a hospital to tackle a disease case, the electronic health record (EHR) of the patient is created and recorded in the clinical information system. The respective functionalities that refer to the involvement of the BD2Decide environment in the case that a patient first visits the hospital are presented in Figure 10.

The patient is assigned to a physician, who is responsible for managing and signing the EHR. The latter is filled in by the clinical personnel, which record demographic and clinical data of the patient, as well as they report on the lifestyle behaviour of the patient, which affects the risks factors for the (re-)occurrence of an HNC case. As shown in Figure 10, these functionalities are implemented by the PDS component, the data of which is integrated with the CDSS for viewing purposes. This means that, PDS maintains a user interface for inserting data comprising the EHR, while the CDSS UI is used to manage and explore this data. Furthermore, in order to support the physician in a pre-assessment of the tumor localisation, the CDSS UI offers a sketching function, in which the physician marks the tumor location in the four disease cases that are examined in the BD2Decide project, namely, oral cavity, oropharynx, hypopharynx, and larynx.

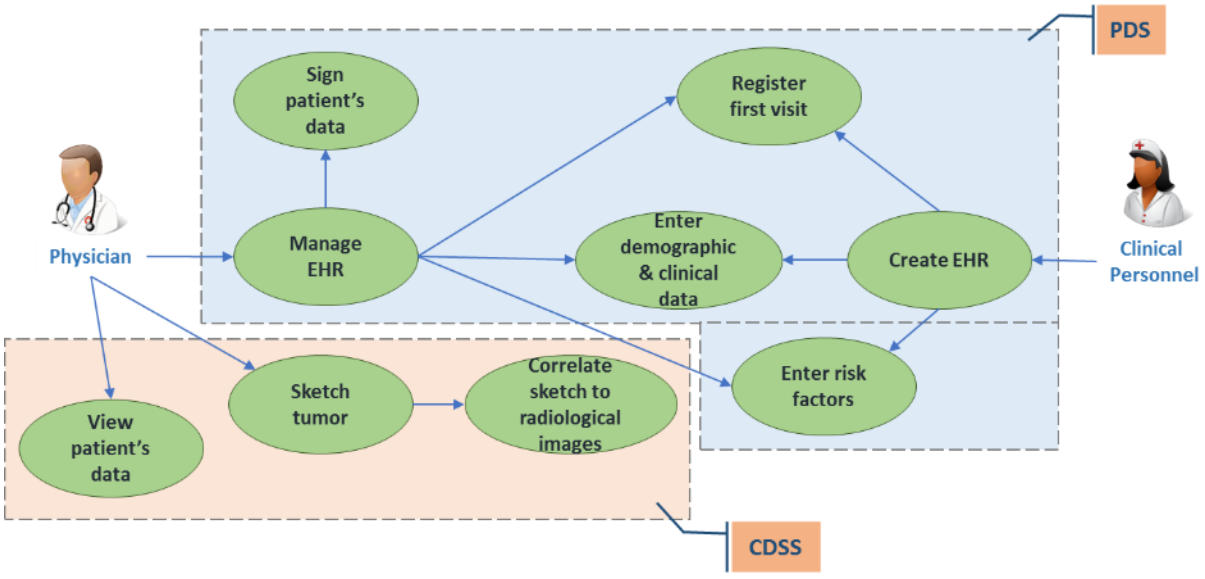


Figure 10: Collecting patient's data at the diagnosis phase - first visit.

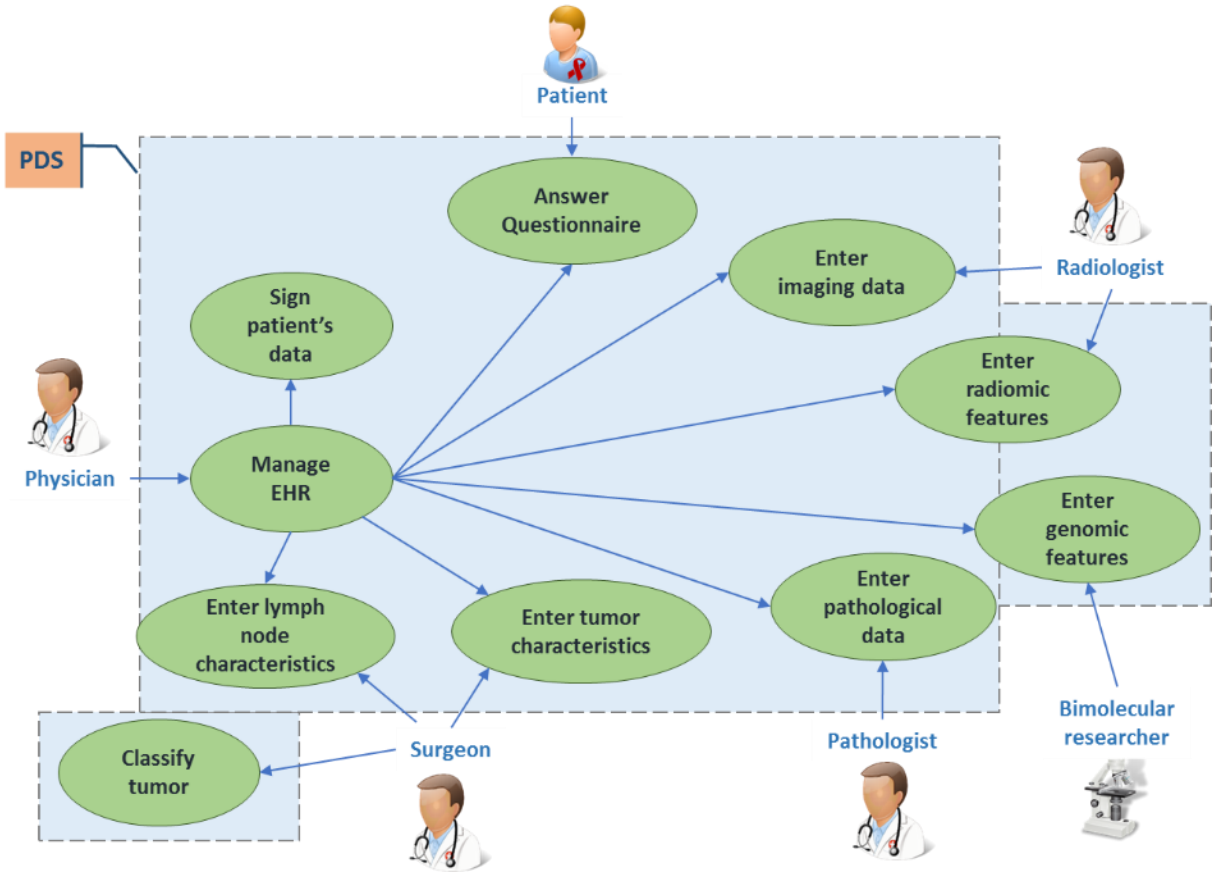


Figure 11: Collecting patient's data at the diagnosis phase - patient's examination from health professionals.

Once an HNC case is suspected, the BD2Decide environment should allow the health professionals in collecting the patients' data that is necessary in EHR for the assessment of the situation. As shown in Figure 11, the EHR is completed as follows:

- The surgeon enters the characteristics for the tumor and the lymph nodes and proceeds in a first classification of the tumor case.
- The pathologist examines the pathological data of the patient and inserts them into the EHR.
- If required, a genomic analysis of the tumor is performed and the bimolecular researcher assesses the genomic features extracted to complete the EHR.
- If a radiological analysis is required, the radiologist invokes the BD2Decide tools to analyse the radiological images and extract the radiomics features. This is further analysed later.
- The patient is asked to fill in three questionnaires, which provide the physician and the other health professionals a baseline assessment of the patient's quality of life at the time of diagnosis.

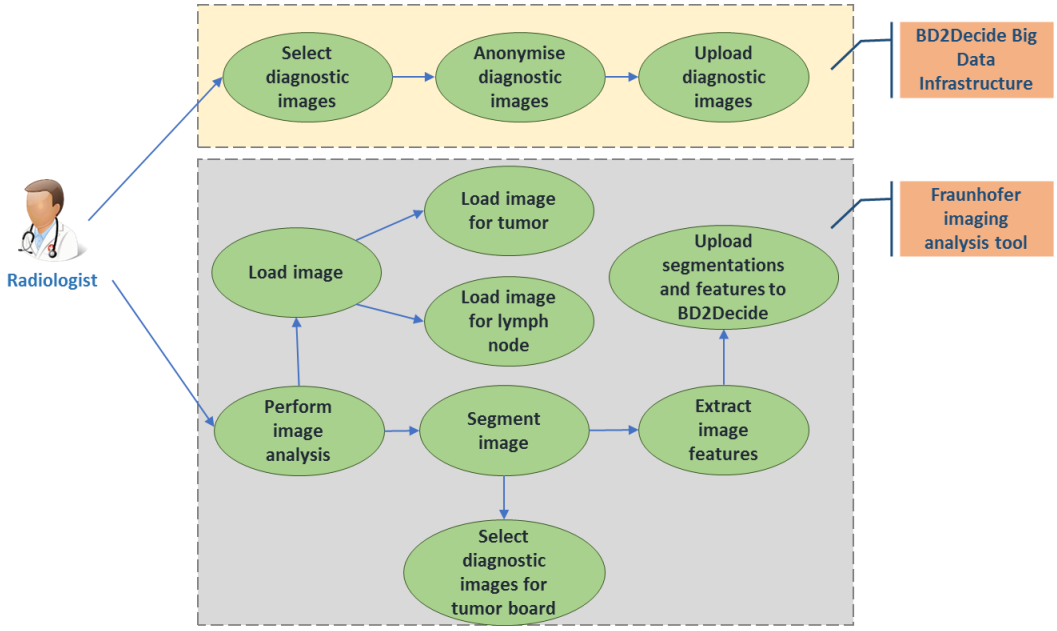


Figure 12: Perform radiological analysis, examination and staging.

As said above, radiological assessment of imaging datasets may be requested by the clinician. In this case, the radiologist can provide structured information by means of the imaging analysis tool implemented in the BD2Decide environment. As shown in Figure 12, the radiologist can retrieve images form the picture archiving and communication system (PACS) or from other media supports (e.g. CD, DVD, USB drive, cloud, etc.) and upload imaging datasets for the purpose of tumor and lymph node standardized assessment. For privacy issues, these images, prior to be uploaded, are processed and anonymised to prevent the image reproduction and the association with a specific person, which allows to circulate the imaging data within the BD2Decide environment and outside the information systems of the clinical centres.

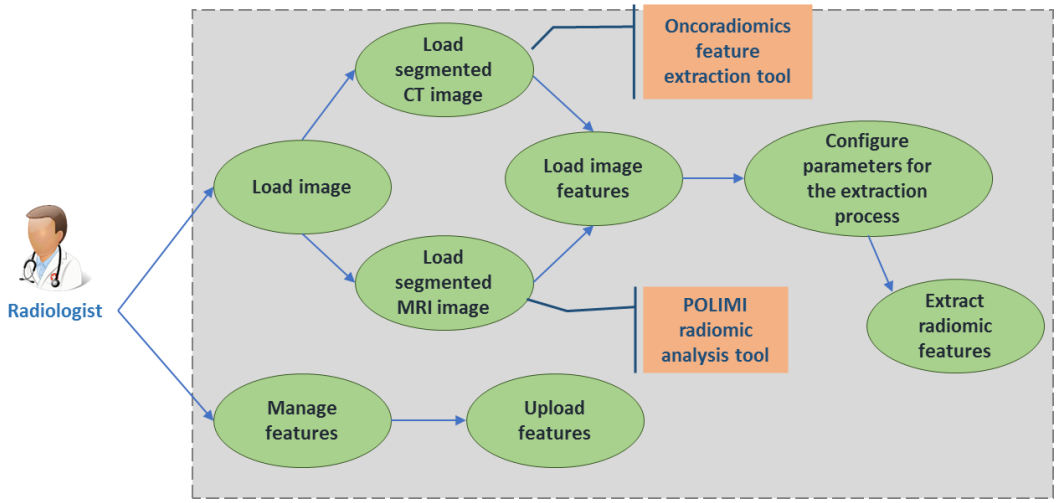


Figure 13: Perform radiomin feature extraction.

Standardized image assessment includes segmentation of tumor and lymph nodes, as well as description of clinically relevant oncologic parameters. Image segmentation is performed semi-automatically and can be edited to obtain volumes for quantitative analysis. Screenshot of tumor and lymph nodes can be uploaded for multidisciplinary discussion in the tumor board.

Figure 13 presents the process for the radiomics feature extraction. In this process, the radiologist exploits the segmented images (of various types, like CT and MRI images) and the corresponding image features extracted earlier to generate the radiomics features of the radiological data, which are inserted into the EHR through the PDS UI (as shown in Figure 11). The radiologists have the ability to configure the parameters of the radiomics extraction process.

During the examination of the patient's status, the physician (and the other health professionals as well) can have access to the overview of the patient's data collected in their EHR. The CDSS UI offers the health professionals the respective functionalities, which are summarised in Figure 14. As shown there, the physician has two options to browse through the patient's data, either in a traditional way (i.e. tabular form) or by initiating the DPEE component of the CDSS (see Figure 4), which loads the virtual patient's view mode. This new way of visualisation provides flexibility of the collected data in the PDS connect to the tumor localisation, so that the health professionals can have a better (and visually pleasant) exploration form of the patient's clinical status and their data.

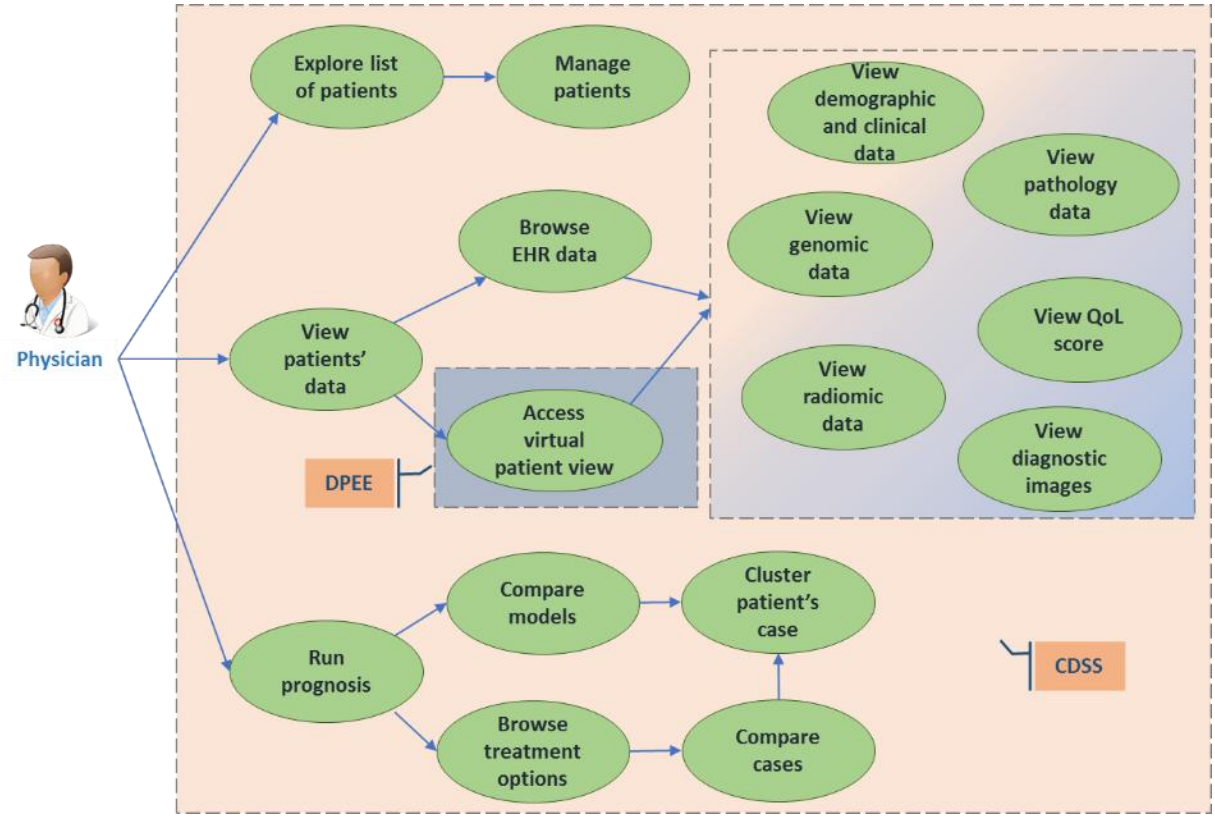


Figure 14: Visualise patient's data.

Of particular importance is the fact that through CDSS the physicians have the chance to invoke the prognostic prediction analysis tool and apply specific prognostic models on the patient's data to

predict on the survival probability rate for the patient, when following certain treatment options. Prediction is based on simulations, which are transparent to the health professionals, who can only view the factors affecting the results of the models. Through CDSS, the professionals may select to compare various models and predict the impact of the selected treatment options. Moreover, this prognostic analysis process allows the physicians to compare their patients' disease case with other similar cases and, thus, cluster their patients to risk groups.

The above functionalities for patient's data visualisation and prognostic prediction analysis are exploited to the assess the criteria for making decisions on which is the appropriate treatment (or treatments) that should be proposed to the patient. The final decision is the result of a professionals' tumor board, who are joined up together (either physically or virtually) to assess the patient's status and decide on the suitable treatments. The tumor board can be organised with the support of the CDSS UI and especially the TBCE component (see Figure 4), which offers the functionalities shown in Figure 15.

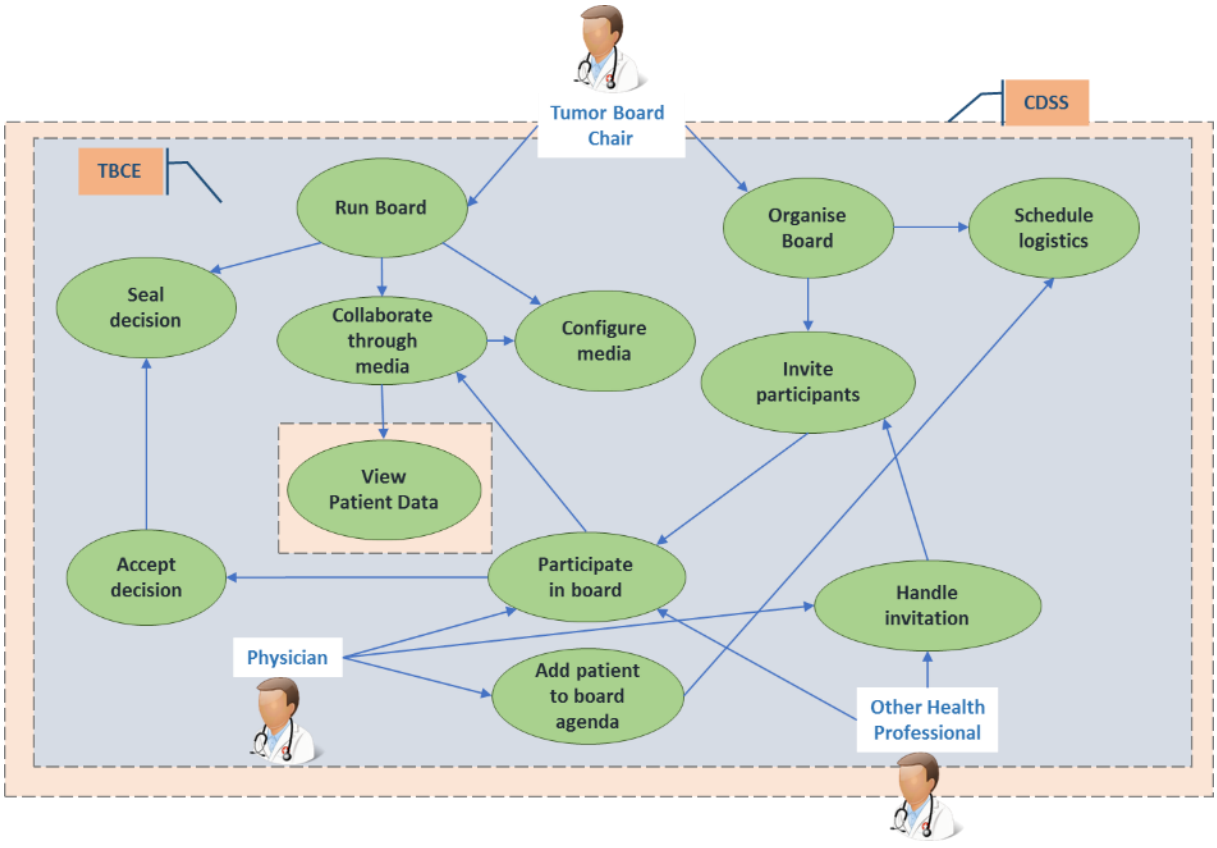


Figure 15: Organise the Tumor Board.

Following the decision of the tumor board, the physician interacts with the patient to explain the available treatment options and their impact of the patient's survival probability and the expected risks in the quality of the patient's life. The functions that are implemented in the BD2Decide environment for the treatment decision process, with the involvement of the patient, are presented in Section 3.

Treatment Phase

In the treatment phase, the main actions performed in the CDSS refer to the update of the patients' EHR with the data about the followed treatment options, which may include a surgery, one or more chemotherapy treatments and/or one or more radiotherapy treatments. Apart from inserting further data to the EHR for the treatment phase, this phase includes the post-treatment period, which includes the process steps for visualising the patient's data, updating the prognosis for the evolution of the patient's HNC case, based on the new data available, and assessing the QoL, on frequent time intervals, which depend on the followed treatment. Moreover, for each treatment (except for surgery), a set of toxicity data is involved, which should be managed by the physician and the other health professionals and be inserted as part of the PDS component.

All these functionalities are made available to the physicians and the health professionals through the CDSS and PDS UI, as shown in Figure 16 and Figure 17.

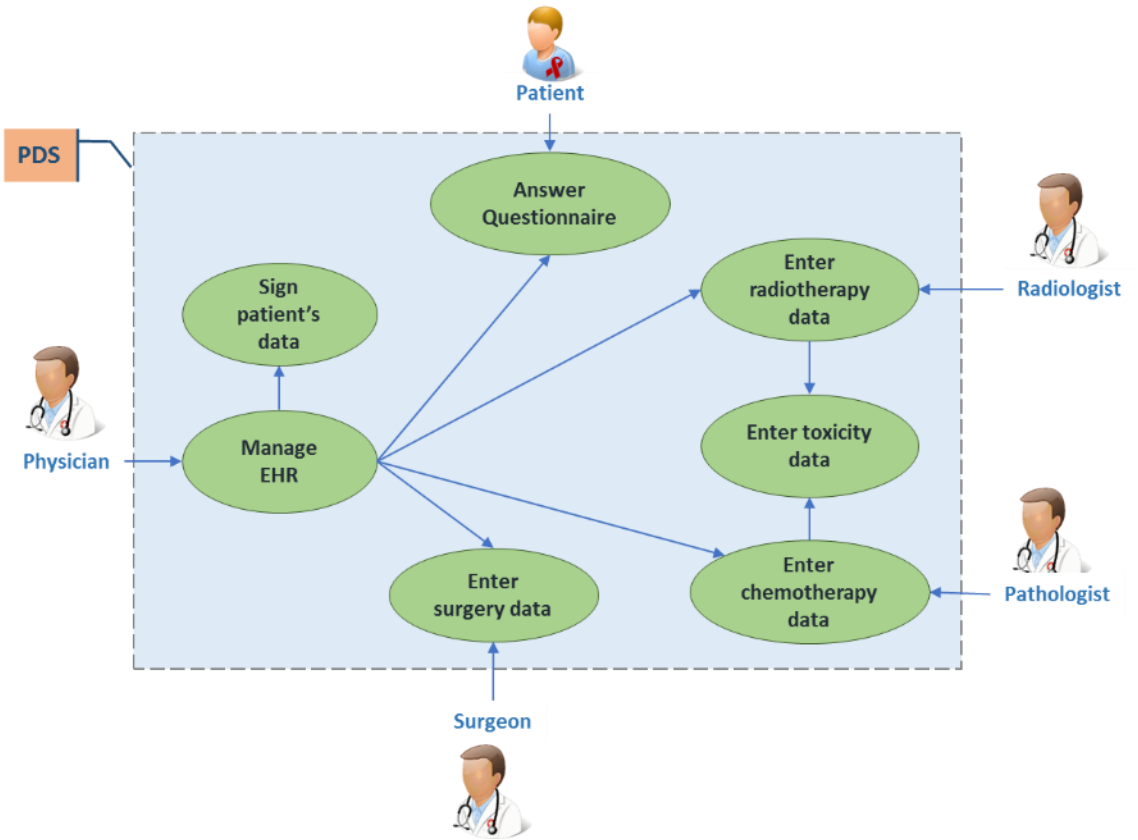


Figure 16: Collecting the patients' data for the the treatment and the post-treatment phases.

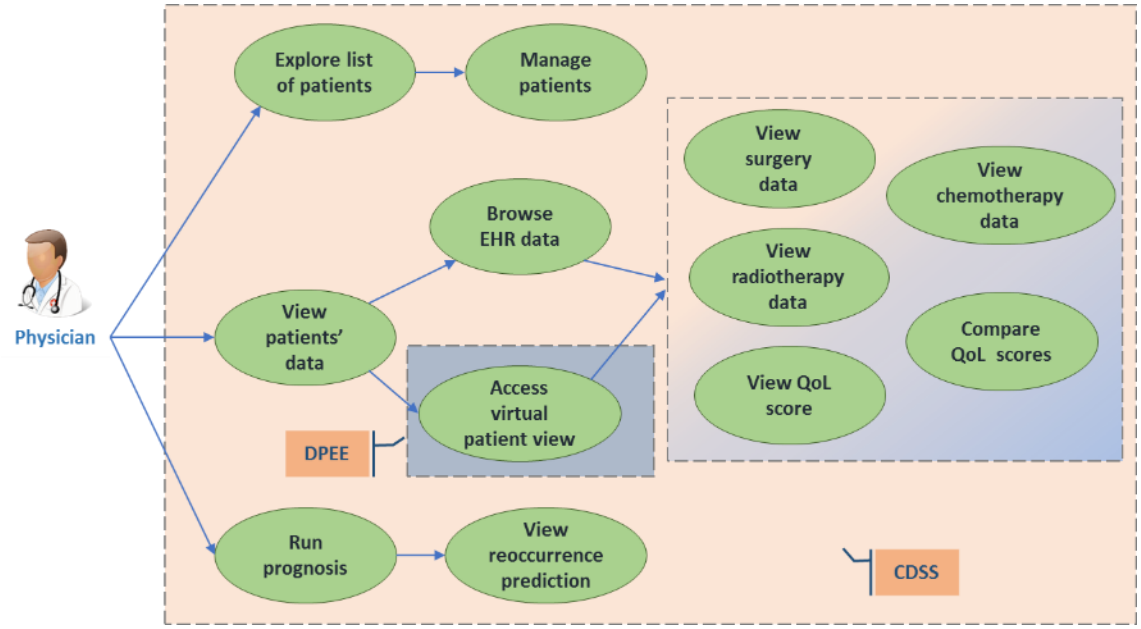


Figure 17: Visualise patient's data after treatment.

Follow-up Phase

Finally, in the follow-up phase of the HNC treatment process, the physician accesses the BD2Decide environment to monitor the clinical status of the patient after a specific treatment or treatments have been applied. In this phase, the CDSS automatically configures the follow-up schedule for the patient's visits to the hospital. This plan is personalised to the patient's data and prognosis, but the physician can always edit it if necessary.

As shown in Figure 18, the follow-up process involves a step for making predictions on the reoccurrence factor, in which the physician may assess how the follow-up period is evolved for the specific patient and, according to similar cases, apply changes in the follow-up schedule. During the scheduled visits, the patient should respond to the questions of the quality of life questionnaire, which are used by the physician, along with other patient's data to assess the progress of this phase.

Finally, the CDSS UI allows the physician to quickly view a report summary of the patient's status and print detailed reports on the way that the HNC patient has been treated, since the diagnosis phase.

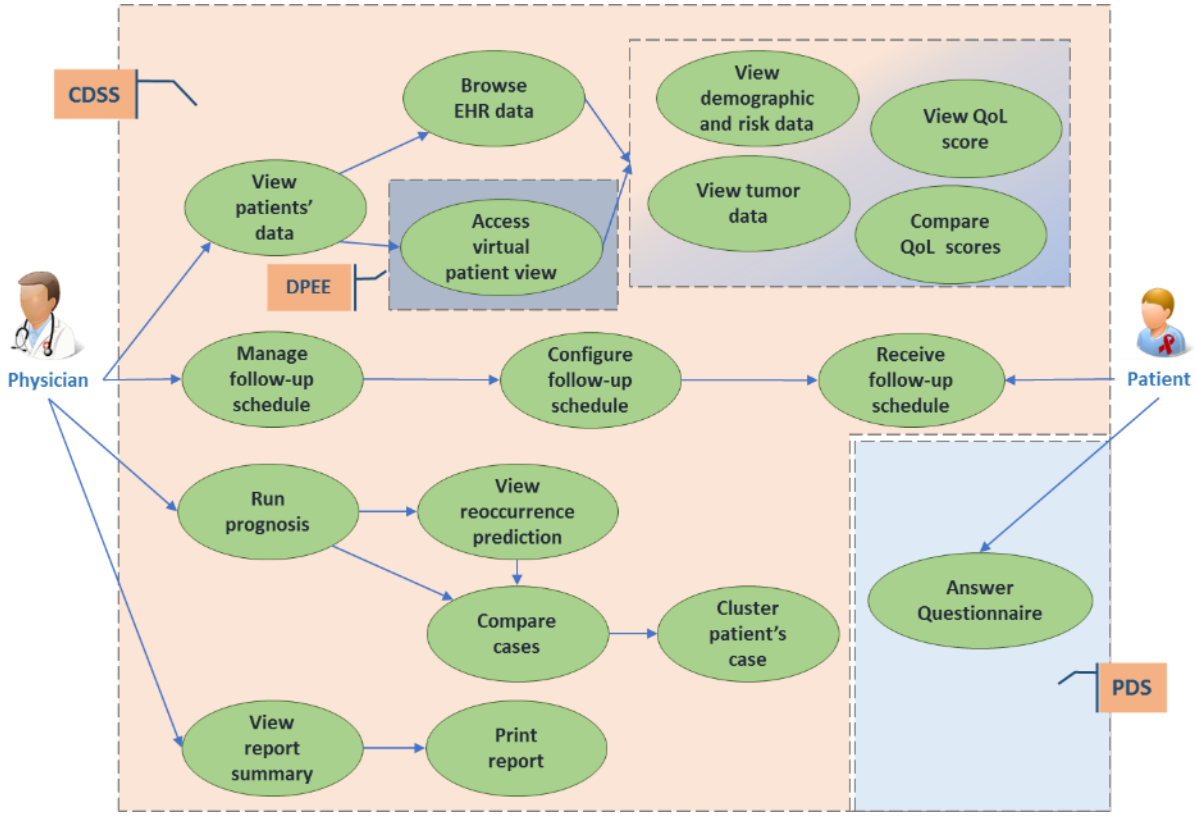


Figure 18: The functionalities of the CDSS and the PDS components in the follow-up phase.

4.2.2 User Interfaces

Following the functionalities presented in the previous section, in this section, we provide sketches of the expected user interfaces for the CDSS (along with the PDS and the imaging analysis tools), which aim to implement these functionalities.

As presented in Section 4.2.1, the physicians have two different components to manage the EHR with the patients' data. The first one is the PDS, which is used to maintain the patients' data, as this is collected from the hospitals and the clinical centres. During the collection phase, the clinical personnel and the health professionals use the PDS UI to submit the patient's data into the BD2Decide environment. Once this data is collected and registered into the storage layer of the PDS component, the BD2Decide environment provides the CDSS tool to allow the health professionals to manage the visualisation of the patients' data, making prognosis on the HNC case and collaborating between each other in the tumor board. Along with these tools, in Section 4.2.1, we also presented the functions for the analysis of radiology images, through the respecting imaging analysis and radiomics extraction tools.

An initial version of the PDS UI for the collection of patients' data has been implemented using the OpenClinica software[6]. This open source software has already been introduced in the project in Deliverable D5.1 [10]. Through this tool, the clinical personnel and the health professionals insert

[6] https://www.openclinica.com/

the patients' data into the PDS in the form of an electronic Clinical Record Format (e-CRF). As shown in Figure 19, the PDS view for the data collection offers the ability to select the category of patients' data that the user wants to insert into the PDS component, like demographic, clinical data, risk factor data, tumor characteristics, etc. The categories follow the template for the e-CRF, which has been described in Deliverable D2.1.

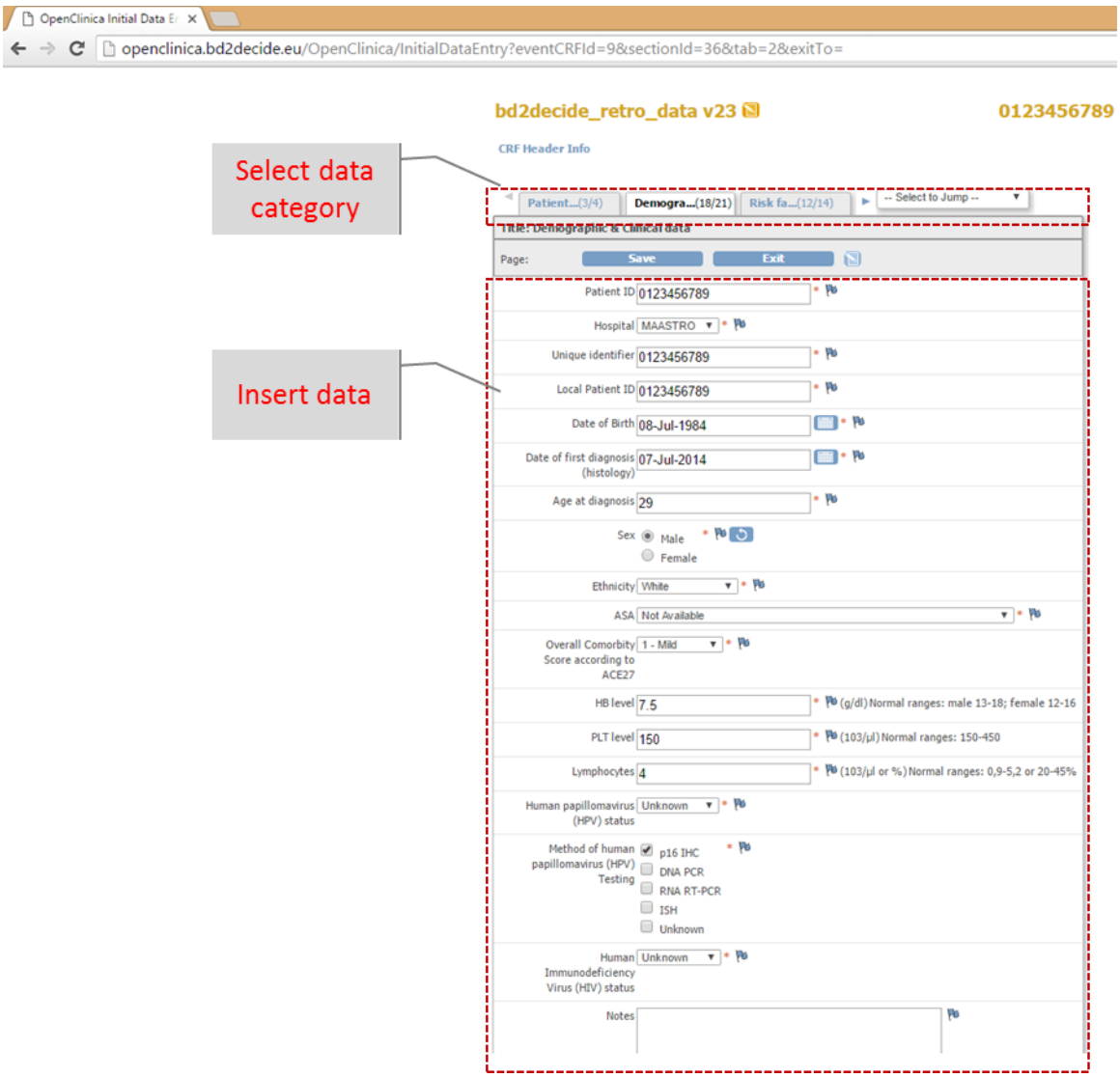


Figure 19: The PDS UI for the collection of patients' data, through the OpenClinica tool.

Through the view of Figure 19, the health professionals and the clinical personnel can access the functionalities of Section 4.2.1, which have been assigned to the PDS (light blue areas in the respective figures, from Figure 10 up to Figure 18).

More specifically, at the diagnosis phase, the clinical personnel can (see Figure 10):

- Create the EHR of the patient under examination and register this patient with the first visit data;
- Enter the patient's demographic and clinical data;

- Enter the risk factor data, based on the patient's lifestyle behaviour.

The physician and the health professionals can manage the collection of the patients' data that refer to their role in the treatment process, as follows:

- The physician can manage the whole dataset for the patient's EHR and sign the final e-CRF (as per Figure 10 and Figure 11.
- The surgeon can submit data with respect to the characteristics of the tumor and the lymph nodes (see Figure 11). The surgeon can also provide an initial classification of the tumor.
- The pathologist can insert the pathological and genomic data (see Figure 11).
- The radiologist can provide links to the segmented volumes of the radiological images and their image and radiomics features extracted from the imaging analysis tools, as it will be presented later (see Figure 11).

The same view implements the PDS functionalities shown in Figure 16. In this case, the physician and the other health professionals access this PDS UI view to complete the e-CRF-based EHR with data from the treatment and the post-treatment phase. Such data include information about the treatment type and details, like surgery, chemotherapy and/or radiotherapy. For the last two cases, this PDS UI view will allow the corresponding health professionals to submit toxicity data (about the followed treatment) to the BD2Decide environment.

The imaging analysis step is implemented through the respective tools provided by the Fraunhofer, MAASTRO and POLIMI partners in WP3. These tools implement the functionalities shown in Figure 12 and Figure 13. A prototype version of these tools is already available, so in this section we present the screenshots from the tools rather than UI sketches.

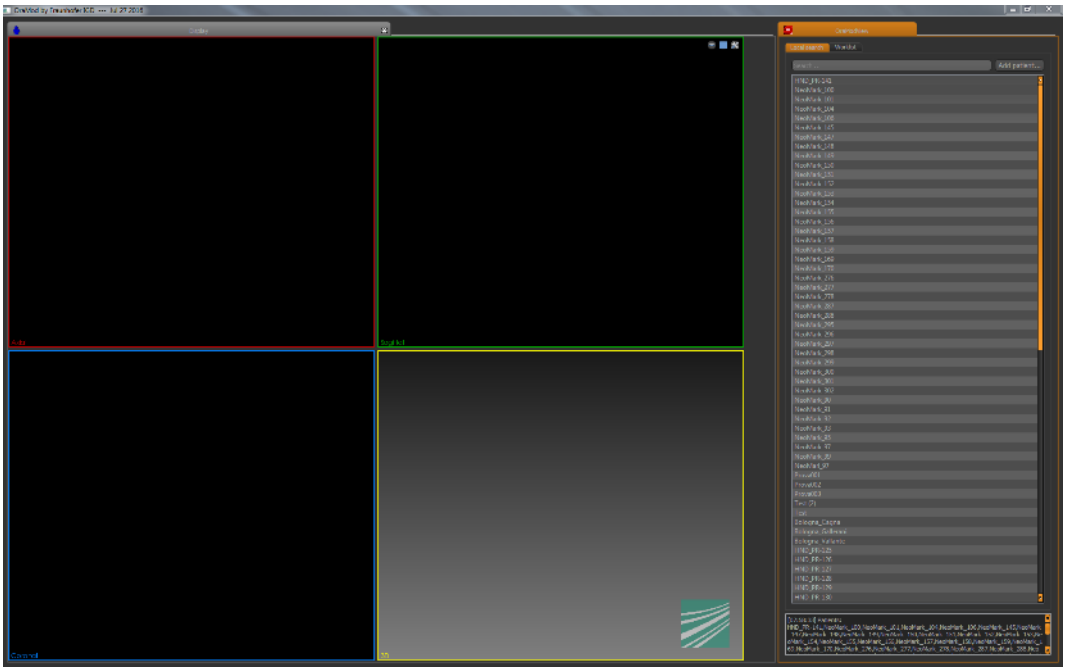


Figure 20: The Fraunhofer image analysis tool – selecting patients.

More specifically, when a radiological analysis is requested, the radiologist opens the Fraunhofer image analysis tool in order to select the patient for whom an analysis is required (see Figure 20). The tool loads the available CT and MRI images for the specific patient, as per Figure 21, and, then, the radiologist can select of them to analyse or to load more images, through the dialog box shown in Figure 22.

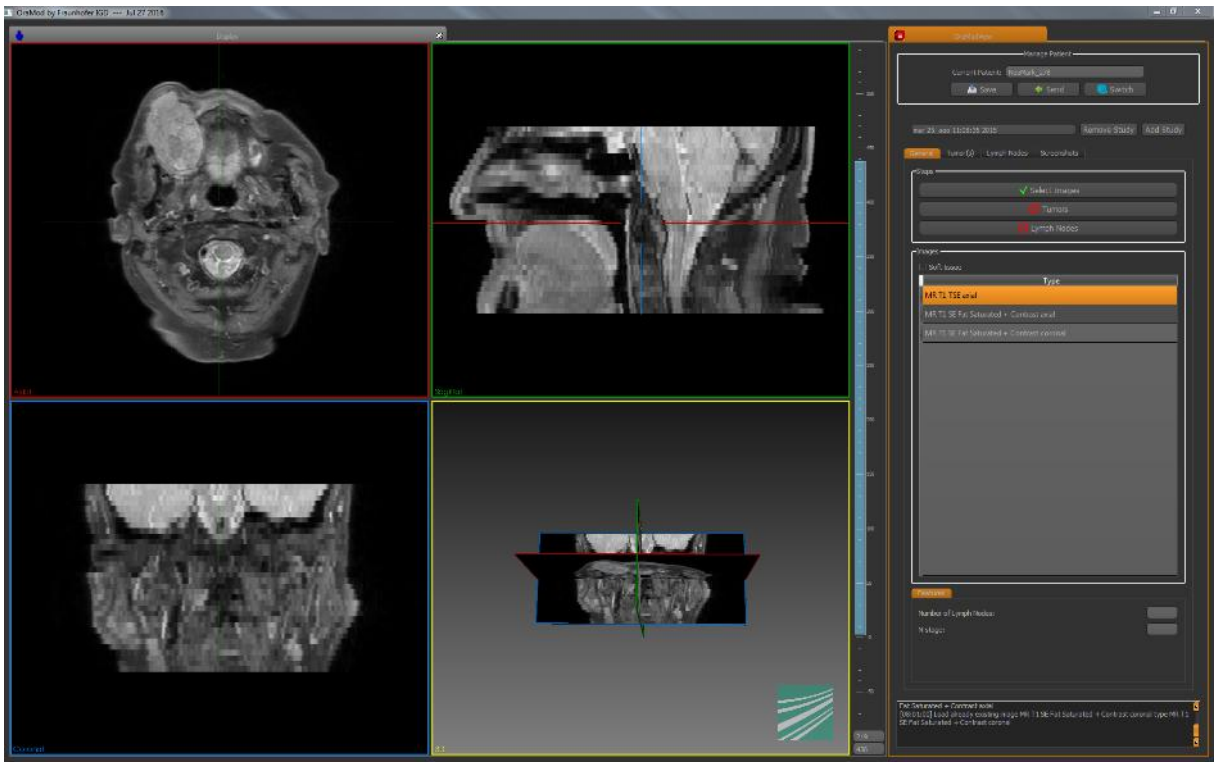


Figure 21: The Fraunhofer image analysis tool - initial view of patient' radiology images.

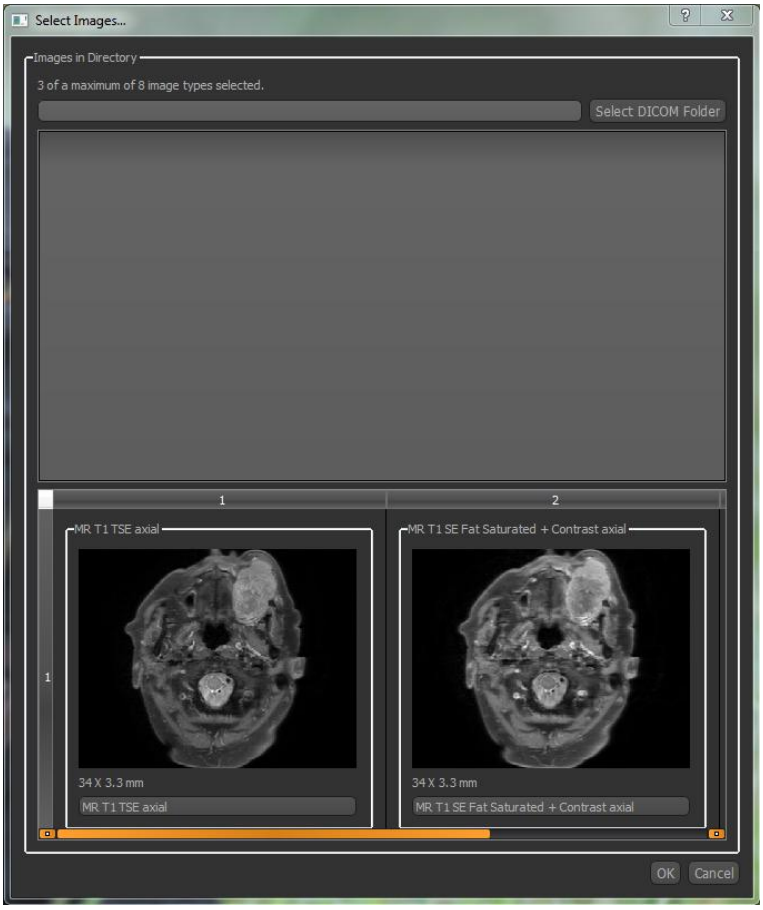


Figure 22: The Fraunhofer image analysis tool – the dialogue box for selecting images for segmentation.

The images that the radiologist can select may refer to a tumor or lymph node. The respective image segmentation to volumes is done through the editor shown in Figure 23 for the tumor case or Figure 24 for the lymph node case.

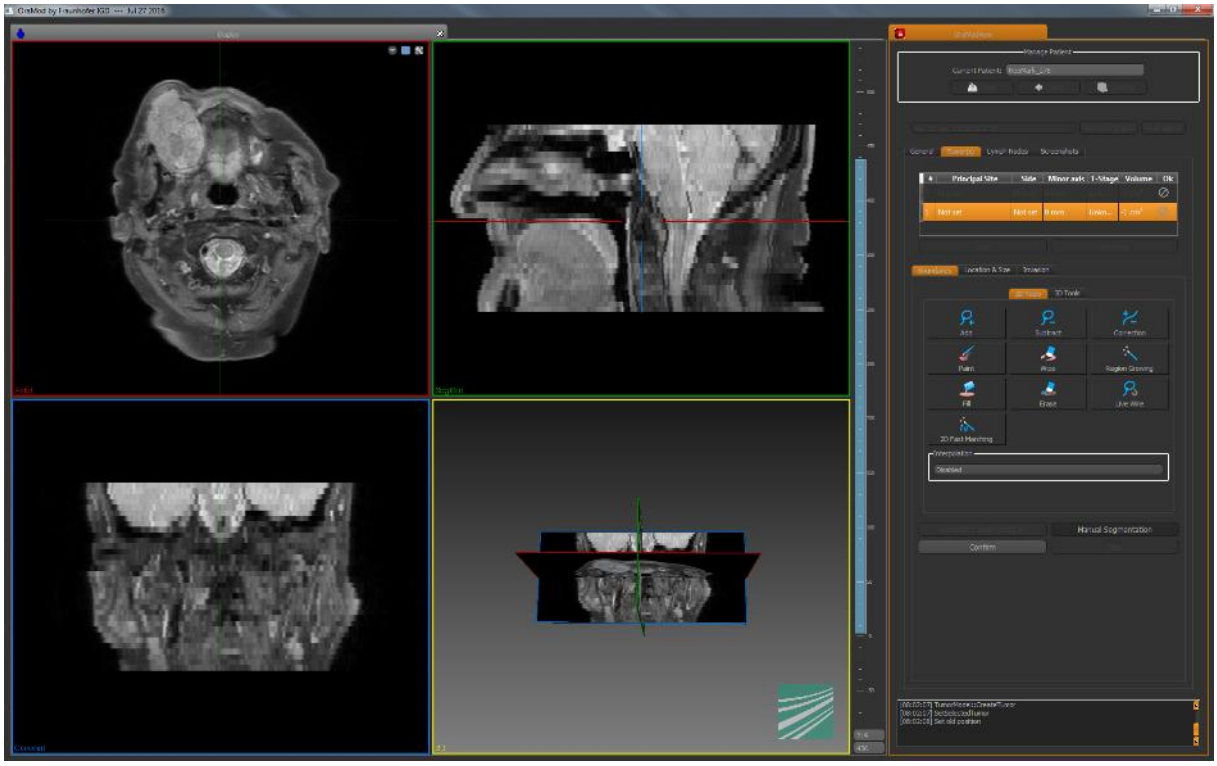


Figure 23: The Fraunhofer image analysis tool – segmenting an image on tumor.

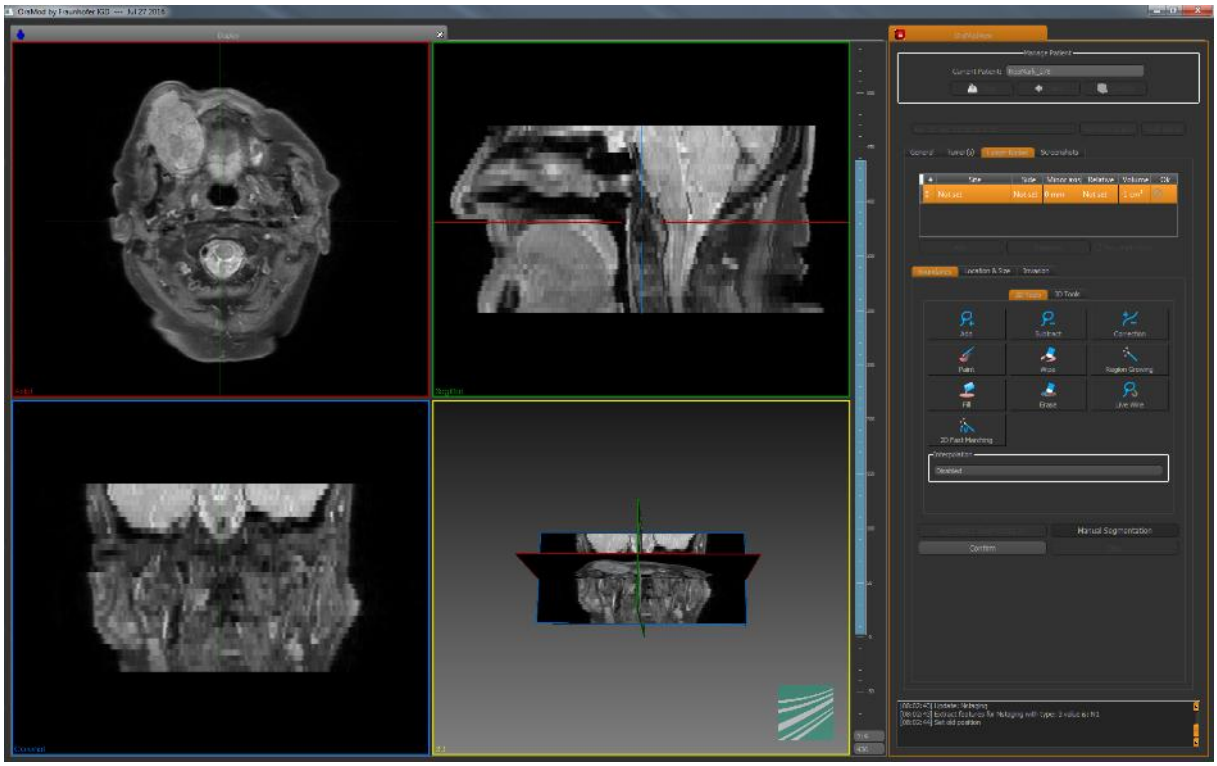


Figure 24: The Fraunhofer image analysis tool – segmenting an image on lymph-node.

The segmentation process extracts some image features, which accompany the image itself when they are saved into the Fraunhofer image analysis tool.

Finally, the radiologist may select a set of segmented image volumes for each patient (see Figure 25) that will be used by the BD2Decide environment as supporting evidence in the tumor board discussions.

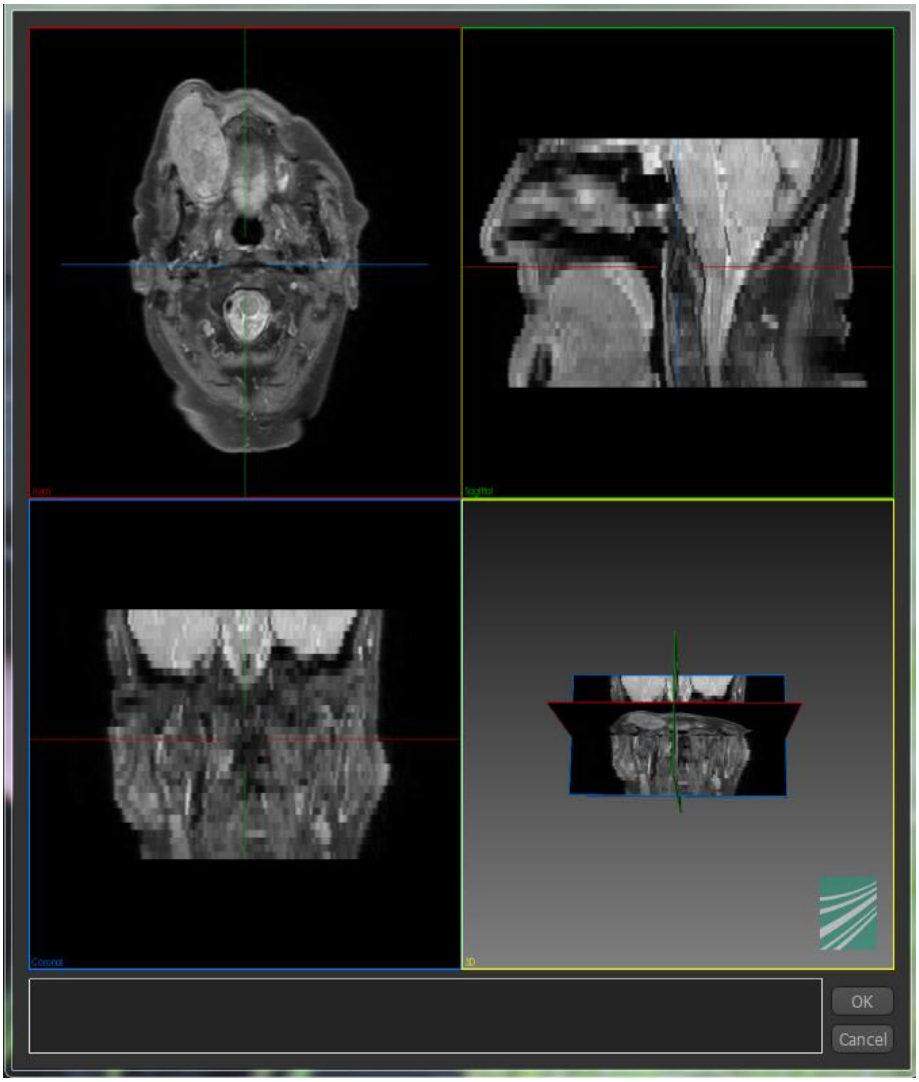


Figure 25: The Fraunhofer image analysis tool – selecting segmented volumes.

As shown in Figure 12, the segmented image volumes and their features are forwarded to the radiomics feature extraction tools. More specifically, depending on whether the radiologist wants to process a CT or an MRI image, he/she can open the MAASTRO Oncoradiomics tool or the POLIMI tool.

In case of a CT image analysis, the MAASTRO Oncoradiomics tool is loaded and the respective view for the management of the radiomics feature extraction process (see Figure 13) is presented in Figure 26. The user can select the appropriate segmentation, according to the decided nomenclature (for example, we can use GTV to describe Gross Tumor Volume and further refer to GTVp for the primary tumor, or GTVnode_L or GTVnode_R for the lymphnode metastases in the left and right neck, respectively), in an automatic way for multiple patients. Afterwards, researchers can select the

most appropriate feature extraction style as presented in Figure 27. A report is finally generated with detailed feature extraction process, therefore data can be exported as spreadsheet for statistical analysis (CVS, Excel File) as shown in Figure 28.

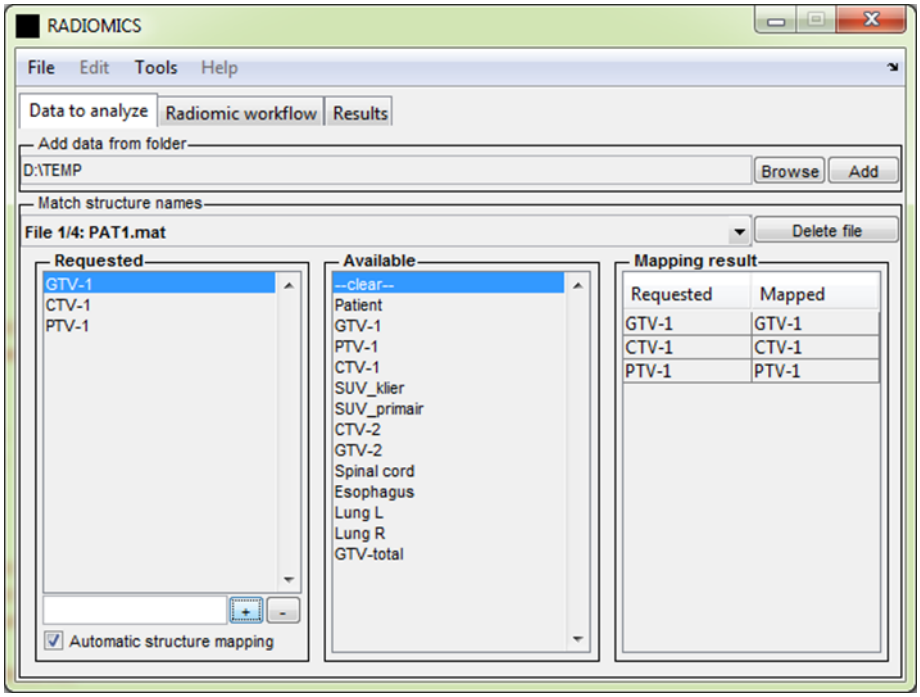


Figure 26: MAASTRO Oncoradiomic tool – home page.

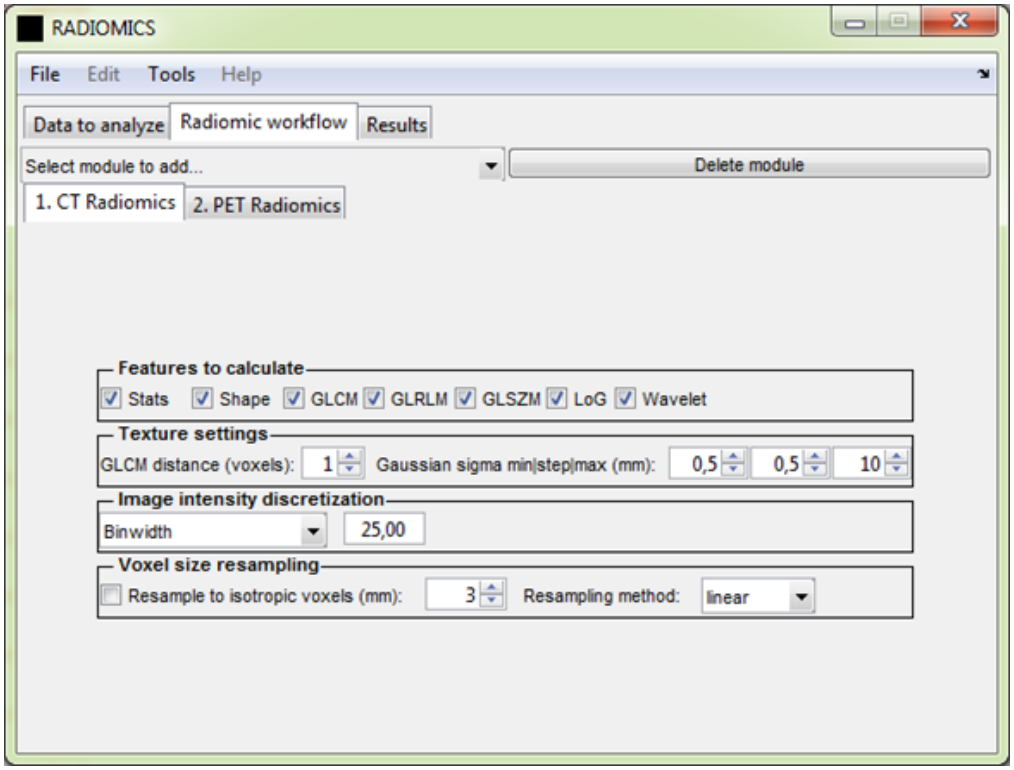


Figure 27: MAASTRO Oncoradiomic tool – CT radiomics extraction selectable options.

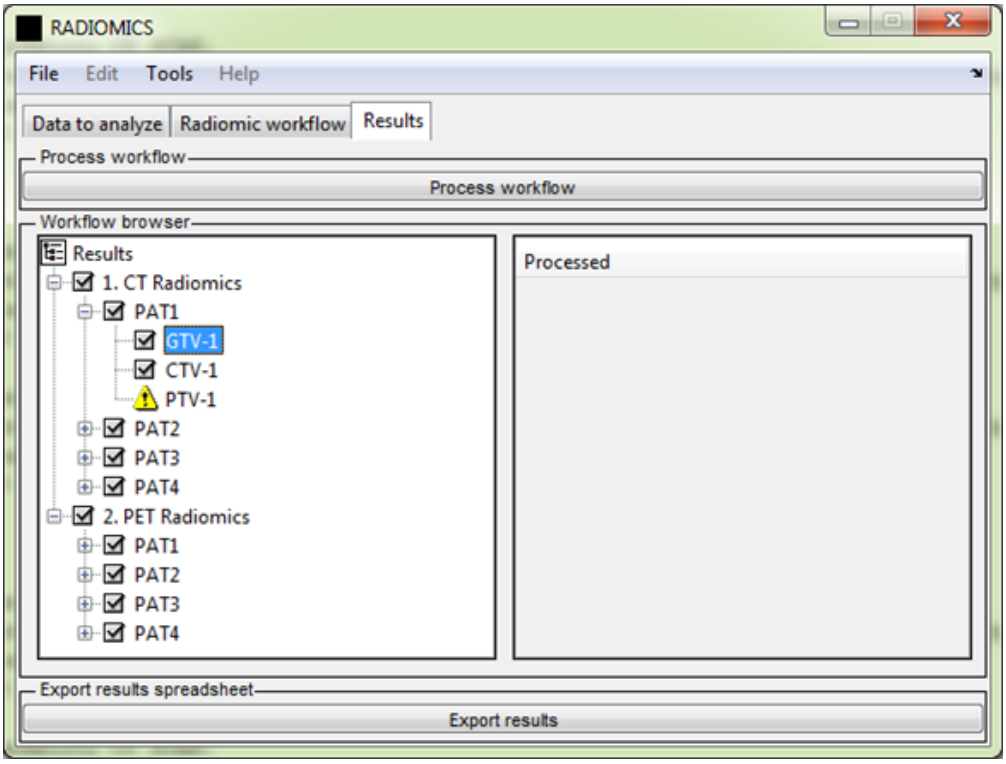
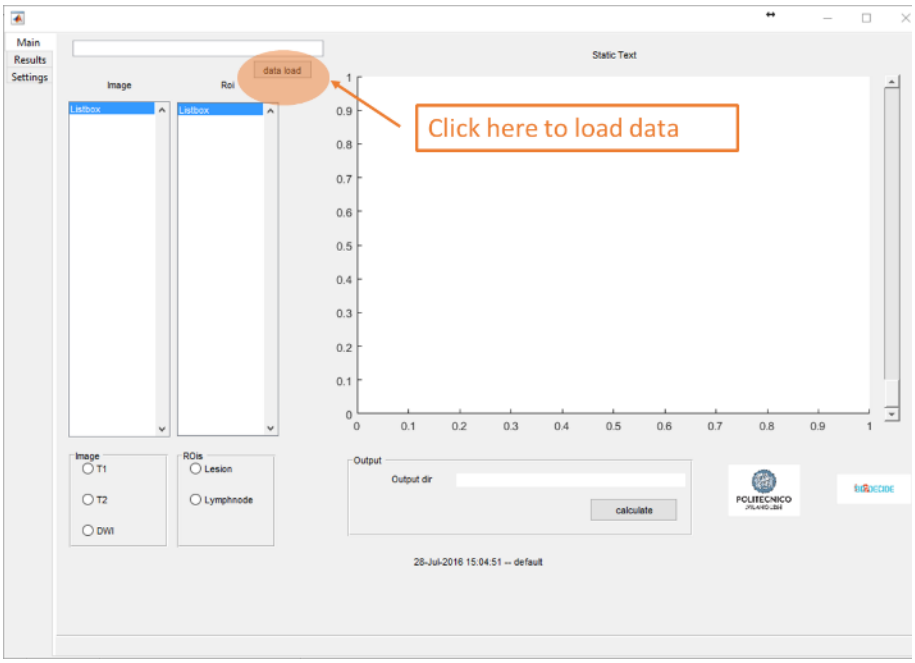


Figure 28: MAASTRO Oncoradiomic tool – CT radiomics results summary.

In case of an MRI image analysis, the radiologist opens the POLIMI tool, which allows loading the image data from the local directory of the radiologist's computer (see Figure 29). Then, the radiologist can select the different parameters for the MRI image to view as shown in Figure 30, while, in Figure 31, we present the interaction of the radiologist with the tool to request for the extraction of the radiomics features for the selected image type.



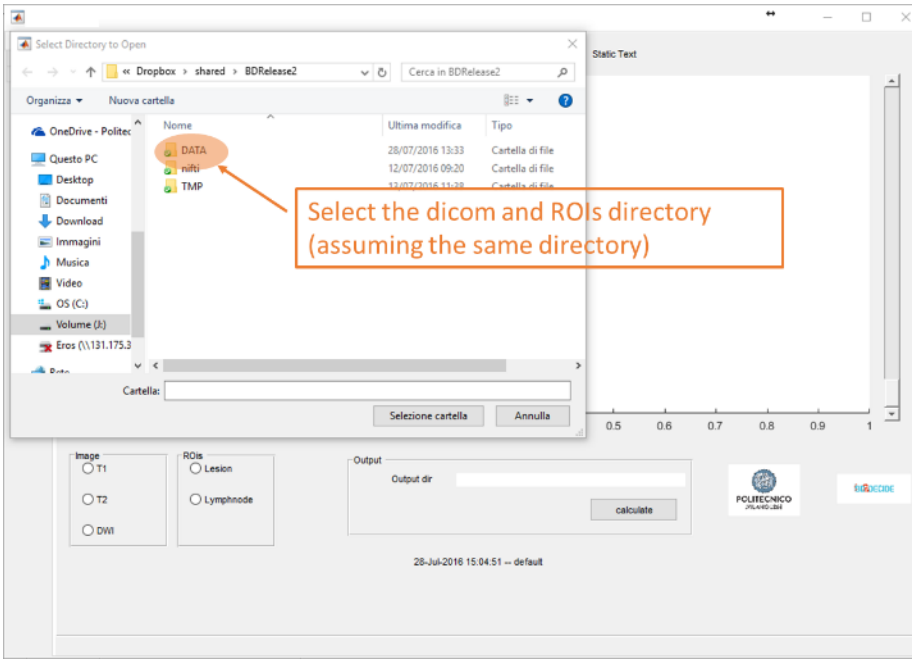


Figure 29: POLIMI tool – loading data.

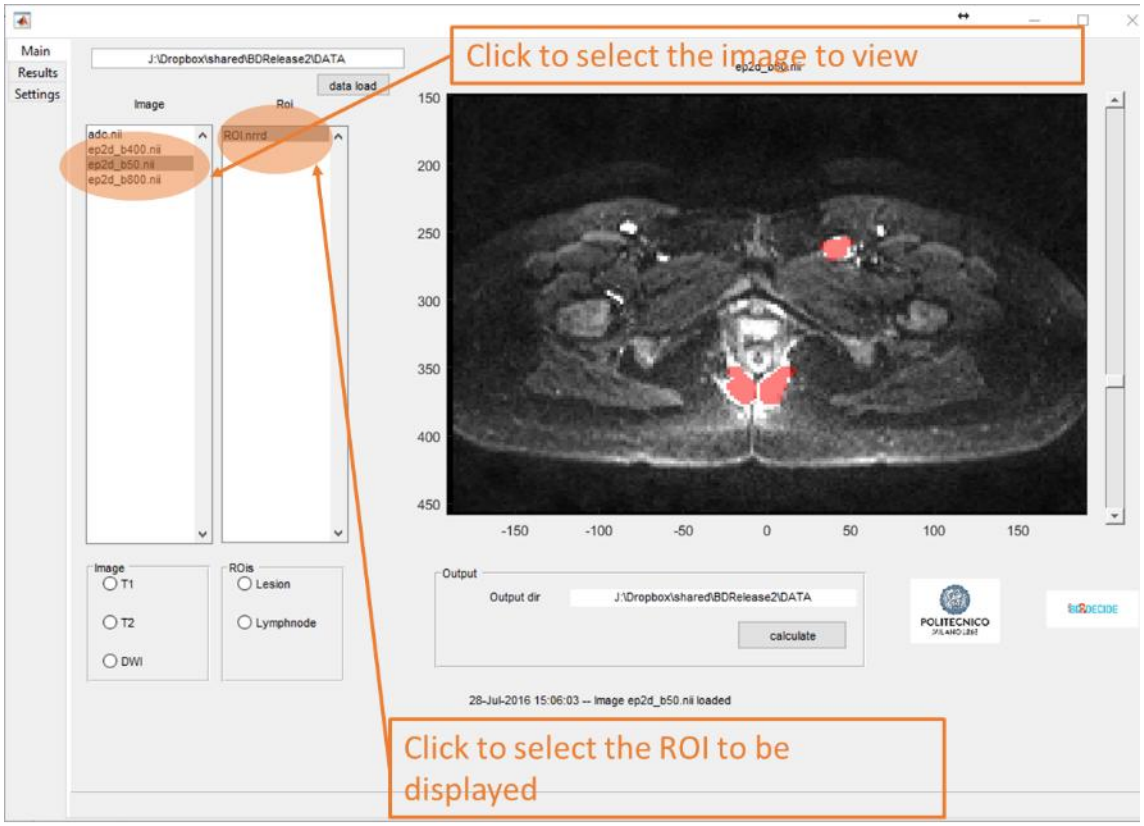


Figure 30: POLIMI tool – selecting an image to analyse.

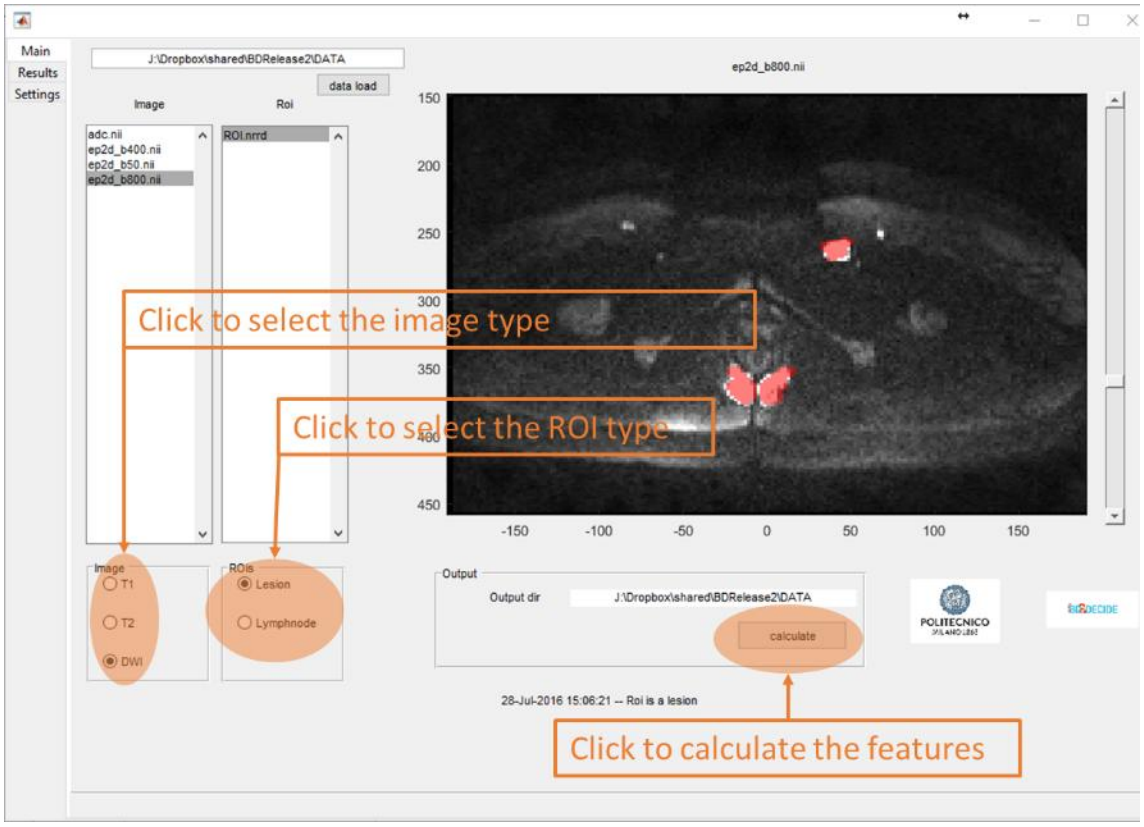


Figure 31: POLIMI tool – calculating the radiomics features.

Moving to the core sketches of the CDSS UI tool, this tool is mainly used to explore the patients' data and manage the processes for the HNC treatment. The physician opens a Web browser and is authenticated to the CDSS tool. The home page is loaded, as shown in Figure 32. In this screen, the general look and feel of the CDSS UI consists of a side navigation pane, the central main screen and a management pane on the top. This philosophy is followed in other screens as well. It is noted that the remaining sketches for the CDSS UI in this section have been designed using the Mockflow tool[7].

[7] https://www.mockflow.com/

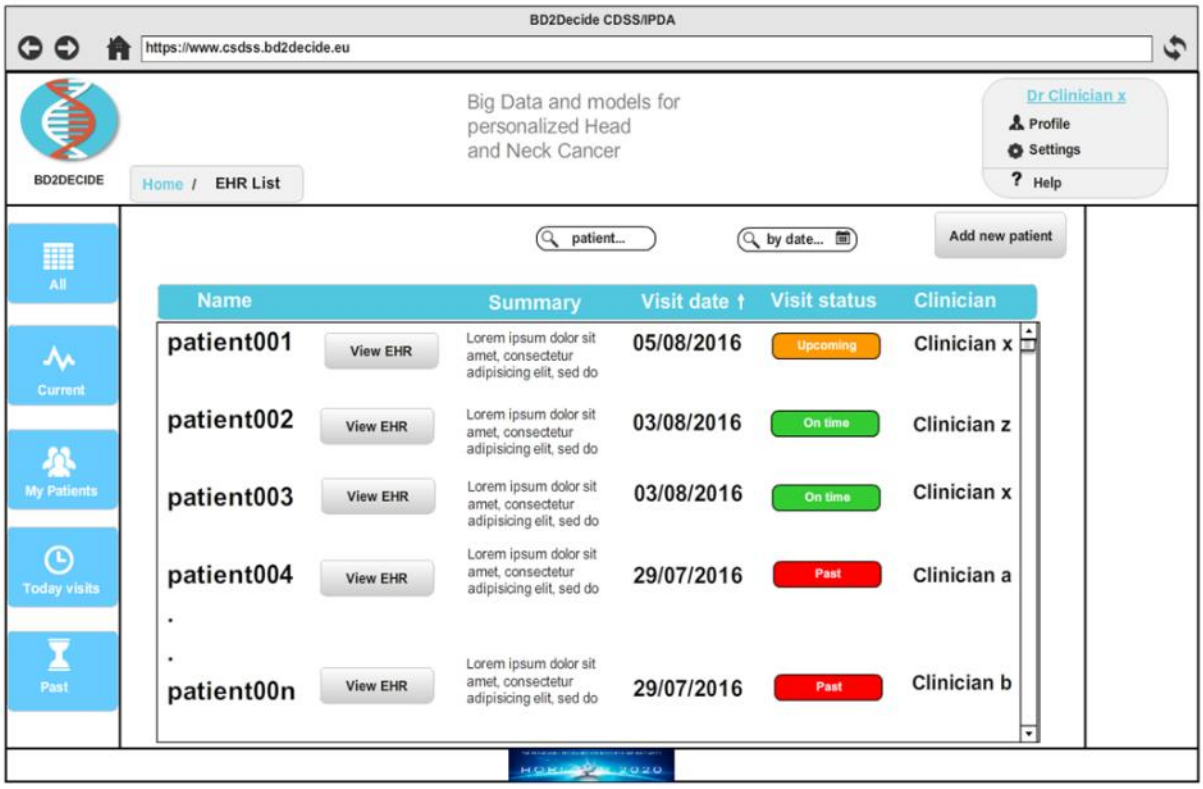


Figure 32: The home page of the CDSS UI.

As shown in Figure 32, the physician (and, subsequently, any health professional) can view the list of patients that have been assigned to them or those patients for whom the specific user is participating in their tumor board session. This specific screen implements the functionality presented in Figure 14 about exploring the list of patients.

By clicking the "view EHR" button, the physician is navigated to the patient's screen of Figure 33. This page consists of the following views:

- The left hand side navigation bar, which allows the health professionals to switch between different data views.
- The top status bar, which presents the progress of a patient's treatment process (i.e. whether the patient has entered the treatment phase, etc.).
- The main central view, which presents the patients' data for the selected category from the left hand side navigation bar. This view is split between the various phases of the treatment process (diagnosis, treatment, post-treatment, and follow-up), while it groups the data in the categories of the e-CRF (demographic, risk factors, etc.).
- The right hand side bar, which allows the health professionals to open external tools.

The specific screen of Figure 33 implements the functionalities presented in Figure 14 about viewing the patients' data.

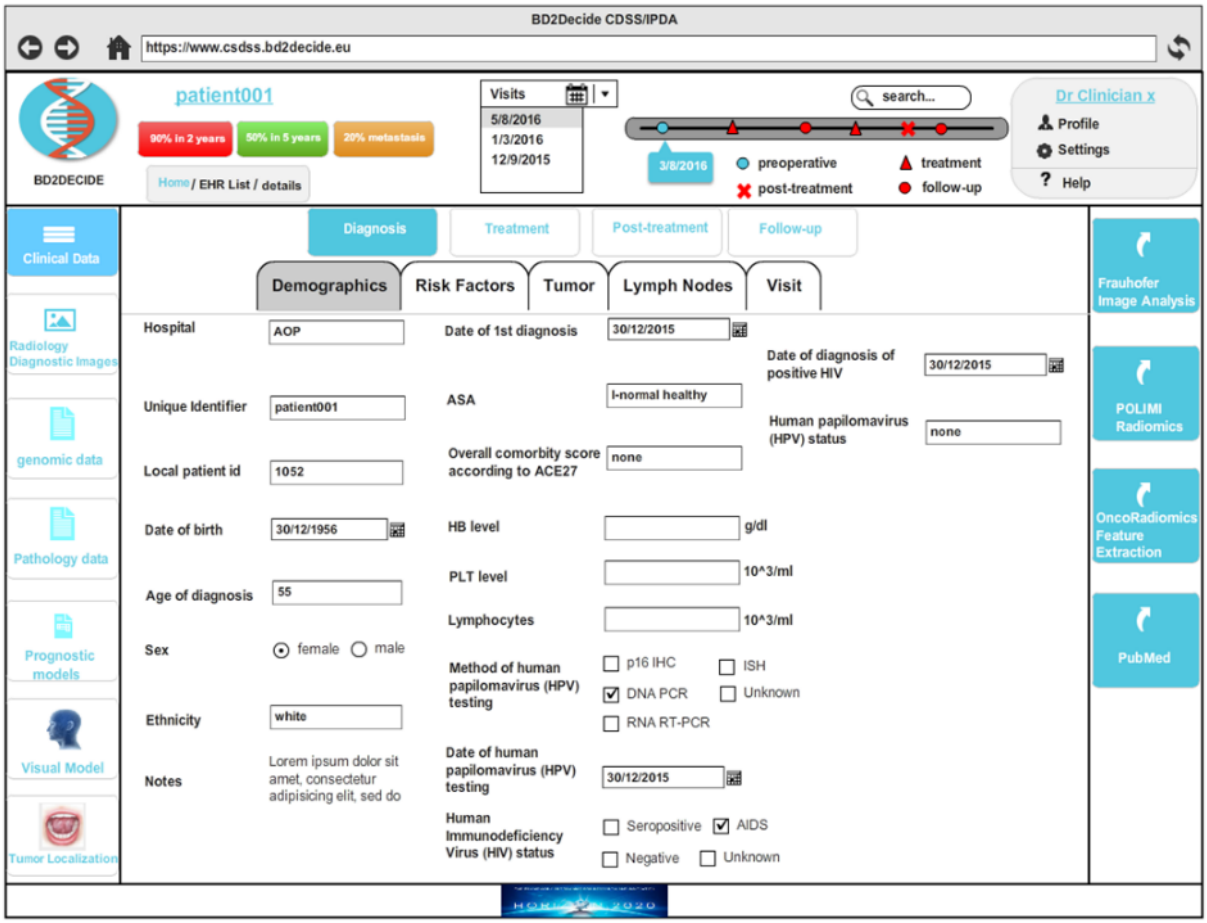


Figure 33: The general view for the management of a patient in the CDSS UI.

During the diagnosis phase, the physician may want to sketch the tumor location in the specific area of the HNC case (see Figure 10), which can then be correlated to radiological images. This is done through the sketch of Figure 34. As shown in this screen, the physician invokes the tumor localisation sketch function from the left hand side bar (when being in the diagnosis phase of the main central window) and may do the following:

- Select the tumor region from a drop down list (for oral cavity, oropharynx, hypopharynx, and larynx);
- Select an image for this region;
- Select the drawing options;
- Mark the tumor location and save the sketch.

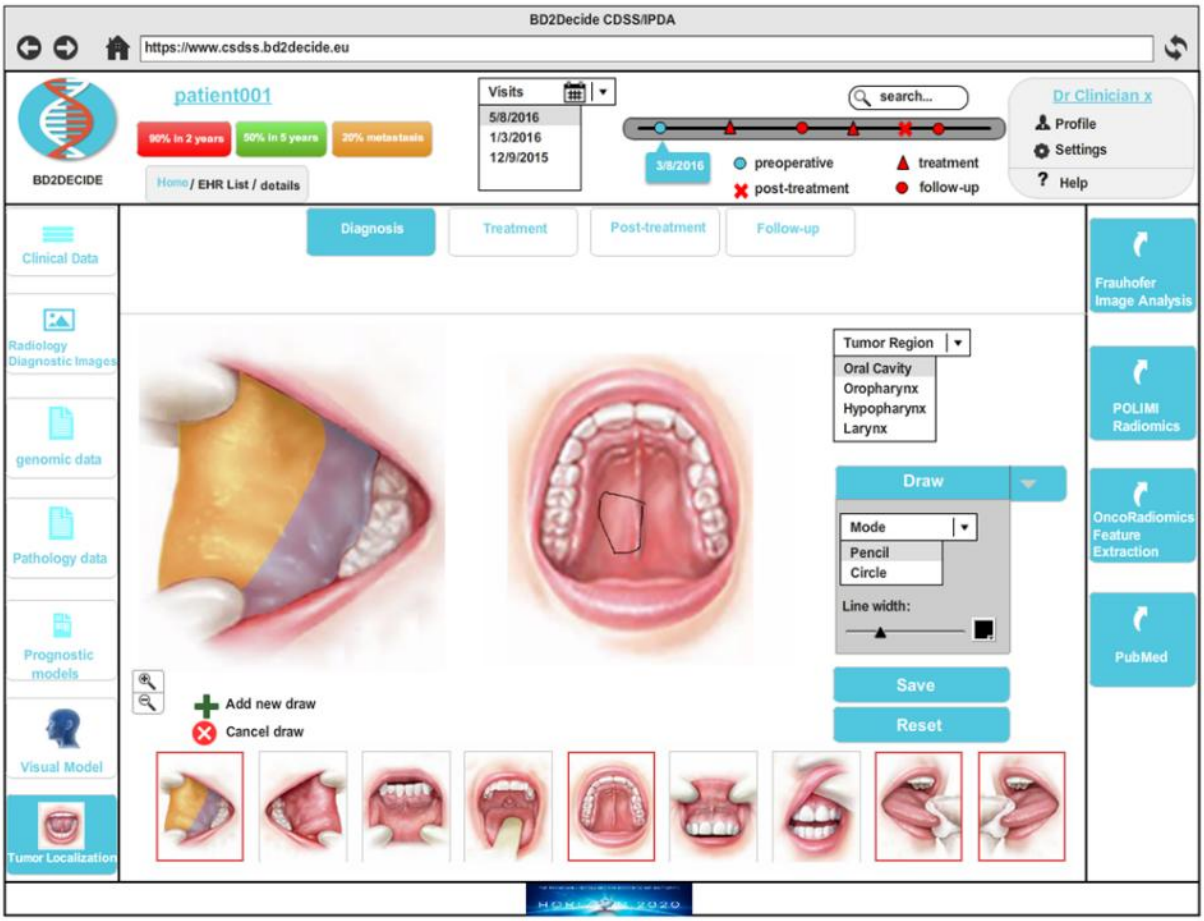


Figure 34: Sketching tumor localisation through the CDSS UI.

An important view of the CDSS is the DPEE UI, which presents a visual model of the virtual avatar representing the patient. This is the function named as "access virtual patient view" in Figure 14. This function should invoke a single page in the CDSS tool, which is the DPEE view and is sketched like the view in Figure 35. As shown in this screen, the physician invokes the visual model function from the left hand side bar (this function is common irrespective of whether the health professional is accessing the diagnosis or any other phase). Through the visual model view, the physician and the other health professionals can manage the patients' data through a 3D avatar model, which can be rotated in 360^{o}. The user can zoom in a specific region of the HN 3D model and select to view patient's data in a box like window on the right of the model.

It must be noted that this screen is an initial approach to the DPEE tool and, through the upcoming steps in the UCD process of the project, we expect that this view will be improved.

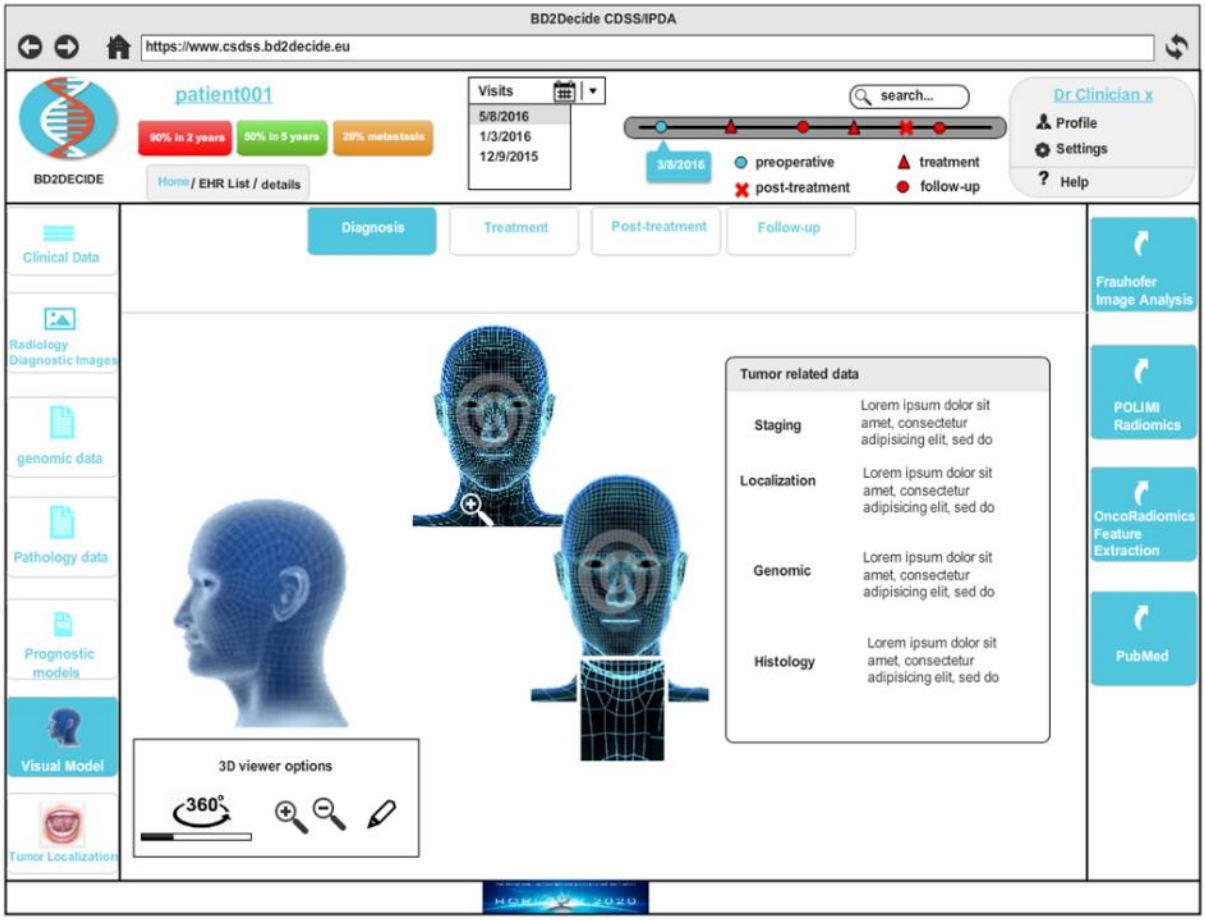


Figure 35: The UI of the Digital Patient Exploration Environment.

As part of the patients' data visualisation process, the physician can request for a prognostic analysis. This is reflected in all phases of the HNC treatment process, as presented in Figure 14, Figure 17 and Figure 18. The prognostic analysis can be invoked from the left hand side bar, as seen in Figure 36. The view which is loaded enables the physician to switch between the prognosis window, the function for comparing the prognosis through the application of different prediction models, the function for comparing the prognosis of the selected patient with patients with similar cases in the BD2Decide environment, the view for the risk stratification of the patient to cluster this patient into groups with other similar cases, and the simulation window, which simulates the current study of the patient with similar cases for the reoccurrence factor, using population-based data.

Figure 36 focuses on the prognostic analysis view. As shown there, the physician can select the prediction model to run and get the prognosis for the survival probability of the patient in various visualisations, according to the model. By clicking on the visualisations, the physician can zoom into the details of the graphs. On the right side of the window, the CDSS UI loads the prediction box, in which the physician can select the time window of the prediction and receive assistance on which factors affect the prognosis for specific prediction cases, like the reoccurrence probability, the survival probability, etc.

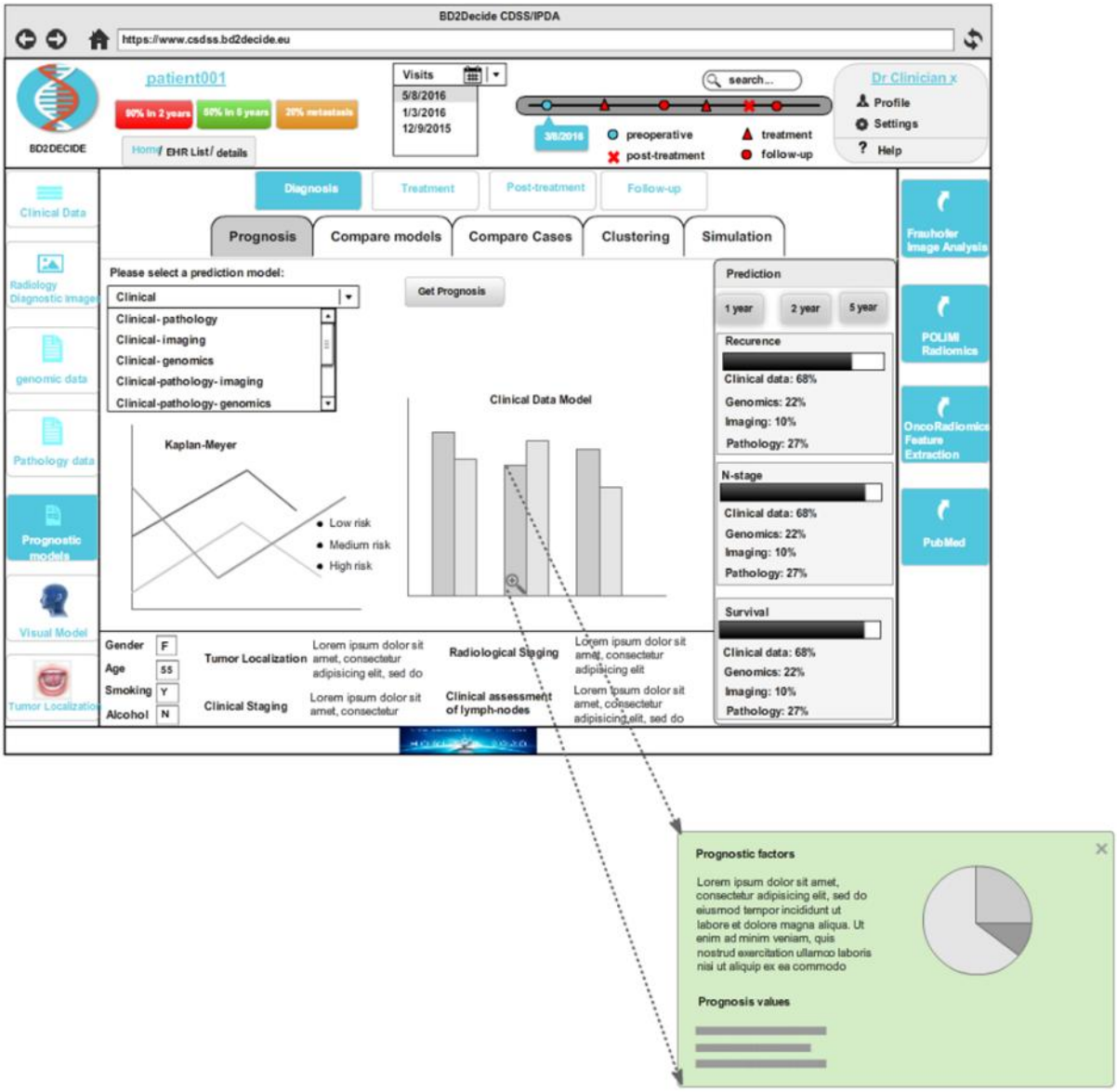


Figure 36: Invoking the prognostic prediction analysis module of the CDSS.

The individual prognosis can also be performed for various prediction models. In this case, the physician selects to compare the prognostic prediction cases for two or more prediction models. This is presented in Figure 37. The comparison case is mainly involved in the functionalities of the diagnosis phase in Figure 14.

During the diagnosis and the follow-up phases in Figure 14 and Figure 18, respectively, the physician can make a comparison of the patient's clinical case with other similar cases. This is shown in Figure 38. The comparison views follow the ones presented for the individual prognosis. In a later stage of the project development, we will examine the possibility with the clinical partners (as evaluators of these sketches) to be able to select specific population criteria (demographic and other criteria) to make comparisons.

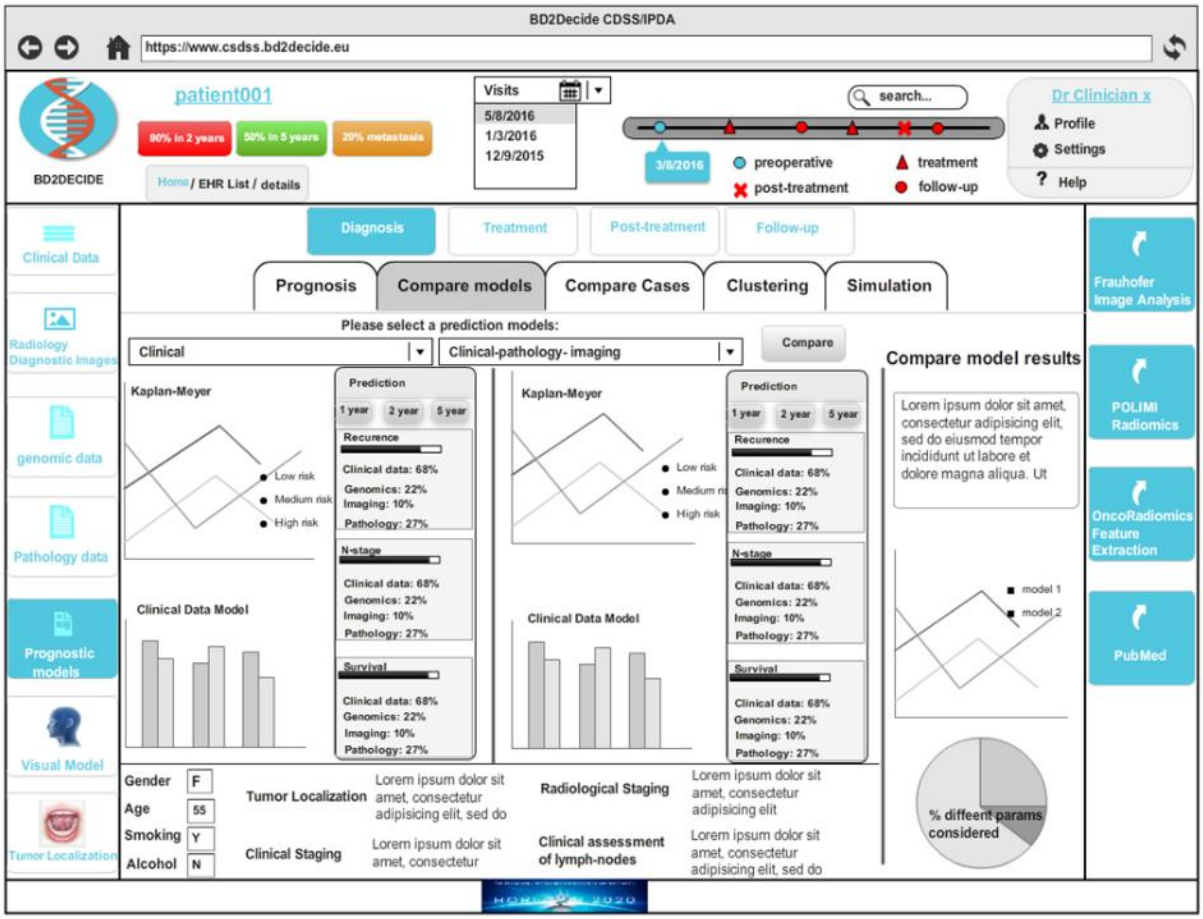


Figure 37: Comparing prognosis through different prediction models in the CDSS UI.

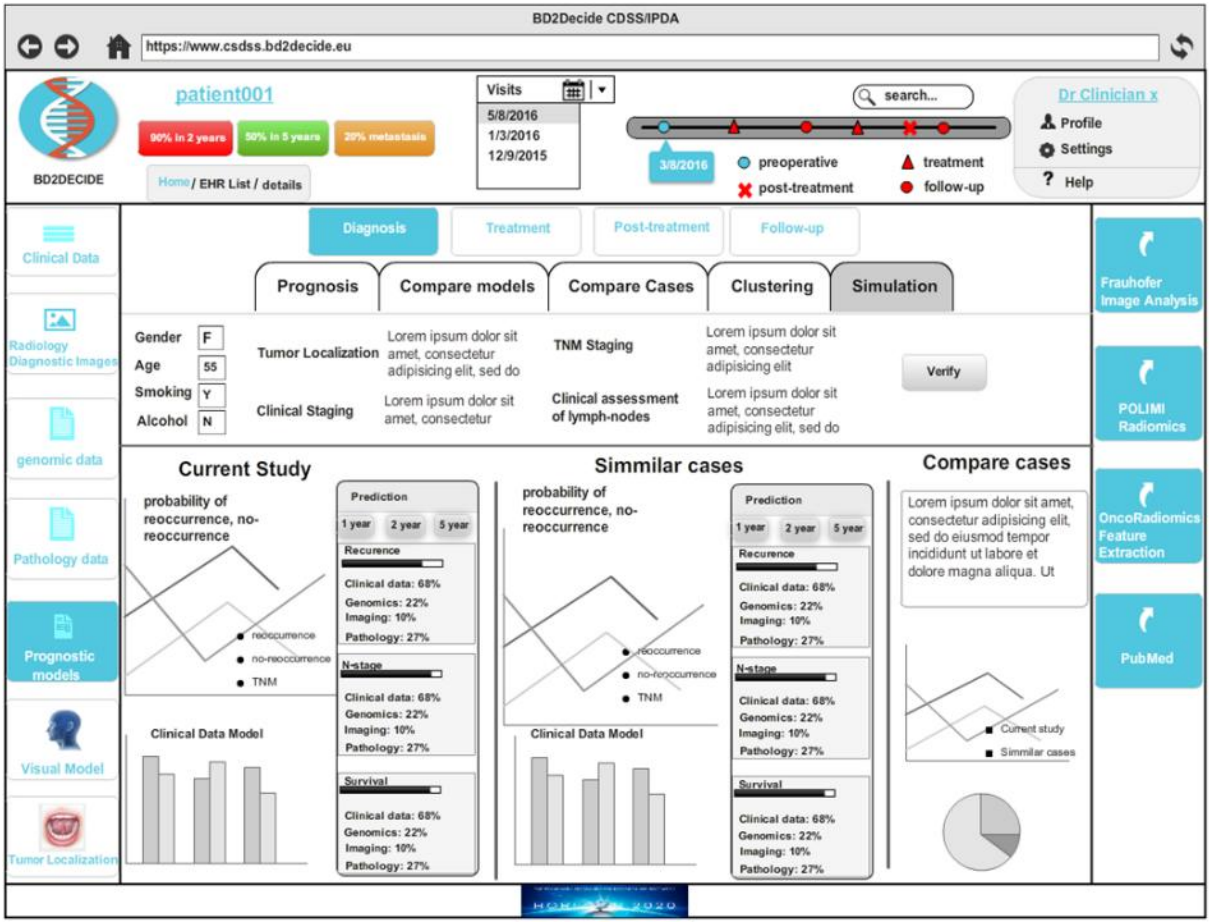


Figure 38: Comparing similar HNC cases in the CDSS UI.

In Figure 39, we present the sketch for the CDSS UI that allows the physician to perform risk stratification of the patients. The clustering approach aggregates the prediction factors for groups of the population and presents them to the physician to visually assess the patient's case, compared to the rest of the population.

It is noted that in all screens of the prognostic analysis view (from Figure 36 to Figure 39), the physician has an overview panel, which summarises the patient's demographic data, the tumor characteristics and the staging.

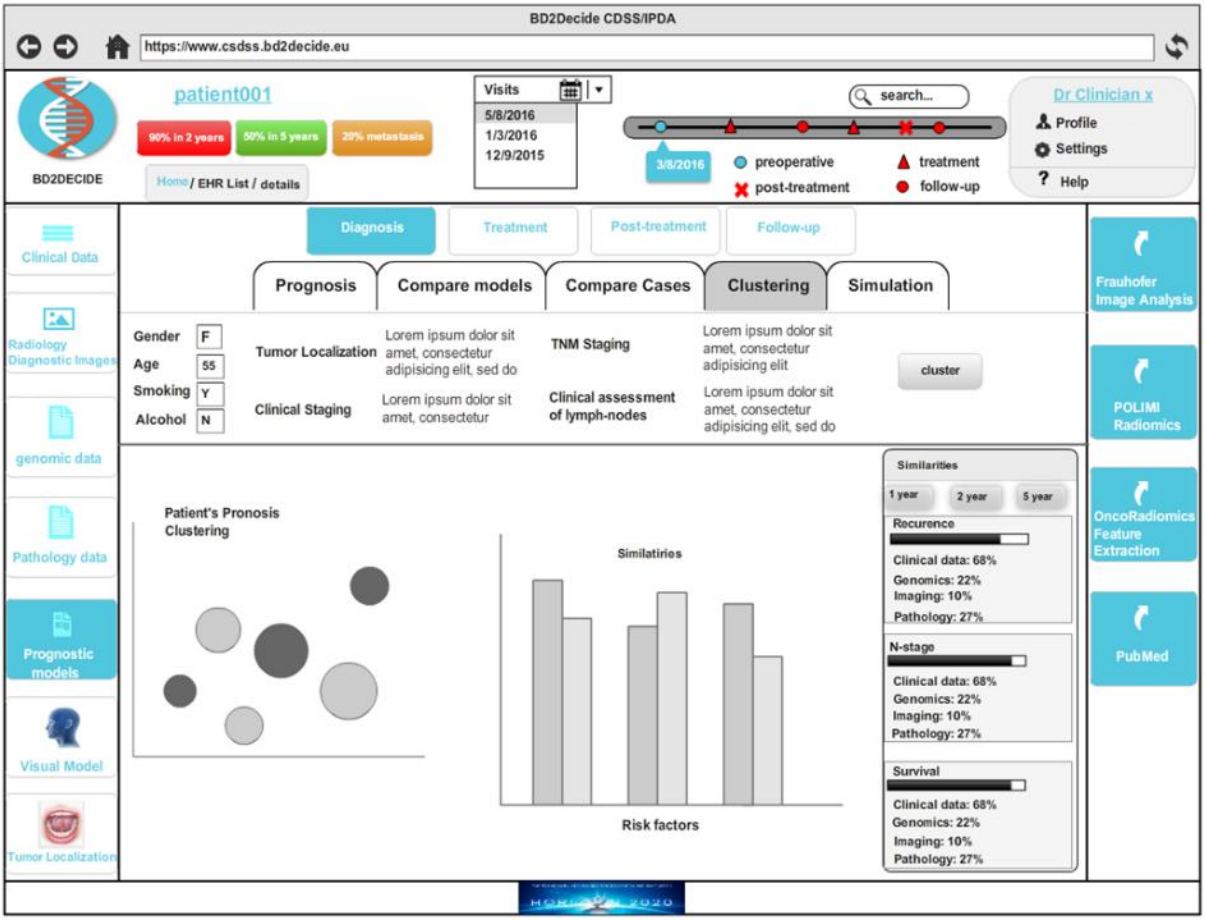


Figure 39: Clustering patients and their cases, based on risks.

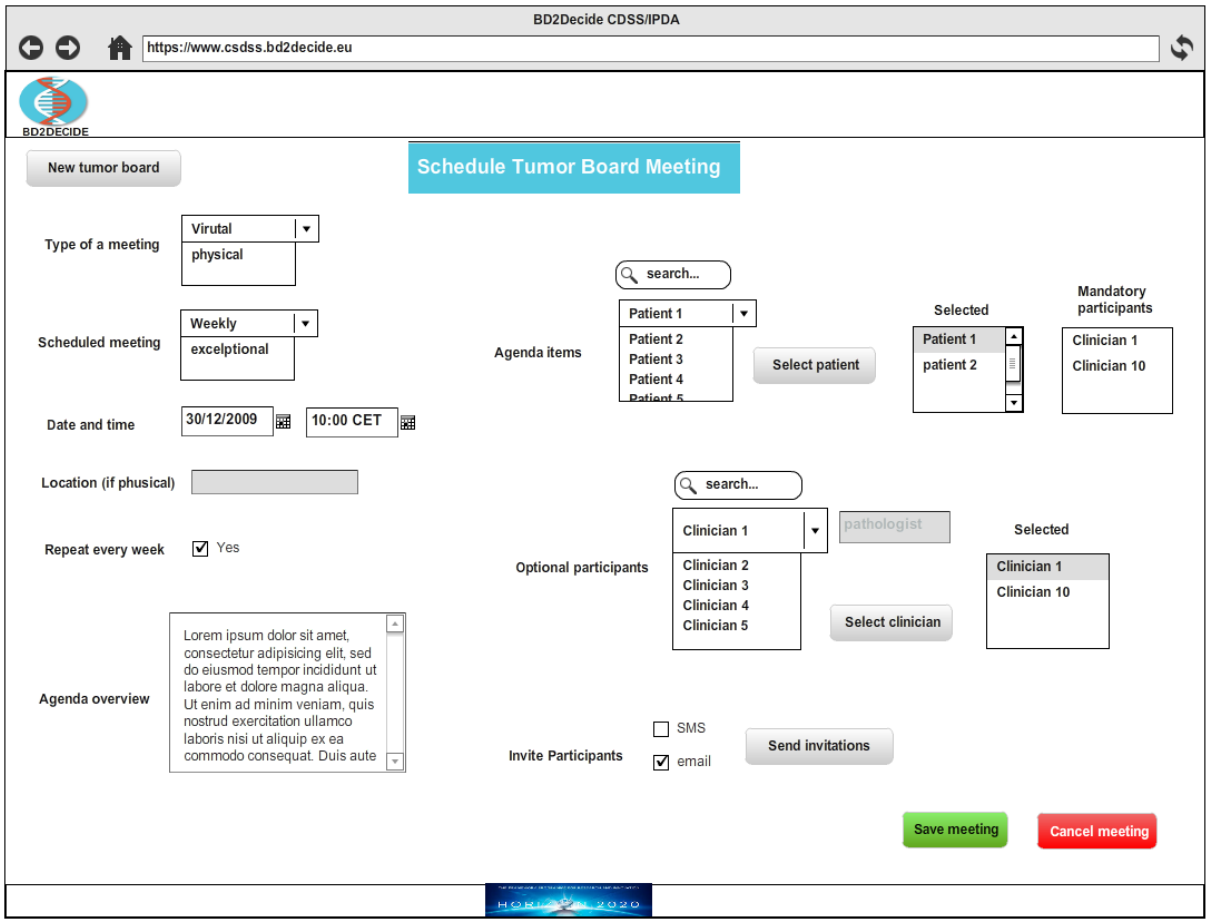


Figure 40: Organising a tumor board through the TBCE module of the CDSS UI.

In order to decide on the most appropriate treatment option for the selected patient, the physician can ask for a tumor board with the involvement of other health professionals. As explained in Figure 15, the different specialties can collaborate through the TBCE view of the CDSS UI. The main functionalities of the tumor board refer to the scheduling of a board from the assigned chairman (as presented in Figure 40) and the execution of a tumor board (as shwon in Figure 41). In the first case, the TBCE allows scheduling the logistics of the board, setting the agenda by selecting the patients to examine and inviting the respective professionals.

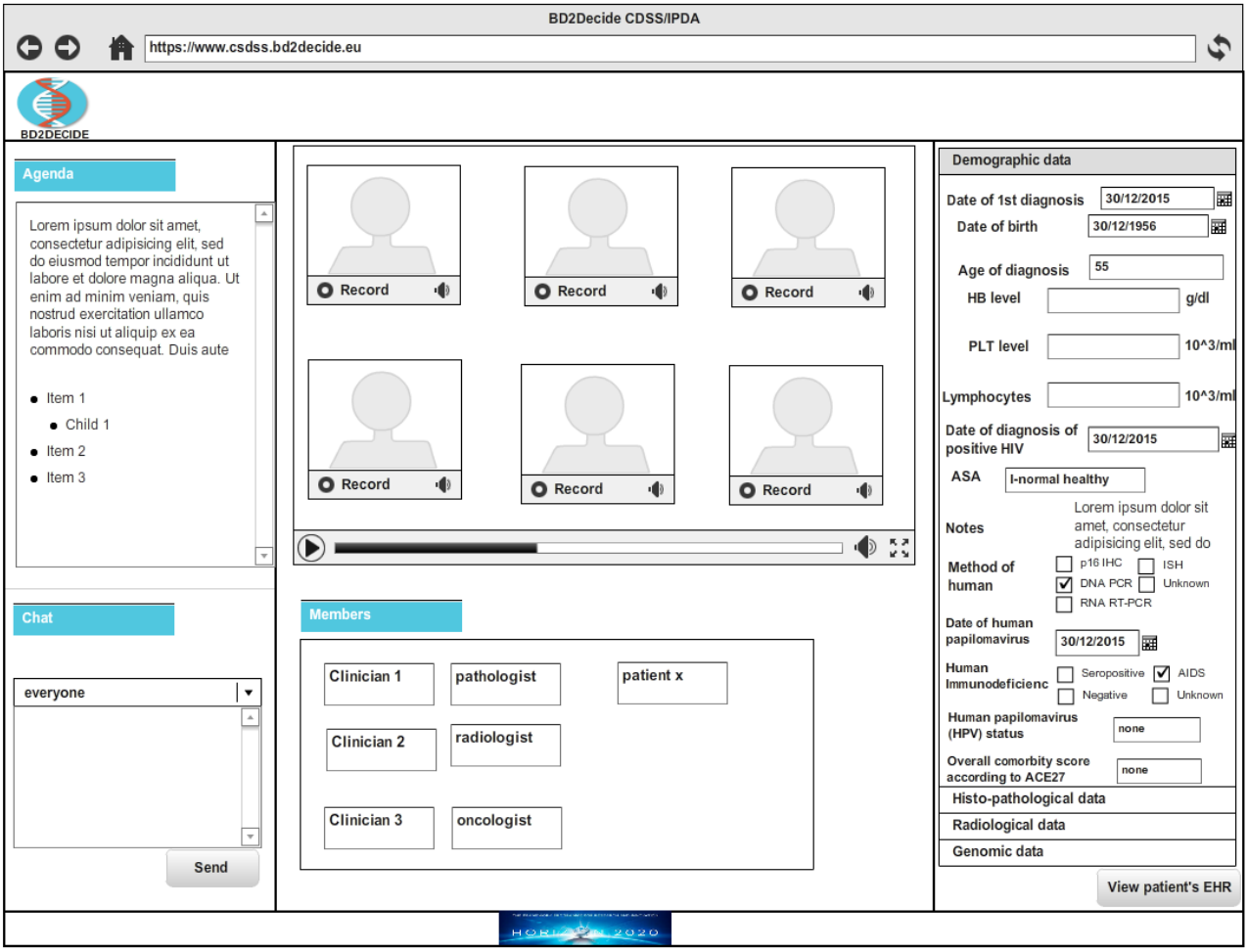


Figure 41: Running a tumor board through the TBCE module of the CDSS UI.

In the latter case of running the board, the invited professionals can use the TBCE to access the planned functionalities, including the exchange of views, which are recorded in the chat panel (on the bottom left side of Figure 41), or the exploration of the patient's data, as shown on the right panel of Figure 41).

At the treatment phase, the functionalities shown in Figure 17 share common views with the diagnosis phase. For example the exploration of the list of patients is the already presented in Figure 32. What is different in this phase is the fact that the physician can browse through the treatment and post-treatment data (surgery, radiotherapy, chemotherapy and toxicity data). As in the case of the diagnosis phase, the data visualisation can be done either through the tabular view or the visual model function. The first one follows the concept for the presentation of the diagnosis data in Figure 33. An example for the surgery data is presented in Figure 42. Thus, in this phase, we maintain the general look and feel of the CDSS UI, in which the visual model is accessible via the left hand side bar (as shown in Figure 43

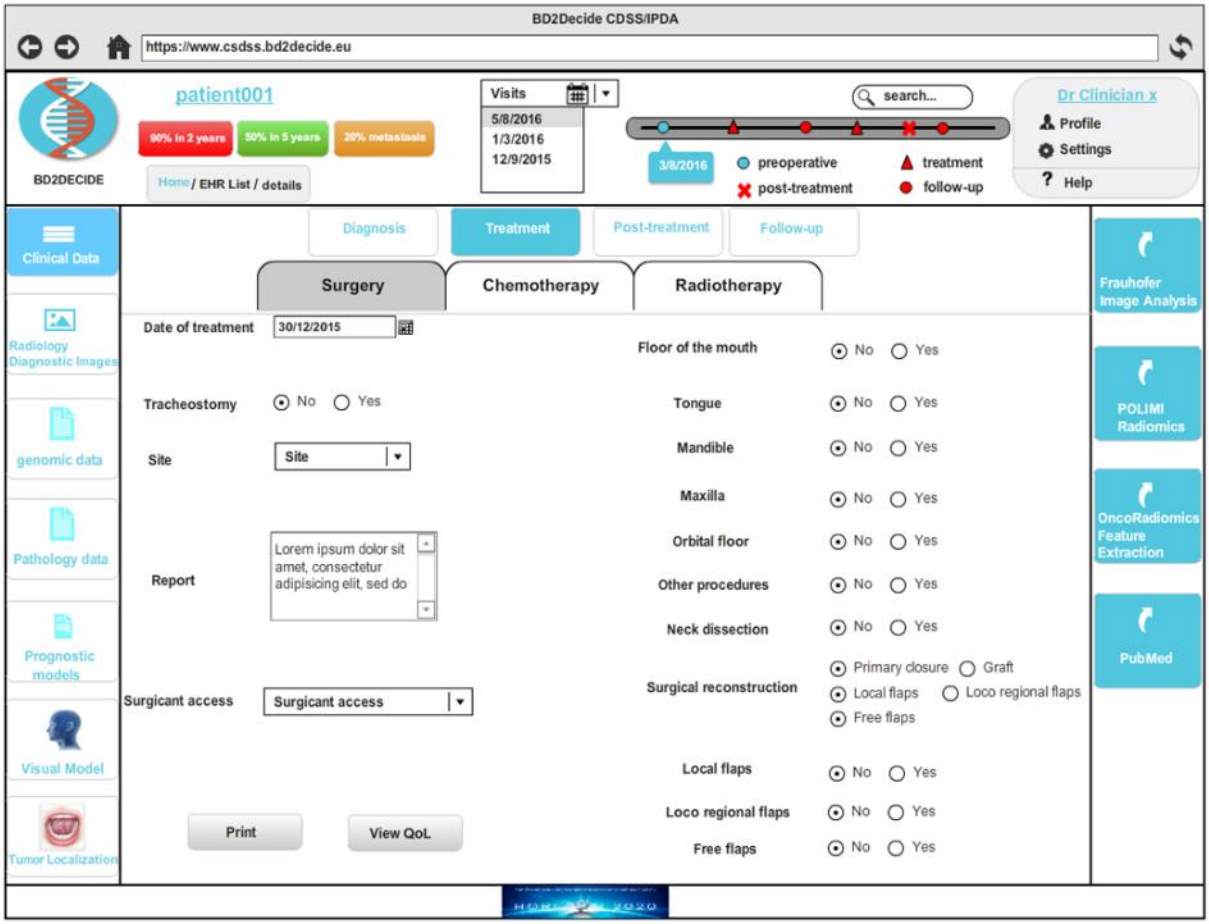


Figure 42: Browsing the treatment and post-treatment data in the CDSS UI.

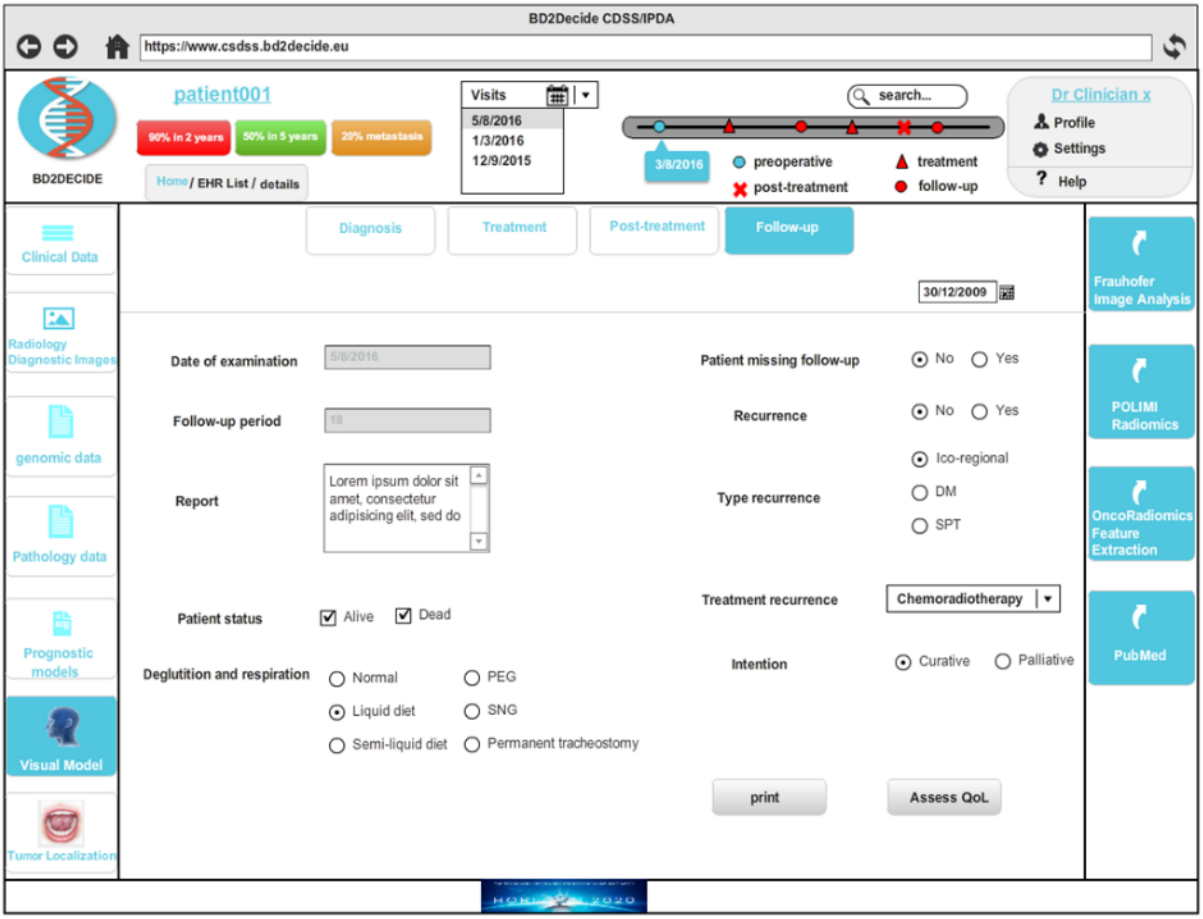


Figure 43: Accessing the virtual patient view of the DPEE in the treatment phase.

Moving to the follow-up phase, Figure 18 introduced two additional functionalities compared to the ones already sketched in this section. These refer to an overview report page and the management of the follow-up schedule.

Although the follow-up schedule could be a classical calendar view, we here focus on the summary report view, which is presented in Figure 44. As shown there, the physician can quickly browse to specific information about the follow-up status of the patient and request to print a detailed report.

In this figure, we also see that the physician may access the QoL assessment view. As mentioned in section 4.2.1, this is a horizontal process taking place across all the phases. This functionality requires two steps to be accomplished:

- The patient accesses the online versions of the questionnaires and responds to the questions listed there. This has been identified as expected functionality for the PDS in Figure 11 for the diagnosis phase, in Figure 16 for the treatment and post-treatment phase and in Figure 18 for the follow-up phase.
- The health professional assesses the quality of life of the patient, according to the scoring being calculated for the questionnaires. This is reflected in Figure 14, Figure 17 and Figure 18 respectively for each phase. In addition to it, in Figure 17 and Figure 18, the physician may also

compare the QoL score in the various phases, based on the baseline score calculated in the diagnosis phase.

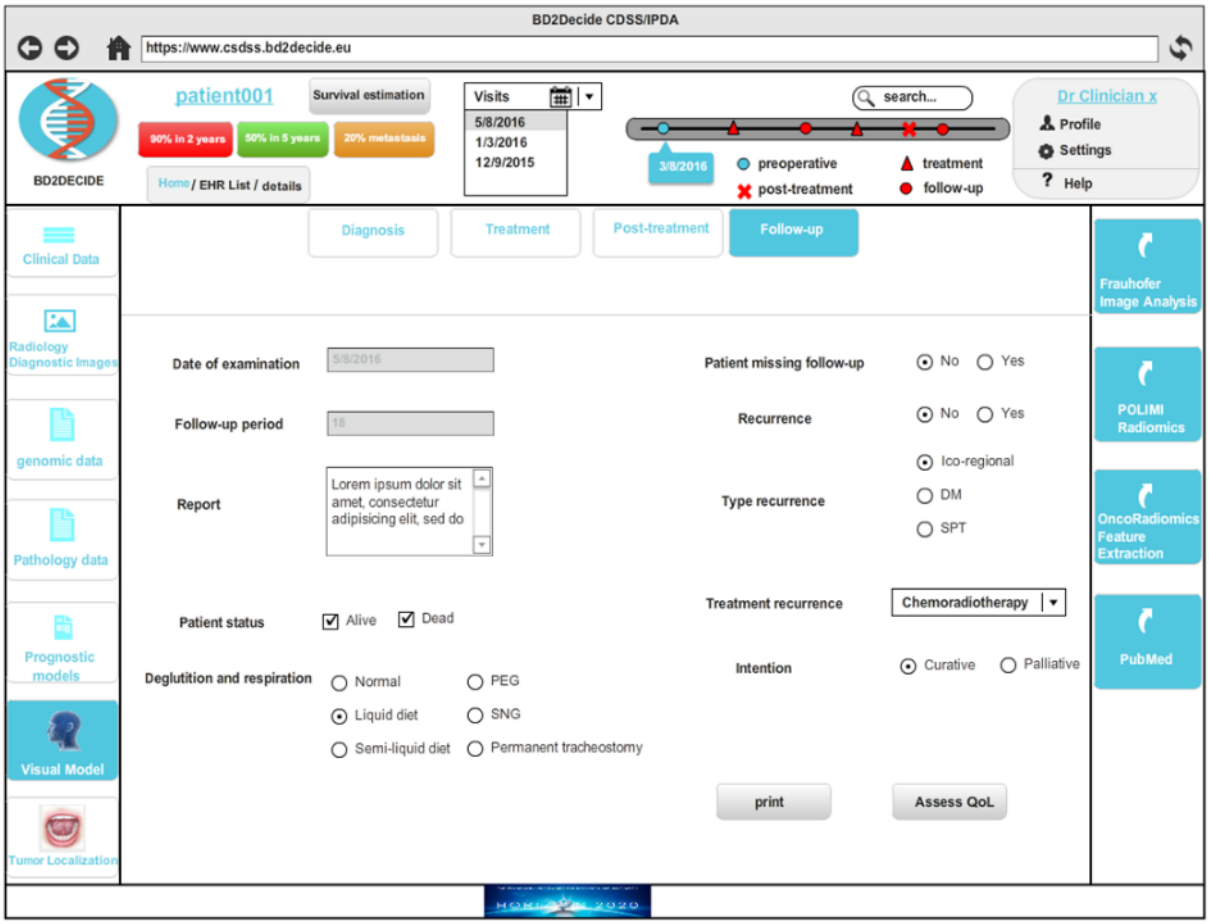


Figure 44: Overview of the patients' schedule summary at the follow-up phase.

As it was described in D5.1 and summarised in section 0, the patient accesses three questionnaires, the EQ-5D-5L questionnaire developed by the EuroQol Group, the QLQ-C30 questionnaire from EORTC and the QLQ - H&N35 questionnaire from EORTC, as well. The response process is supported by the PDS UI, which has been implemented as an initial prototype for the questionnaires case through the Limesurvey[8] open-source software, and in line with the guidelines provided by the questionnaire providers. The respective views have been designed for both a tablet and a computer device.

[8] https://www.limesurvey.org/

Figure 45: Example of the interface for responding to the EQ-5D-5L questionnaire (reference from footnote 4).

The sketch of the QoL scoring page for the selected patient in the various phases is presented in Figure 46. As shown there, the physician may select for which QoL questionnaire is interested (whether they want to browse the baseline score, which was collected in the diagnosis phase, or any other score calculated during the (post-) treatment or follow-up phase). By clicking on the "view patients' results" option, the physician can directly access the data, which the patient filled in (through for example the view of Figure 45) and through which the score has been calculated.

As shown in Figure 46, the physician may want to monitor the evolution of the QoL in time for the specific patient. This is presented in Figure 47. This screen presents the scoring the three questionnaires used in the project

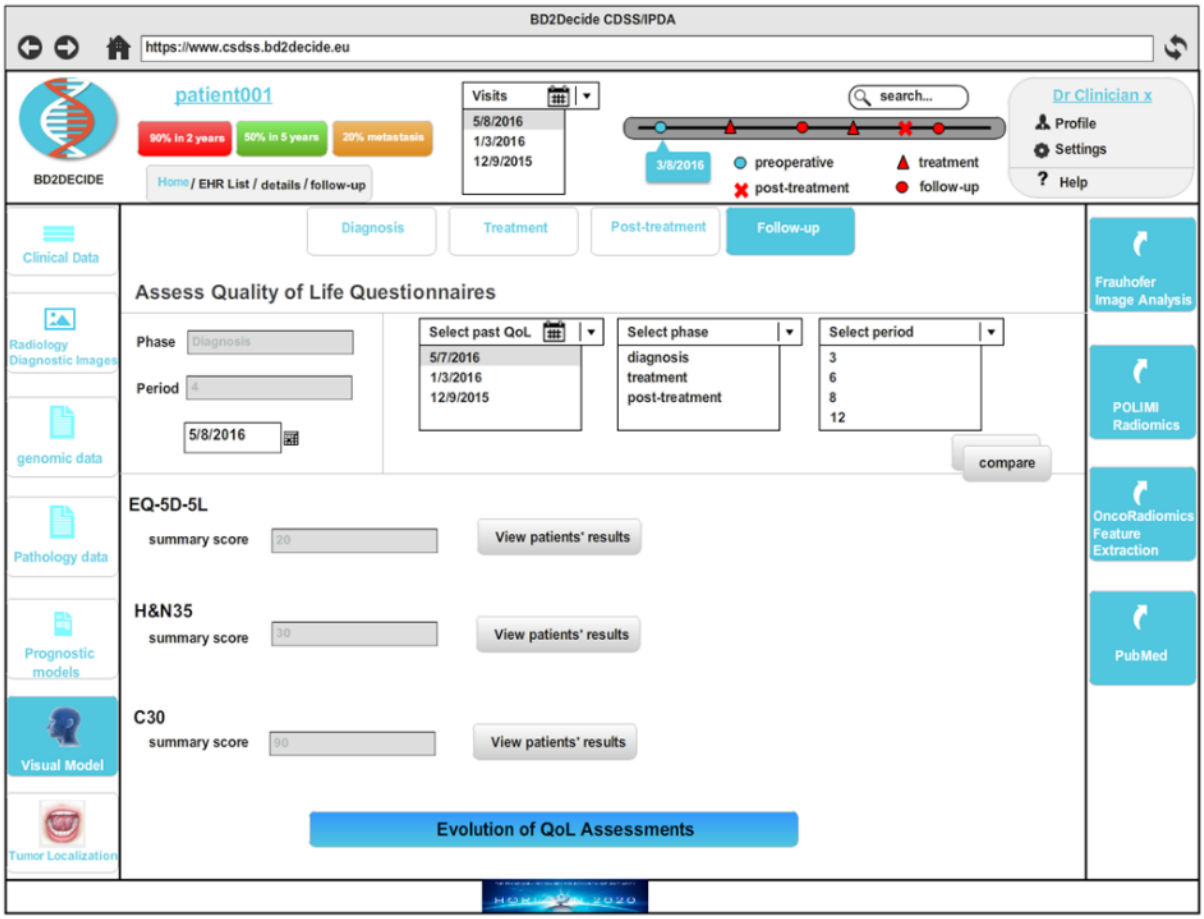


Figure 46: Assessing the quality of life score in CDSS UI.

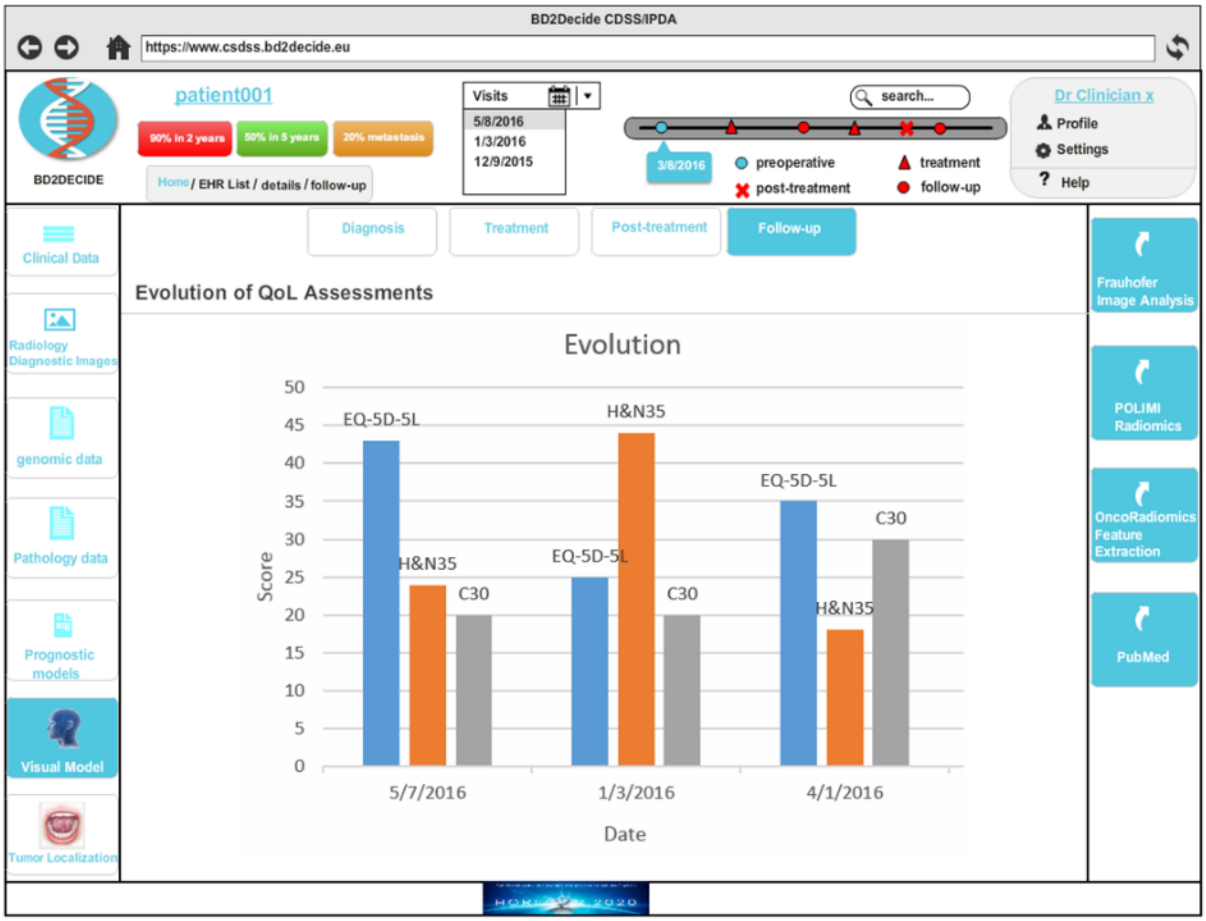


Figure 47: Monitoring the evolution of the QoL scoring in CDSS UI.

4.3 Interfaces and functionalities validation

In this section, we present the validation planning for the functionalities and the user interfaces presented in the previous section 4.2. To do so, we consider the BD2Decide UCD design approach that was introduced in Figure 3.

The functionalities for the CDSS tool and other BD2Decide components have been identified from the analysis of Deliverable D2.1 and the user needs. The approach that was followed in this deliverable included a definition of user scenarios and use cases for the various roles and stakeholders expected to use the BD2Decide tools. These scenarios have been identified by the clinical partners of the project, and, as such, we assume that they exhibit a high level of validity, as they reflect real problems for the HNC processes.

In the compilation of the user functionalities in Section 4.2.1, we provided a first assessment on how the user scenarios and the use cases in D2.1 can be mapped to system level functionalities. This mapping process has been initiated by the technical partners of the project and it has been presented to the clinical partners, as the most relevant ones to validate that the translation of stories to functions is correctly depicted in the functionalities defined in that section. However, we do see the need for a second round of the functionalities validation due to the fact that the design sketches

provided in section 4.2.2 may reveal the lack of proper explanation of a scenario through these functionalities. This will result in the need for a better or more accurate definition of the functionalities.

Going to the user interfaces, the initial validation has already been performed in the context of this deliverable. More specifically, following the definition of the user functionalities, we prepared a first version of the user interfaces for the various modules involved, namely the CDSS, including the DPEE and TBCE, the PDS and the imaging analysis tools. Further to it, the involvement of many BD2Decide partners in the ORAMOD project[9], and the objectives of that project compared to BD2Decide, allowed us to base our work on the user interfaces that the ORAMOD platform prototype already provides. Since those interfaces have already been validated within ORAMOD, we claim that this is an excellent starting point for the BD2Decide project as well.

These interfaces were a first attempt to place the functionalities in context and give the clinical partners an overview of what they should expect in the actual implementation. The next steps in the validation of the user interfaces include the following:

- Consider any changes in the user functionalities, as mentioned above, which affect the design of the user interaction sketches for the CDSS and the other tools.
- A second round of validation of the case that the user functionalities have been correctly placed in the interfaces. It might be the case that when developing the sketches into software modules, the clinical partners may revise their perception on a functionality through a certain interaction screen.
- Organisation of face-to-face and virtual meetings with the clinical partners (and potentially with external to the project clinical partners) to iteratively discuss and agree on how the initial sketches can be evolved to detailed views of the final functionalities. CDSS integrates a set of complex functions for the clinical domain, which, in some cases, exhibit a totally new approach for the end users towards exercising with the HNC practices. Thus, the current interaction sketches might be a very rough approach, which needs to be revised in the future.

It is noted that the usability validation of the prototype interfaces will be performed in the context of WP5.

[9] http://www.oramod.eu/

5 VISUAL ANALYTICS TOOL

The Visual Analytics tool will assist the work of clinical researchers active in H&N cancer. This tool allows querying and aggregating data, considering trends and identifying patients' clusters. Also, it eliminates the complexity typically associated with blending and correlating data sets.

This suite aims to create a visual analytics module focused on the exploitation, representation and visualization of information (e.g. patients' clinical cases, population-based information, etc.) retrieved from heterogeneous sources. It is composed of two main elements:

- Knowledge Representation: Data presentation, exploratory visualization for EHR exploration and smart visualization techniques such as multivariate visualization, scatterplot matrix, and starplot, will be investigated and used to handle big data sets, heterogeneous information from individual or populations of patients.
- Knowledge-based contouring: Using Data Abstraction and Data Mining techniques, the system will extract from repositories, general rules and statistics regarding Cancer patient health condition, progress in relation with treatment, diagnosis and potentially prognosis of the disease course, similar cases, recommendations, etc. The creation of 'what if' scenarios and augmented information will be implemented by visually overlay information to help clinicians to visualize the data.

5.1 User needs

User needs have been collected in D2.1 [9] as a result of brainstorming meetings with clinical partners. A succinct review of existing tools has been carried out in order to define the main functionalities that must be included in the research tool.

As a results of these meetings and surveys, the following user needs were defined:

- Access to public data for evidence-based knowledge;
- Comparing similar patient cases;
- Patient's stratification and clustering by risk;
- Diagnostic imaging databases/genomic databases;
- Data extraction for research and scientific publications;
- Data extraction for research and scientific publications and decision maker.

Taking into account this previous information some of the functionalities of the Visual Analytics tool have been defined. In this way, the tool should be able to:

- Correlate BD2Decide data with other data;
- Identify subgroups of patients using correlation methods;

- Allow to select specific factors relevant for one target patient and extract prognostic information of the patient as compared to a subgroup of similar cases;
- Make use of available external diagnostic imaging and genomic databases;
- Have inputs as logical fields, ideally through drop-down menus and not encoded;
- Extract data in .pdf, .csv, access and SPSS formats;
- Export all graphs, images and illustrations;
- Estimate the value and the cost of adding certain types of information to the analysis (in this case the profile of the researcher is a PI or a Decision Maker).

5.2 Sketches design

5.2.1 Balsamiq Mockups

The sketches and workflow of the Visual Analytics Tool have been developed using Balsamiq Mockups tool[10], a wireframing tool that reproduces any idea by building a user interface. Mockups offer the same speed and rough feel as sketching with pencil, with the features of drag and drop to resize and rearrange elements, and make changes without starting over. In Figure 48, Figure 49 and Figure 50 a set of samples are shown.

Figure 48: Using Balsamiq - mobile apps sample.

All the mockups created are stored in groups as projects in one file and it is possible to link them making the design smart. The default extension for a project (.bmpr) allows the user to present all mockups showing the interaction between them. Furthermore, it is possible to export that file into .png or .pdf format with the purpose to show or attached in any context.

[10] https://balsamiq.com/

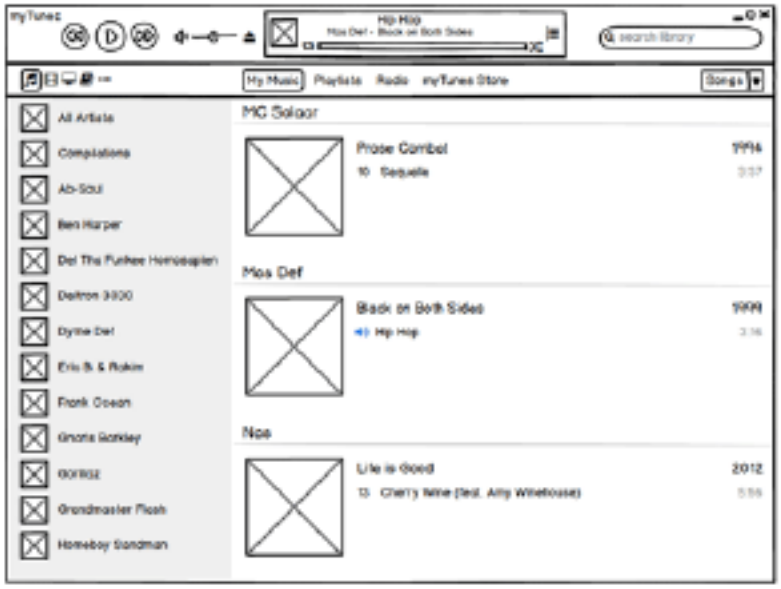


Figure 49: Using Balsamiq - Desktop apps sample.

Balsamiq Mockups is a mockup builder application that is very useful in the early stages of a project, because it offers a friendly layout and a wide variety of pre-built widgets.

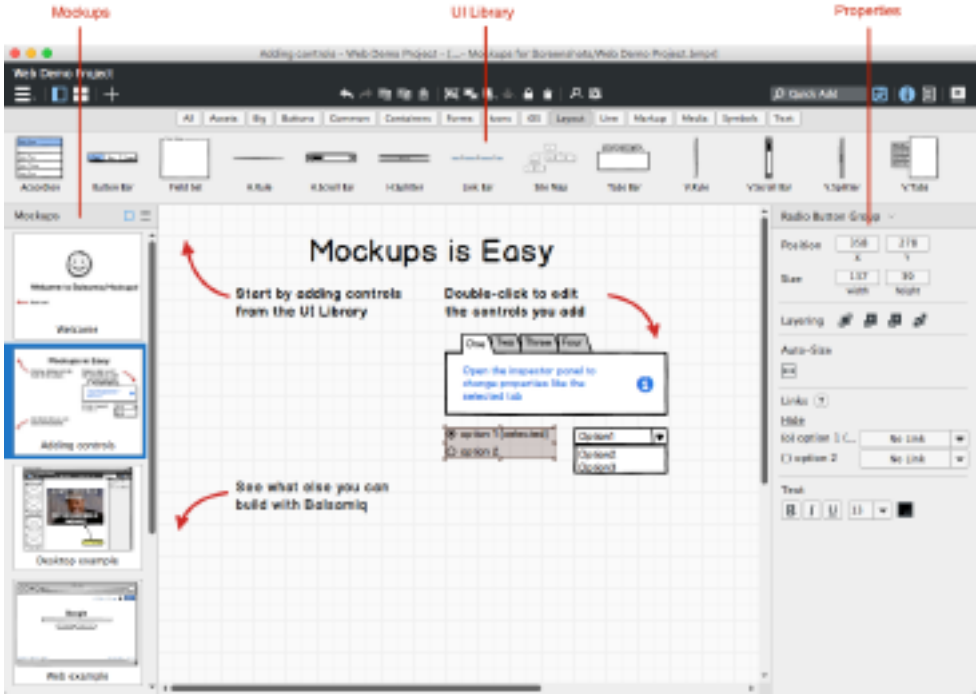


Figure 50: Balsamiq Mockup panels.

5.2.2 User functionalities and workflow

After analyzing all requirements involved in the researcher scenario, a first mockup of the tool was designed. There are four different modules in the application:

1. Research network. In this module, it is possible to create a profile with the aim of getting notifications about user interest regarding of the field of specialization and to getting in touch with other researchers within the tool. Each session or work can be stored as a project, keeping this way all reports consulted, all data explored, outcomes achieved, etc. All these projects can be shared in the researcher network and can be archived when the investigation is finished.
2. Dashboard. In this module, an overview of the global HNC status is shown, with the possibility of switching among datasets. It is possible to save custom configurations of interest for further reviews.
3. Data analysis. This workspace is divided in three modules:
    a. Queries. This module allows to query all BD2Decide datasets, and any additional external sources available. It is possible to save the queries for further reutilization.
    b. Correlations and clustering. This module performs automatic clustering and correlations based on the query specified by the user. It is used for comparing similar cases and achieving correlations by means of big data analytics.
    c. Decision maker. This module allows the principal investigator to assess whether running additional test is valuable or not, based on cost-utility metrics derived from other similar cases.
4. User management. This module includes all actions needed to create, edit and delete users, and to create different roles to be assigned to the users. The creation of the role includes separately actions depending of the module selected.

Also, an integrated chat is included. The purpose of this chat is to allow the users to get in touch and communicate not only with other researchers within the tool but also with the clinicians who have access to the physician scenario or Decision Support System.

Figure 51 shows the interaction between different modules and the workflow that has been defined for the research tool.

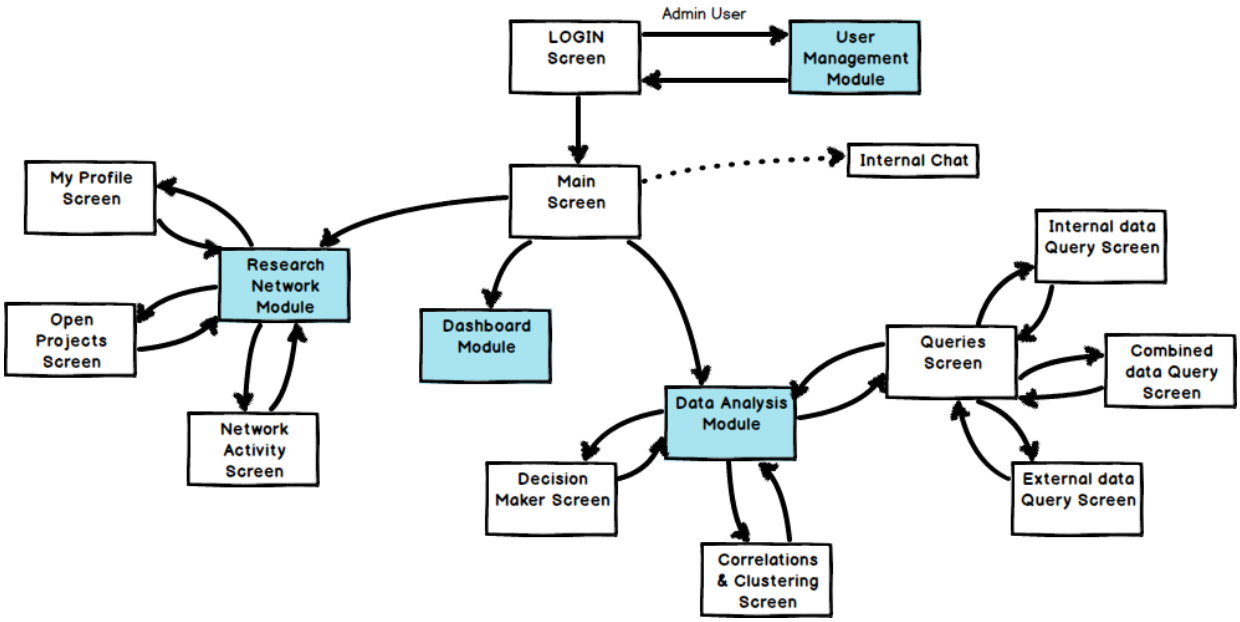


Figure 51: Workflow of Visual Analytics Tool.

5.2.3 Actors involved

For the Visual Analytics tool, the following roles are proposed:

- Administrator researcher: principal researcher with rights to manage users.
- Principal investigator: project management role.
- Other researcher: other researchers within the application who pertain to a project.

Table 2 presents a preliminary proposal of the permissions for each user/role.

Table 2: Roles and permissions proposed for the Visual Analytics tools

Module	Permissions	Administrator researcher	Principal investigator	Other researcher
Research network	View network	Yes	Yes	Yes
	Edit projects	Yes	Yes	Yes/No
	Create projects	Yes	Yes	Yes/No
	Save projects	Yes	Yes	Yes/No
	View history activity	Yes	Yes	No
Dashboard	View	Yes	Yes	Yes
	Edit	Yes	Yes	Yes/No
	Save	Yes	Yes	Yes/No

	Export	Yes	Yes	Yes
	View history activity	Yes	Yes	No
Data analysis	View	Yes	Yes	Yes
	Edit	Yes	Yes	Yes/No
	Save	Yes	Yes	Yes/No
	Export	Yes	Yes	Yes
	View history activity	Yes	Yes	No
User management	View	Yes	No	No
	Edit	Yes	No	No
	Create	Yes	No	No
	Save	Yes	No	No
	Export	Yes	No	No
	View history activity	Yes	No	No

The Yes/No option means that both options are possible depending on the role desired, i.e. 'read-only' researchers would only be able to View and Export.

The work of a researcher in the field of medicine, and concretely in HNC research, involves consulting a wide range of scientific sources to acquire knowledge about the disease and combining all the gathered data to extract useful information. This is a time consuming process that requires the use of highly specialized software, and sometimes the heterogeneity in data (different sources usually implies different formats, not directly combinable) is a remarkable obstacle. These factors make researches to advance slowly, thus not taking full advantage of the amount of data we produce and store.

With the Visual Analytic tool included in BD2Decide system, specially focused on the research scenario, this situation gets simplified, by presenting the user different data in a homogenous way, allowing direct comparisons and correlations, and thus making it possible to identify relationships easily and quickly. This tool assists the investigation enhancing the data analysis phase by giving not only the results the researcher is looking for, but also unexpected results that can make the difference for a new strategy against this disease.

5.2.4 User interfaces

The user interfaces will be developed using adaptive design methodology to allow proper display of the tool from any device (e.g., computer, tablet or mobile). A selection of the most relevant user interfaces of each module is presented in Figure 52 (*Login*), Figure 53 (*User management*), Figure 54 and Figure 55 (*Research network*), Figure 56 (*Dashboard*), and Figure 57 (*Data Analysis Workspace*).

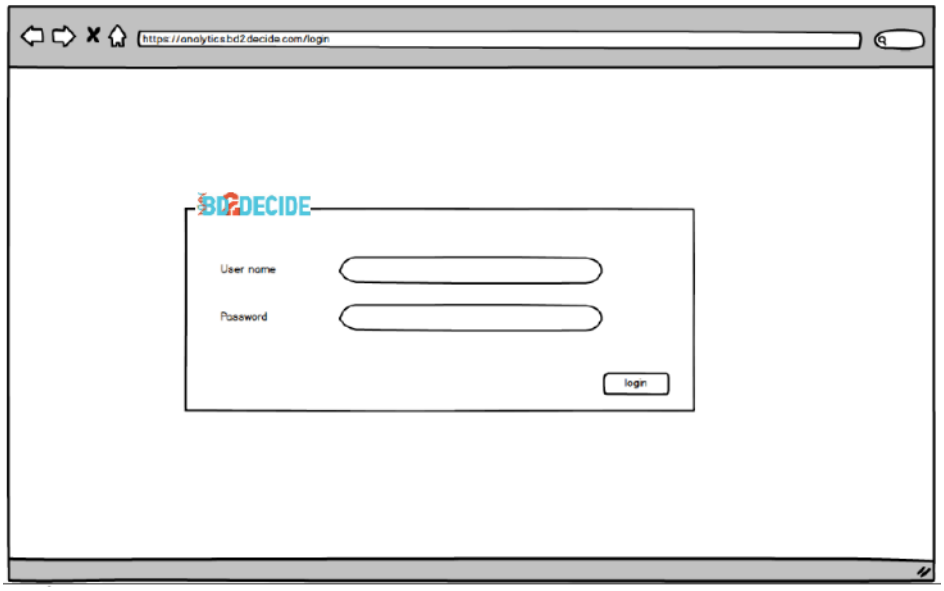


Figure 52: Login Screen.

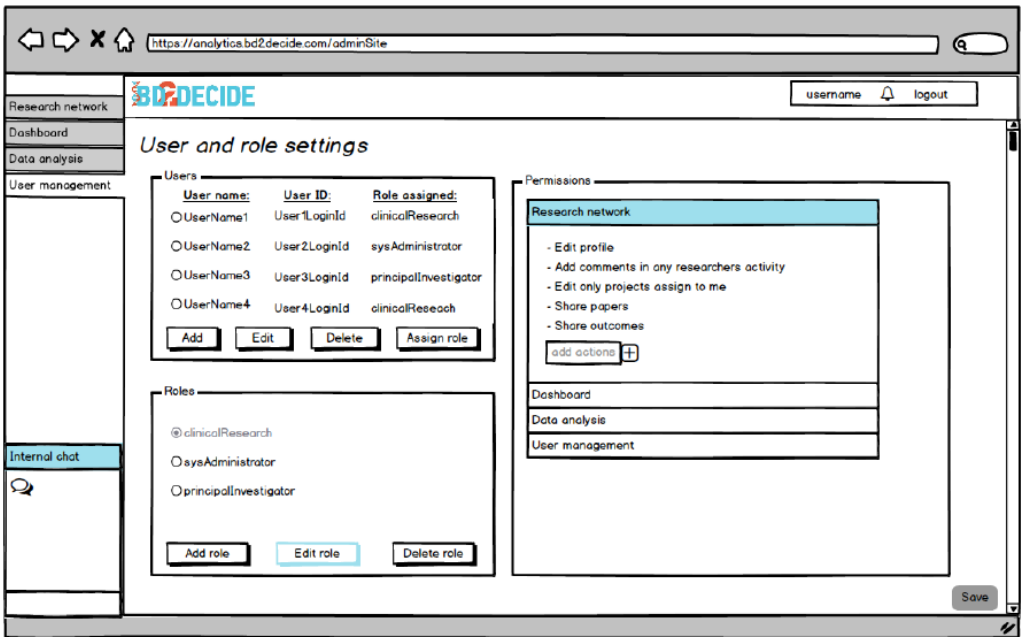


Figure 53: User management Screen.

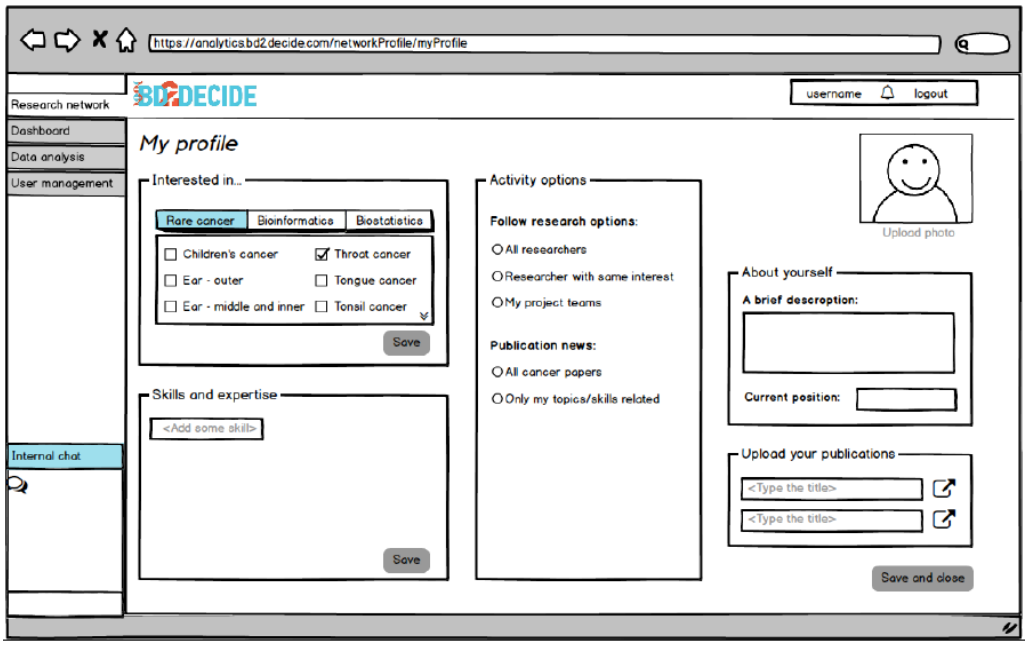


Figure 54: Researcher profile Screen.

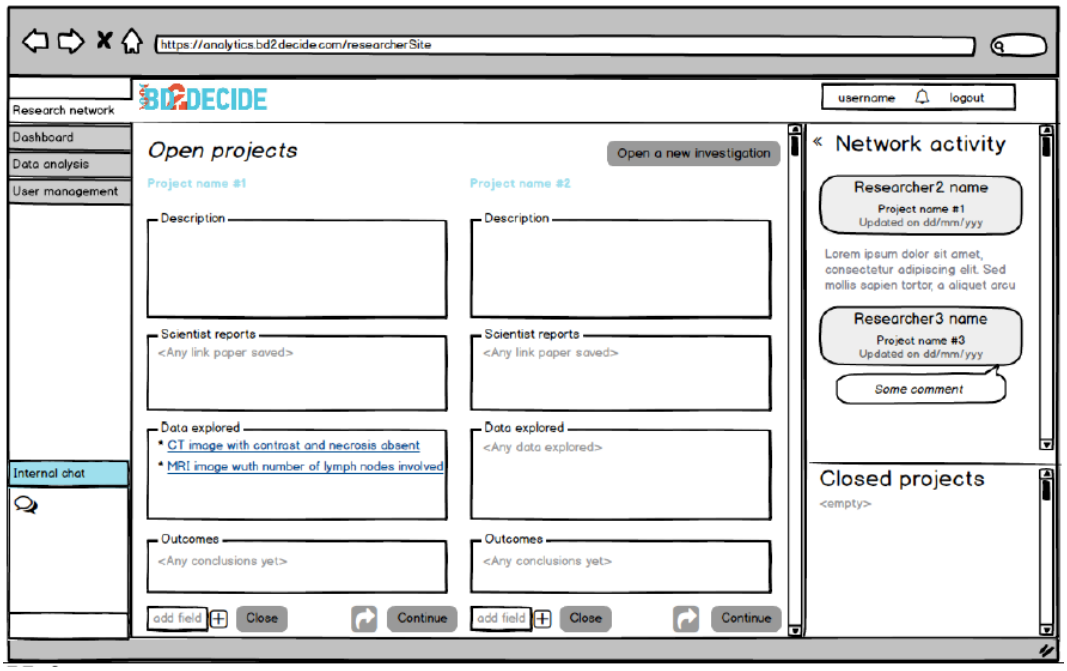


Figure 55: Researcher site Screen.

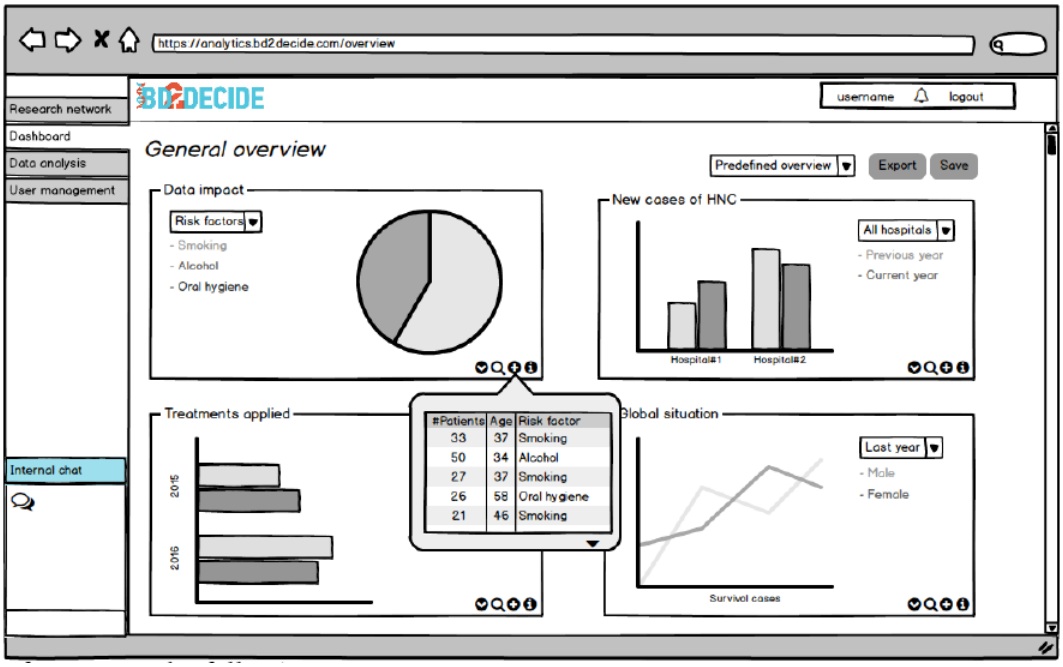


Figure 56: General Overview Screen.

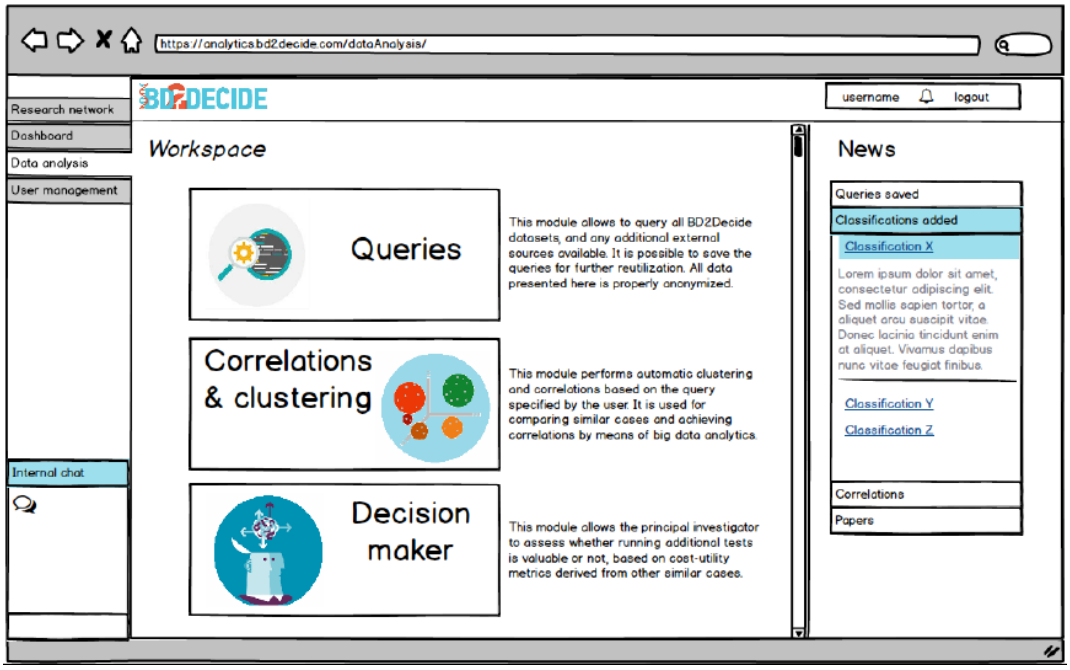


Figure 57: Data analysis workspace.

5.3 Interfaces and functionalities validation

An open survey using Google forms was sent to several clinical partners of the project, with the purpose of solving the doubts that arose during the first concept definition. The survey is included in Annex 8.2. A brief conclusion of the feedback received is presented below.

Regarding the first question about the roles involved in the tool, for most of the surveyed users the clinical researcher role is the only necessary role. However, one of the clinical centres answers that internal and external researcher roles must be included, and profiles such as clinical and biological should also be considered.

The answers regarding questions 2 and 4, which refer to the use of external databases, are not conclusive. Another question rises up: should external datasets be an optional and independent module, or must be a default option for any BD2Decide query, thus being completely transparent to the user? It has been decided to design these functionalities on an independent way until receiving more detailed feedback on this matter.

Relative to question 3 and 6, similar cases and decision maker should be available both for specific patients and for a group of patients marked by diverse parameters. However, the most solid response regarding the 'similar cases' question states that the patient specific option is a must.

Question 5 has not consistent answers but it is possible to conclude that decision maker module should at least include the survival rate in different scenarios, the eventual recurrence, the lymph node prediction and a suggested therapy if possible.

Finally, for question 7, the decision maker module should be available for any researcher who has access to the tool.

Furthermore, thanks to additional meetings it was defined that system administrator is only able to use the User Management module.

Considering the results of the survey and the validation made by some clinical partners, the following changes in the involved actors as presented in Section 5.2.3 are introduced:

- System administrator: user with rights to manage users.
- Internal researcher: researchers within the application who belong to a certain project. They can have clinical or biological profiles.
- External researcher: other researchers who temporally take part in project. They can have clinical or biological profiles.

Table 3 presents the current proposal of the permissions for each role after validation.

Table 3: Roles and permissions defined after validation

Module	Permissions	System administrator	Internal researcher	External researcher
Research network	View network	No	Yes	Yes
	Edit projects	No	Yes	No
	Create projects	No	Yes	No
	Save projects	No	Yes	No

Module	Permissions	System administrator	Internal researcher	External researcher
	View history activity	No	No	No
Dashboard	View	No	Yes	Yes
	Edit	No	Yes	Yes
	Save as predefined	No	Yes	Yes
	Save in project	No	Yes	No
	Export	No	Yes	Yes
	View history activity	No	No	No
Data analysis	View	No	Yes	Yes
	Edit	No	Yes	Yes
	Save as predefined	No	Yes	Yes
	Save in project	No	Yes	No
	Export	No	Yes	Yes
	View history activity	No	No	No
User management	View	Yes	No	No
	Edit	Yes	No	No
	Create	Yes	No	No
	Save	Yes	No	No
	Export	Yes	No	No
	View history activity	Yes	No	No

Also after the validation, all mockups are modified by removing the user management tab for all of them, because of the before-mentioned changes in role. Additionally, the following mockups have been also modified according to the answers.

Flow ID	UC#12_v2
Title	**Correlations & clustering module**
Actor	**Clinical researchers (internal and external)**
Description	This section allows to compare a patient's data or a group of patients' data with other similar cases. The flow of the latter is detailed below.
Steps	
1	Switching between 'By patient' or 'By clusters' buttons it is possible to change the data selection based on whether individual patients or patient groups will be compared
2	By choosing 'By clusters' and selecting the data (first example), the second view appears with the results of the comparison
3	Clicking on the pencil icon the selected value can be updated
4	By adding extra information of the patient (in the left side of the results section), choosing in the drop-down menu between the possible values and clicking Go button, the similar case results are shown
5	Clicking Back button the user returns to 'Clustering selection' (similar to UC#8) to change the data selected
6	Clicking Save button, the query performed (the cluster created) could be saved for later use. This query is also stored in the project section mentioned in UC#3
7	Clicking Export button, export options appear like in UC#5
8	Click the icons in each graph to export, search for papers related to the data, review data that generates the graph or get information about the data
9	Switching between the drop-down menus available in 'Dynamic correlation graph', different data is shown, with the aim of discovering new relationships

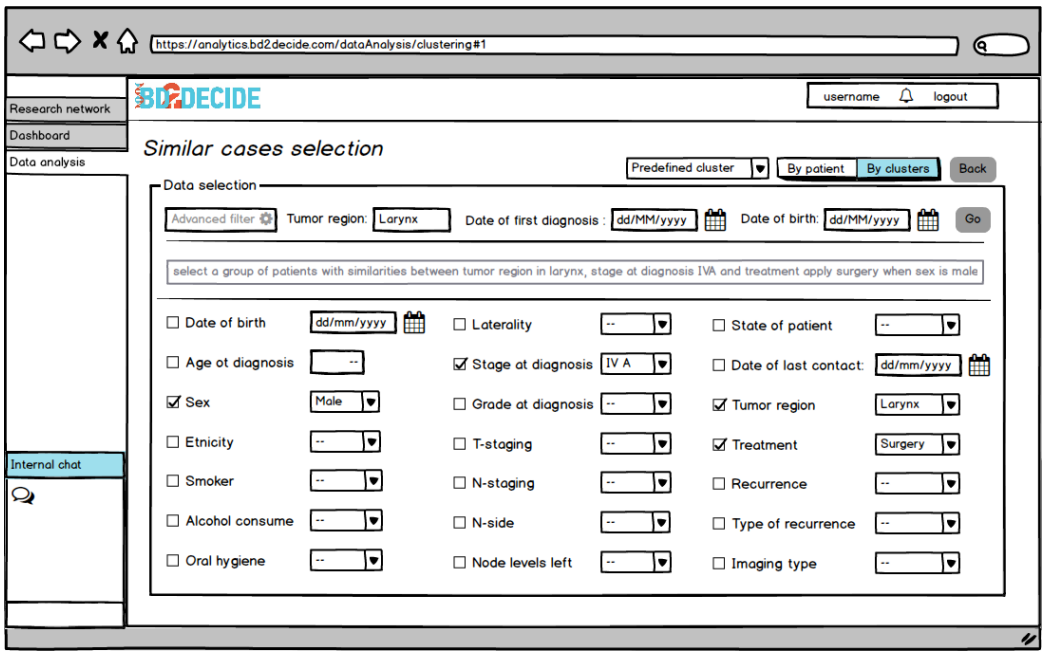
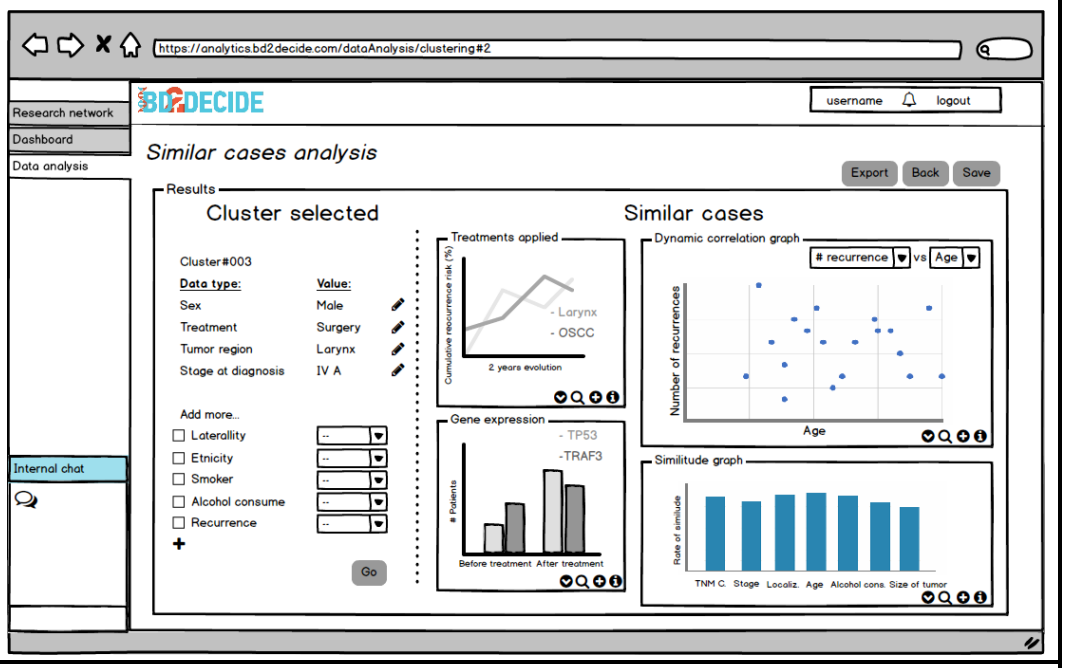
Example	 
Precondition	PR.0
Description	The user should have opened a project and select ‘Correlations & clustering’ module in UC#6
Postcondition	PO.0
Description	The user is able to switch to other data analysis

Table 4: Correlations & clustering module version 2 mockup.

Flow ID	UC#13_v2
Title	**Decision maker module**
Actor	**Clinical researchers (internal and external)**
Description	This section allows to evaluate the cost-utility ratio of adding an extra test comparing between similar cases and other clusters or patient. In this version of the mockup a patient selection will be evaluated against similar cases. This module calculates the estimated cost based on previously stored data. This information will be updated periodically, and the results will strongly depend on the clinical center.
Steps	
1	After selecting 'By patient' option and a target patient (as in UC#12 v2), the results appears like in example 1
2	By clicking Refresh button, a list of possible graphics appears in order to show the desired data
3	Clicking Back button the user returns to 'Decision maker selection' (as in UC#12 v2) to change the patient selected
4	Clicking Export button, export options appear like in UC#5
5	By selecting additional test to evaluate the cost-utility and clicking Go button, the first view appears showing the survival rate estimated in both scenarios and the improvement and cost calculated adding the test to the target patient. Optionally, whenever there are enough information, a potential treatment for the clinical case under analysis is suggested.

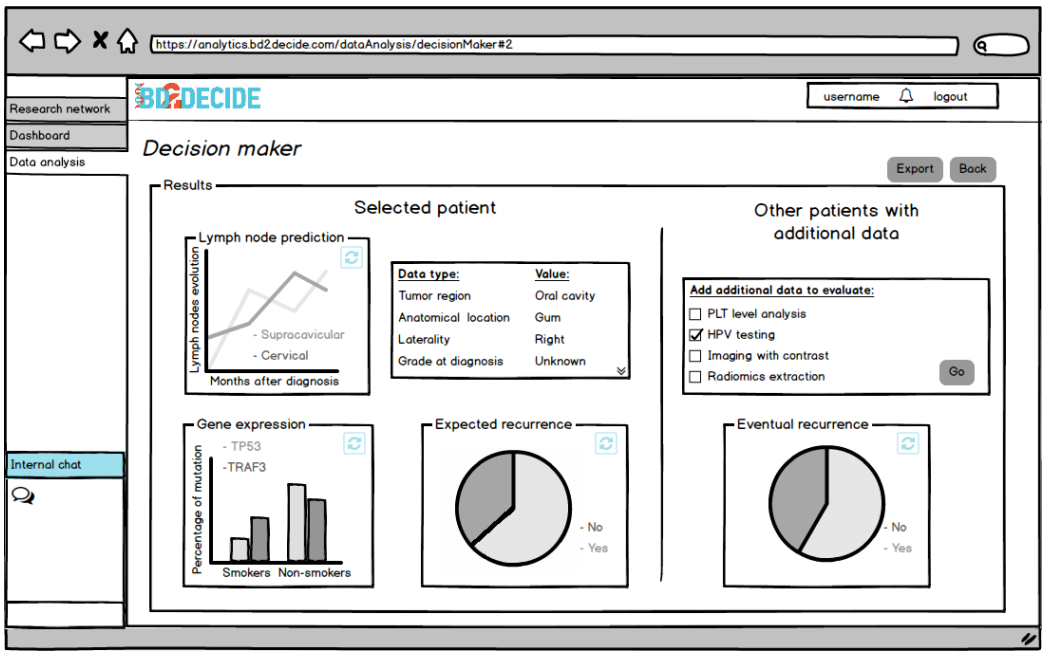
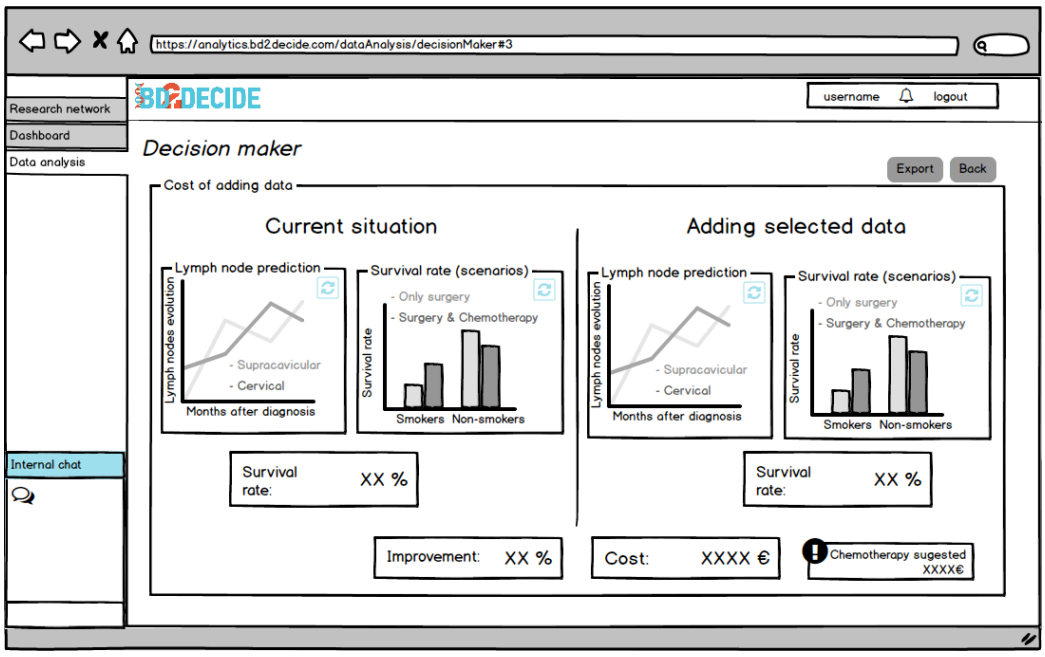
Example	 
Precondition	PR.0
Description	The user should have opened a project and select ‘Decision maker’ module in UC#6
Postcondition	PO.0
Description	The user is able to switch to other data analysis

Table 5: Decision maker module version 2 mockup.

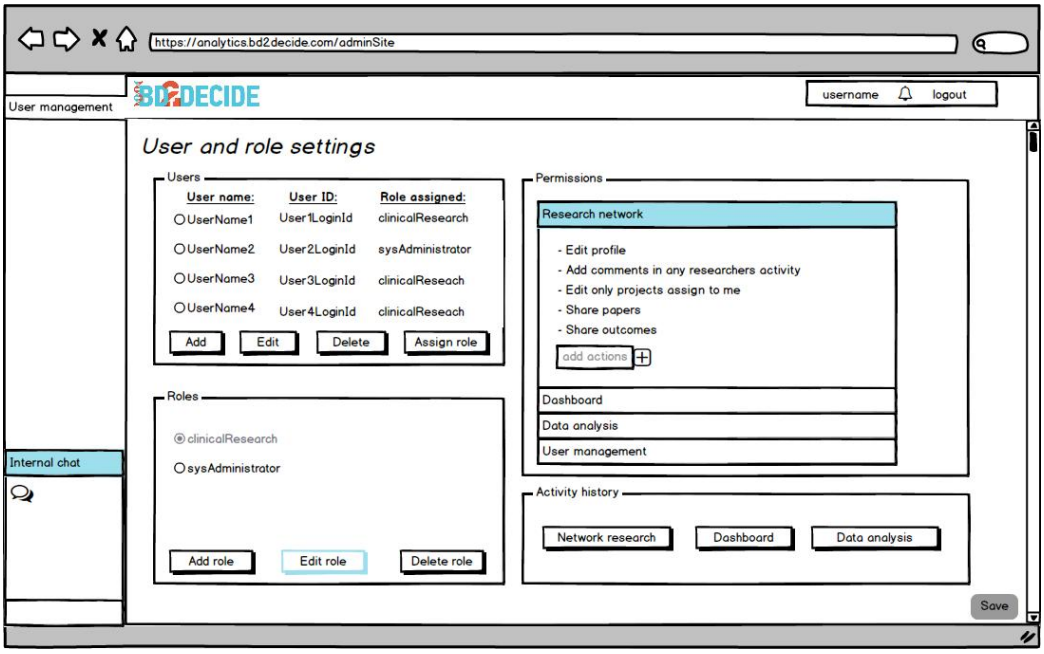
Flow ID	UC#14_v2
Title	**User management module**
Actor	**System administrator**
Description	Administrator site allows the administrator to manage users and roles to adapt their permissions according to their needs.
Steps	
1	After accessing to the application the 'User and role settings' tab is displayed, then the user is able to add new users clicking the 'Add' button and providing a username and password. The administrator is able to edit existing users as well, by selecting them and then clicking the 'Edit' button.
2	By selecting one or more users and clicking the 'Delete' button the users selected are erased from the application.
3	By clicking a specific user and 'Assign role', one of the roles created before could be assigned to the current user selected.
4	To add, edit or delete roles, the procedure is similar. When 'Edit role' or 'Add role' is selected, the roles section becomes active giving the flexibility to add or delete the proper actions in each module to the role selected
5	With the aim of auditing the researchers' work, a history section is available for the system administrator.
Example	
Precondition	PR.0
Description	The user should have administrator permissions

Table 6: User management module version 2 mockup.

A more detailed description of the use cases for the Visual Analytics Tool is provided in Section 8.3.

6 CONCLUSIONS

This deliverable describes part of the work performed in WP 2 for sketching the design of the interactions among the BD2Decide software environment and the target end users. More specifically, the document presented the outcome from the involvement of clinical professionals and researchers and, to some extent, patients in the early stages of the BD2Decide development activities. Based on a well-defined user centric design process that aims to achieve high degree of usability for the BD2Decide components, we elaborated on the initial sketches of the user interaction design. These sketches provide the initial conceptualisation of the functionalities expected from the BD2Decide software for each stakeholder group.

The deliverable analysed the needs of the target stakeholders to interact with the BD2Decide components and, subsequently, presented the visual representation of the BD2Decicde concepts and the expected wireframes that should eventually constitute the user interface components of the BD2Decice environment. These wireframes refer to: i) patients, who are made aware of the candidate treatment methods proposed by their physicians (and the tumor board), and the impact of these treatments in their life and survival conditions, ii) clinicians, who want to collect and manage their patients' data, in the context of assessing their clinical status, along the phases of the HNC treatment process, assess the evolution of their patients' disease case, through personalised prediction, and collaborate with other professionals, in the context of the organization of tumor boards, and iii) clinical researchers, who use the BD2Decide environment to query for big data analysis from various sources, including patients' data from clinical studies, research activities and statistical bodies on HNC disease cases.

The next steps of this work include the implementation of the usability evaluation planning. An initial validation approach for the three families of BD2Decide components has already been presented in Sections 3.3, 4.3 and 5.3. As explained there, the sketched presented in this deliverable comprise an initial approach to the visualisation of the BD2Decide concepts, and they need to be validated when a functional mock-up version of the BD2Decide software environment is available. The main validation steps follow the UCD concepts illustrated in Figure 3.

As such, during the usability design, an additional level of validating the design sketches will be performed with the end users to fine tune the visualisation of the expected functionalities and the involved data, according to the use case scenarios, presented in D2.1. This work aims to evaluate the design sketches and further drive the development of the UI mock-ups by M12 (December 2016) on the high priority functions that should be made available to the target end users. Upon this, the usability validation activities will be initiated, which will be grouped into three main milestones:

- An initial evaluation of the implementation for the individual UI mock-ups and the realisation of the functions offered by the BD2Decide tools will be performed between M13-M18 (first semester of 2017). This validation will allow us better position the user expectations in the context of individual functionalities provided by the BD2Decide tools and components.

- An initial evaluation of the BD2Decide initial prototype will be performed between M19-M24 (second semester of 2017). This validation will allow us better position and assess the user expectations in the context of an integrated BD2Decide prototype.
- The overall BD2Decide evaluation will be performed till M29 of the project (May 2018) and will span across the usability dimensions, metrics and criteria, which will be elaborated in the context of T5.5 and the work in WP 5.

Overall, as concluded from the above analysis, the results of this Deliverable are the guiding lights for communicating the implementation results to the target professionals in this demanding field.

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8 ANNEXES

8.1 The schema for interviewing Dutch larynx cancer patients and their clinicians

8.1.1 Interview schema IPDA – Patients

Introductie

- De onderzoeker stelt zich voor.

- De onderzoeker vraagt of de deelnemer de informatiebrief heeft gelezen.

- De onderzoeker geeft kort informatie over het onderzoek (duur, onderwerpen, anonimiteit en het gebruik van de voicerecorder).

- De onderzoeker vraagt de deelnemer om het toestemmingsformulier (informed consent) te lezen en indien hij akkoord gaat deze ondertekenen.

A. Algemene informatie

Kruis het rondje aan bij het juiste antwoord of vul het juiste antwoord in.

1 Wat is uw geboortedatum? ……. (dd/mm/jj)

2 Bent u gehuwd?

- Gehuwd of samenwonend

- Alleenstaand

3 Heeft u kinderen?

- Ja

- Nee

4 Wonen u kind(eren) nog thuis?

- Ja

- Nee

5 Wat is de hoogste opleiding die u hebt genoten?

- Voltooid met een diploma

- Gestopt, zonder diploma

6. Diploma

a. Lager algemeen onderwijs/ basisschool of een gedeelte hiervan

b. Lager beroepsonderwijs, bijvoorbeeld: LTS, LHNO, LEAO, VMBO

c. Middelbaar beroepsonderwijs, bijvoorbeeld: MEAO, MTS, UTS, MBA

d. Algemeen voortgezet onderwijs, bijvoorbeeld: 5-jarig HBS, MMS, gymnasium, lyceum, VWO, HAVO

e. Hoger beroepsonderwijs, bijvoorbeeld: HTS, HEAO, sociale academie, HBO-V, kweekschool

f. Wetenschappelijk onderwijs, bijvoorbeeld: universiteit, promotie

7 Heeft u een computer, laptop of tablet (iPad) in uw bezit?

- Ja

- Nee

8 Heeft u thuis of elders toegang tot internet?

- Ja

- Nee

9 Maakt u gebruik van internet?

- Vaak

- Soms

- Nooit

Open Vragen

B. Algemene ervaring ziekteproces (openingsvragen om het gesprek op gang te krijgen)

1. U bent hier omdat de diagnose strottenhoofdkanker bij u gesteld is. Hoe is het proces vanaf het moment dat u klachten kreeg verlopen?

a. Wat voor klachten had u?

b. Welke behandeling heeft u gehad en hoe heeft u dit ervaren?

c. Hoe ervaart u uw gezondheid nu?

d. Kunt u me vertellen welke mensen betrokken waren tijdens uw behandelingsproces? Welke relatie had u met hen?

C. Impact op het dagelijks leven

1. Hoe heeft de strottenhoofdkanker uw dagelijkse leven veranderd?

    a. Had u dit verwacht naar aanleiding van de informatie die u gekregen of gelezen had?

    b. Waren deze veranderingen vlak na de behandeling erger dan nu?

2. Wat mist u het meest van de tijd voordat u behandeld werd voor strottenhoofdkanker?

    a. Waarom mist u dit het meest?

    b. Had dit volgens u voorkomen kunnen worden?

D. Diagnose en informatie

1. Begreep u alle informatie die u kreeg van uw behandelend arts?

    a. Waar had u meer over willen weten t.a.v. uw ziekte?

    b. Welke arts speelde een belangrijke rol in dit proces (bijvoorbeeld uw huisarts, de hoofd-hals chirurg, de radiotherapeut?)

    c. Heeft u tegenstrijdige informatie gekregen?

2.Welke onderdelen van informatie zijn het belangrijkst voor u (bijv. voor of nadelen behandeling, duur van behandeling, etc.) en waarom?

    a. Vond u dat er informatie ontbrak? Zou u misschien meer technische informatie willen of meer emotionele ondersteuning? Toegang tot bepaalde informatie bij Maastro Clinic of thuis?

3. Heeft u zelf nog voor aanvullende informatie gezocht?

    a. Welke soort informatie heeft u opgezocht en waar heeft u deze opgezocht?

    b. Wat vond u prettig aan deze informatie?

    c. Hebben uw familie en/of vrienden u geholpen met het zoeken van informatie?

    d. Heeft u contact gehad met een lotgenoten vereniging?

4. Op welke manier zou u meer informatie willen krijgen over de verschillende soorten behandelingen? (tekst, video, etc.)

E. Behandelingskeuze

1. Was u betrokken bij het maken van een behandelingskeuze?

a. Zo ja, hoe verliep dit proces?

b. Wat vond u moeilijk in het proces om tot een behandelkeuze te komen?

c. Zo niet, waarom heeft u geen rol gespeeld in het maken van een beslissing?

2. Wat was de rol van uw familie en vrienden in het proces van een keuze maken?

3. Als u drie dingen kon verbeteren in het proces van een behandelingskeuze maken, wat zouden deze zijn?

4. Wat zorgde ervoor dat u gekozen hebt voor de uiteindelijke behandeling?

5. Welk advies zou u geven aan iemand die net gediagnostiseerd is met strottenhoofdkanker?

F. Computervaardigheden

1. Zou u toegang willen hebben tot een computerprogramma wat u begeleidt door de verschillende behandelopties en de voor-en nadelen van iedere optie weergeeft. Dit zou u dan kunnen gebruiken bij het maken van een behandelingskeuze? Waarom?

Afsluiting:

- Wat vond u van het interview?

- Heeft u nog iets toe te voegen of wilt u nog iets kwijt?

~ Voice recorder uit ~

- De onderzoeker deelt mede dat alle gegevens anoniem verwerkt worden.

- De onderzoeker stuurt zo spoedig mogelijk een samenvatting van het interview per e-mail naar de deelnemer toe. De deelnemer mag hier op reageren.

- De onderzoeker bedankt de deelnemer voor deelname aan het interview.

8.1.2 Interview schema IPDA - Clinicians

Persoonlijke gegevens:

Leeftijd:
Geslacht:
Medisch specialisme:

Opleiding:
Aantal jaren ervaring:

Ervaring met decision aid tools:

Vragen om te komen tot de optimale decision aid tool voor larynxkankerpatiënten.			
	Topic	**Hoofdvragen**	**Inhaakvragen**
1	Huidige voorlichting	Welke informatie gebruikt u bij het inlichten van uw patiënten?	Welke vragen ontstaan hierdoor bij de patiënt?
2	Huidige voorlichting	Welke voorkeuren en informatie betreffende de patiënt zijn noodzakelijk om een passende behandelingskeuze te kunnen maken?	Kunnen patiënten deze voorkeuren en informatie geven na de inlichting? Waar hebben ze nog moeite mee of waarover twijfelen ze vaak?
3	Huidige voorlichting	Welke informatie, middelen en afbeeldingen gebruikt u tijdens het consult bij het adviseren van een behandeling?	Wat zijn daarmee u goede en minder prettige ervaringen?
4	Moeilijkheden	Welk uitdagingen komt u tegen terwijl u patiënt gerelateerde informatie behandeld?	Welk info zorgt voor de grootste uitdaging, en waarom?
5	Moeilijkheden	Als u patiënten helpt bij het maken van een behandelingskeuze, wat zijn dan de uitdagingen die u daarbij tegenkomt? Is er een behandeling waaraan u de voorkeur geeft maar die niet de voorkeur van de patiënt heeft?	Zijn er onderwerpen die moeilijk te bespreken zijn? Wat zijn de cruciale punten?
6	Moeilijkheden	-Wat roept tijdens het consult nog onduidelijkheden op bij de patiënt betreffende de behandelingsopties?	Welke vragen hebben de patiënten nog gedurende de behandeling? En hadden deze vragen de behandelingskeuze nog kunnen beïnvloeden als u deze vraag vooraf had gekregen?
7	Ervaring	Heeft u het idee dat patiënten behoefte hebben aan een decision aid tool om te komen tot gezamenlijke besluitvorming?	Zal het een verkeerde behandelingskeuze doen voorkomen?

8.2 The Questionnaire used for the validation of the concepts for the Visual Analytics Tool

BD2Decide - Visual Analytics tool

Gathering information on researcher needs, this survey focus on the overview of Visual analytics tool in researcher scenario. The following questions refer to your experience working as researcher in oncology field. Thank you for sharing your opinions.

* Required

Please insert your clinical center: *

Your answer

1. In order to properly focus the tool, the user profiles should be defined. Which user roles should be involved in the researcher tool? *

- System administrator
- Main investigator
- Clinician research
- Other :

2. Should external databases (i.e. IARC, OECD, Embase) be available in the researcher tool? If yes, please insert which one or add others databases. *

Your answer

3. Should a researcher be able to query for a specific patient or should only be possible comparing clinical cases through clustering methods? *

Your answer

4. Should imaging information databases (i.e. TCIA, MAASTRO, TCGA, CGHub) be available by default in the main query tool? If yes, please insert which one or add others databases. *

Your answer

Decision Maker

The tool will include the 'Decision maker' functionality. This will allow the researcher estimating the cost effectiveness of a patient treatment during the diagnosis phase.

5. What should be the expected outcomes of 'Decision Maker' section? (i.e. graphics showing the impact, the cost of the information added, the improvement that this data implies and the survival rate in both scenarios, ...) *

Your answer

6. Should the ‘Decision maker’ section be used by choosing a specific patient or should also be possible comparing groups of patients? *

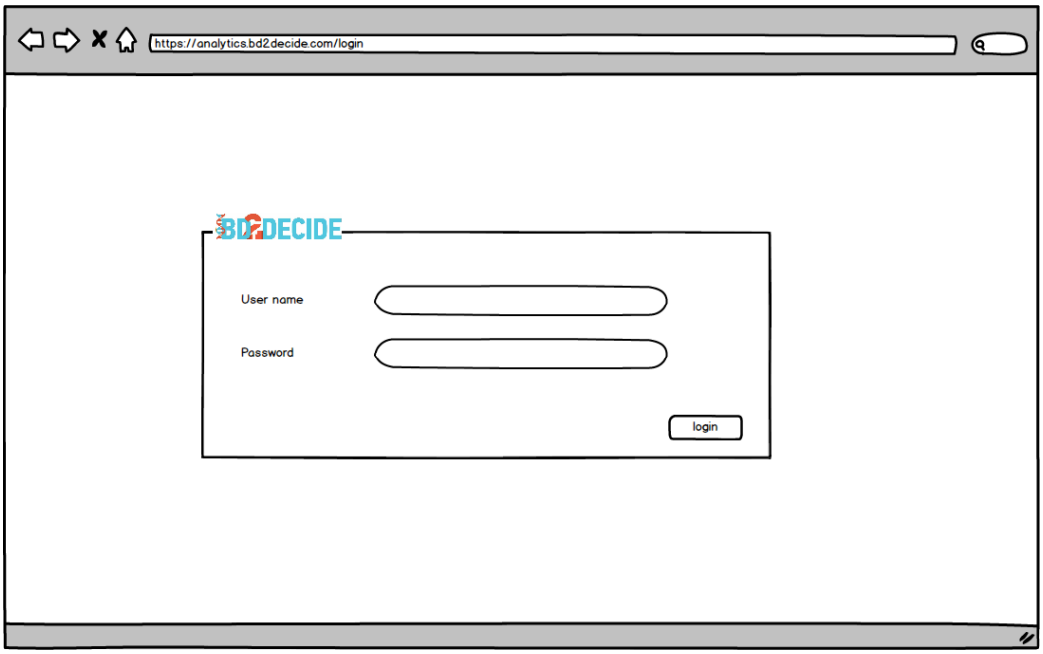
Your answer

7. Should the ‘cost-utility analysis’ of the ‘Decision maker’ being available for all types of researcher users (i.e. a researcher that is not a clinician)? If not please specify. *

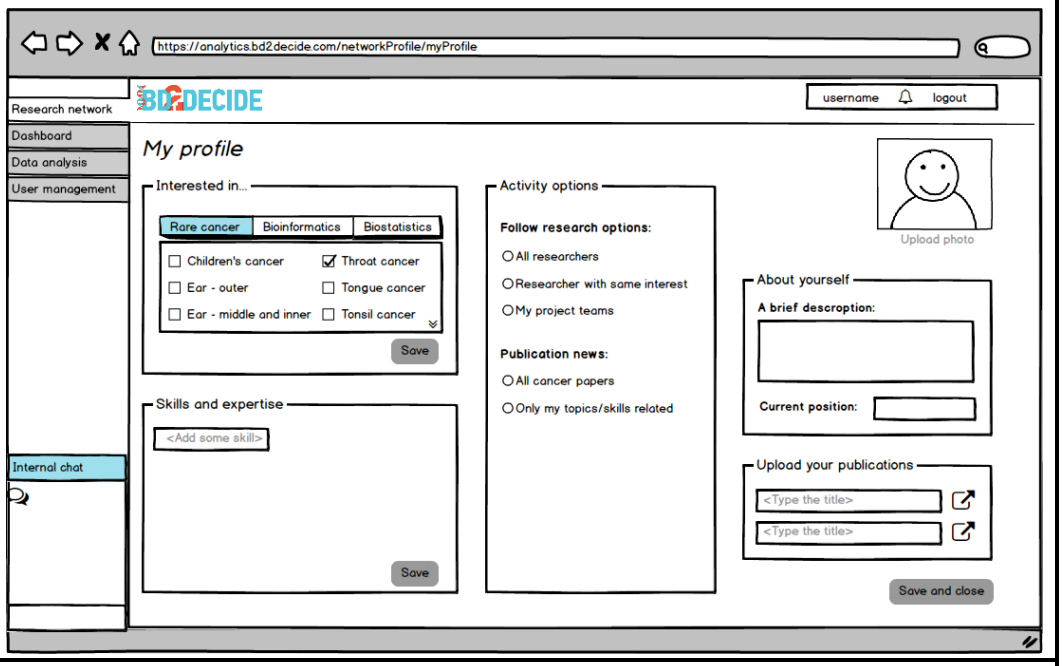
Your answer

8.3 The set of use cases for the actors using the Visual Analytics Tool

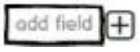
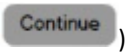
Tables with UCs for each mockup defined, and brief description of functionalities defined in each module and mockup.

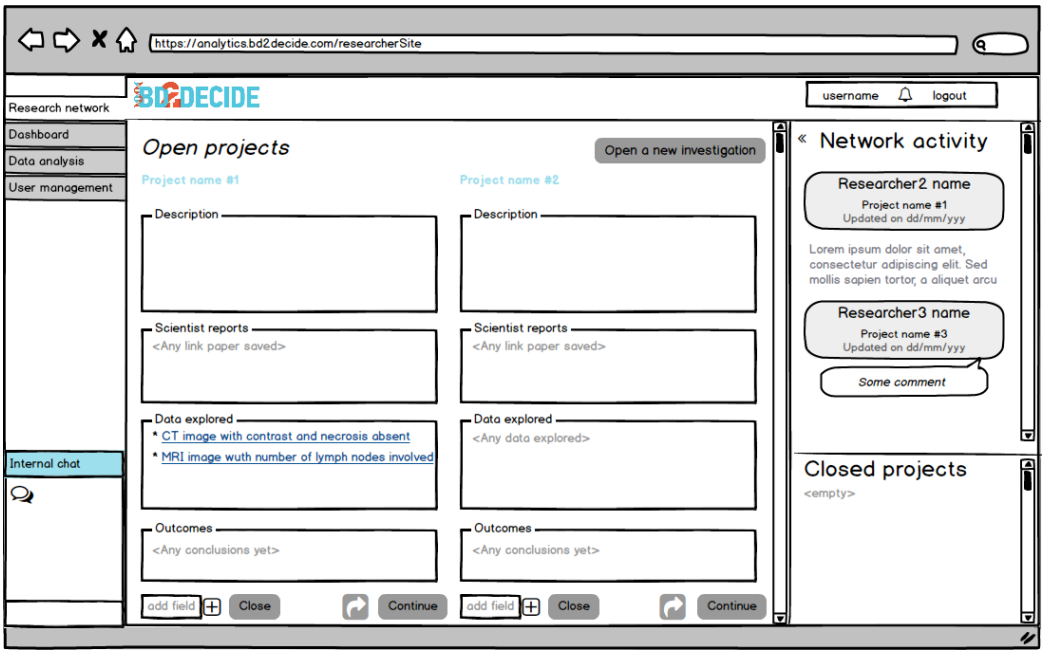
Flow ID	UC#1
Title	**Login**
Actor	**All researchers and administrators**
Description	The way to access the BD2Decide Research tool with user and password
Steps **1** **2** **Example**	 Go to the URL Enter username and password in the login window that appears in the browser 
Precondition	PR.0
Description	The admin of the application must create the credentials for users

PostCondition	PO.0
Description	The logged user is able to use the tool

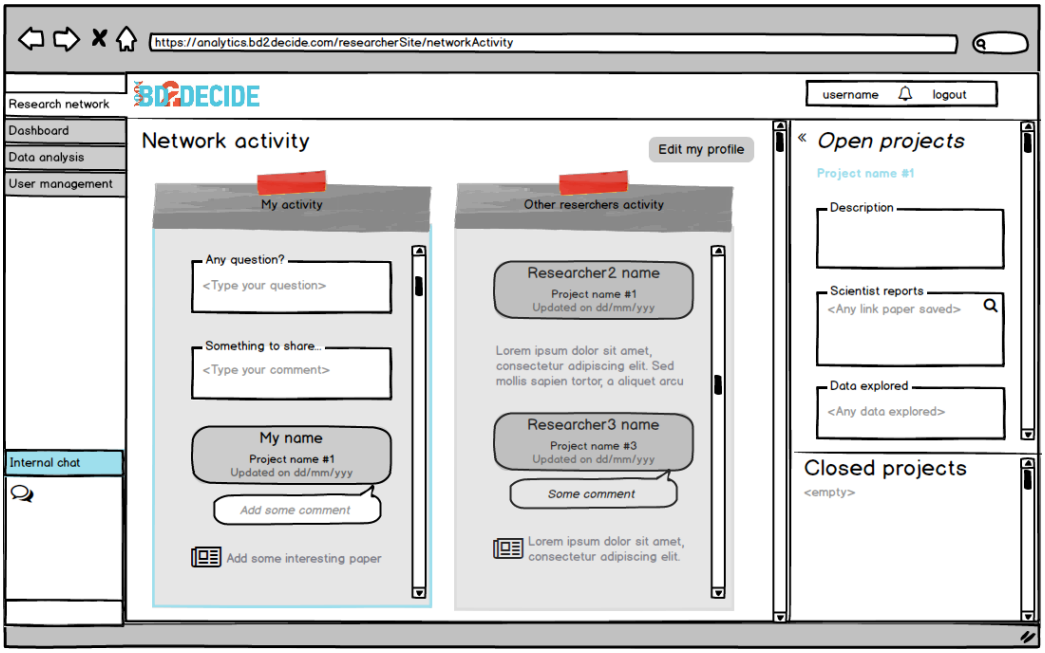
Flow ID	**UC#2**
Title	**Research profile**
Actor	**All researchers and administrator**
Description	Researcher network profile. It allows to customize all notifications, share ideas, questions and projects in the researcher network.
Steps	
1	Get updated all topics the user is interested in, write about user skills and expertise
2	Indicate the activity options preferences, specifying the privacy of the user work in the tool
3	Describe user profile and current position. Also it is possible to upload researcher's publications
Example	
Precondition	PR.0
Description	The first time the user logins in the application, a welcome pop-up appears asking for the creation of the network profile.
PostCondition	PO.0
Description	The user is able to access research network (UC#4)
Alternative	Users who have no permissions for user management do not have the 'User management' tab

flow	on the left side of the tool

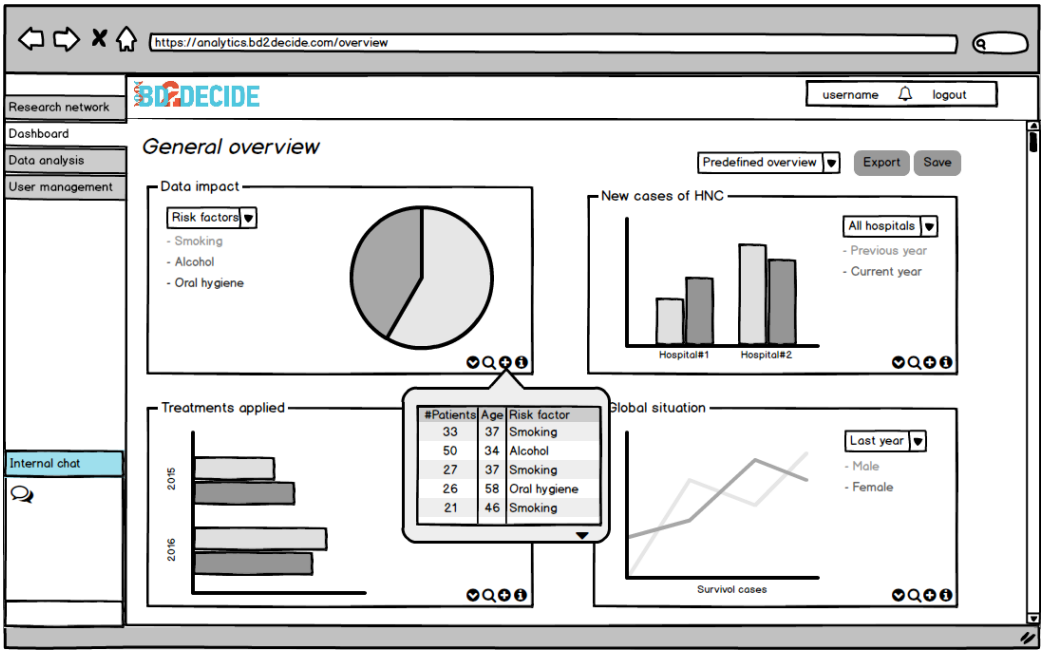
Flow ID	UC#3
Title	**Researcher site**
Actor	**All researchers and administrator**
Description	Workspace to have all the information stored about any investigation. Each line of investigation could be created as new projects in order to have all works categorized and archived.
Steps	
1	Include a name and description of the project
2	
3	
4	Save all scientific reports consulted Save all data of interest explored. These queries are available with a direct link for later searches
5	Add more fields to complete the information of the project (typing the name of the custom section and clicking in plus button: )
6	Share the project with other researcher in the research network (clicking ) Indicate any outcomes before closing (clicking ) the project
7	Continue the investigation through the Data analysis module (clicking )
8	Open a new investigation line clicking 
Example	

	
Precondition	PR.0
Description	After creating the network profile, a pop-up appears to create the first project
PostCondition	PO.0
Description	The user is able to access research network (UC#4) clinking « icon
Alternative flow	Users who have no permissions for user management do not have the 'User management' tab on the left side of the tool

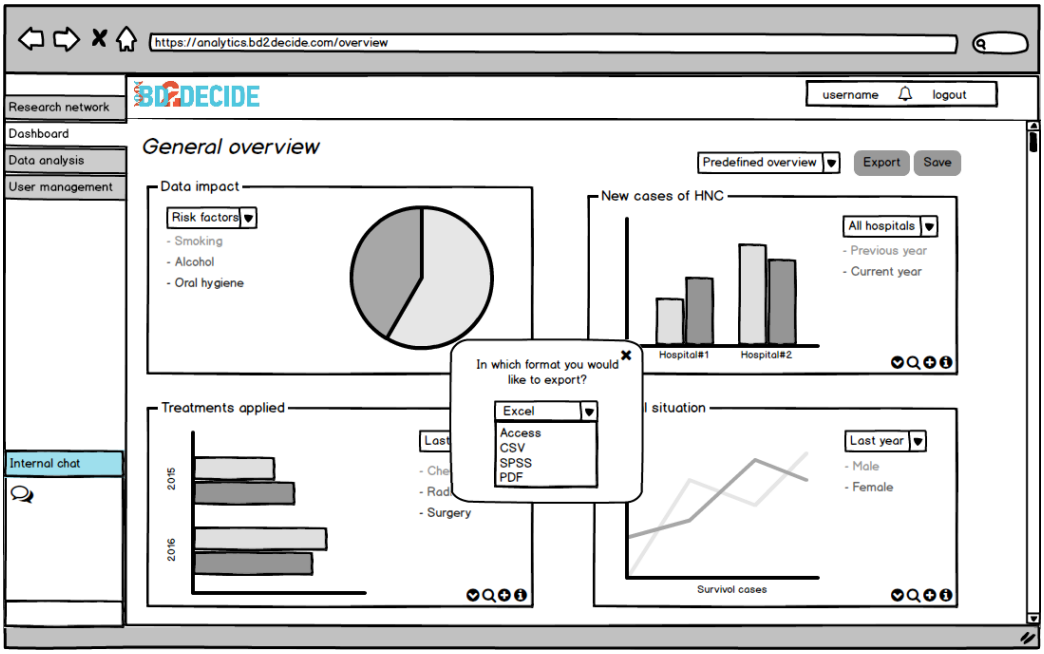
Flow ID	**UC#4**
Title	**Researcher network**
Actor	**All researchers and administrators**
Description	Researcher network allows the user to share any item with other researchers within the application, to ask about any topic interested in and to add some comments in other researchers' posts.
Steps	
1	Include any question or any topic the user wants to discuss
2	Share some interesting papers with other researchers
3	Edit the user profile clicking Edit my profile

Example	
Precondition	PR.0
Description	Network profile should be created (UC#2)
PostCondition	PO.0
Description	The user is able to go back to the research site (UC#3) clicking the « icon
Alternative flow	Users who have no permissions for user management do not have the 'User management' tab on the left side of the tool

Flow ID	**UC#5**
Title	**General overview**
Actor	**All researchers and administrators**
Description	This module contains a set of predefined graphics about the current situation of HNC in the world
Steps **1** **2**	Change the data displayed in each box clicking in the drop-down box Click icons for each graph to export, search for papers related to the data, review data that generates the graph or get information about the data

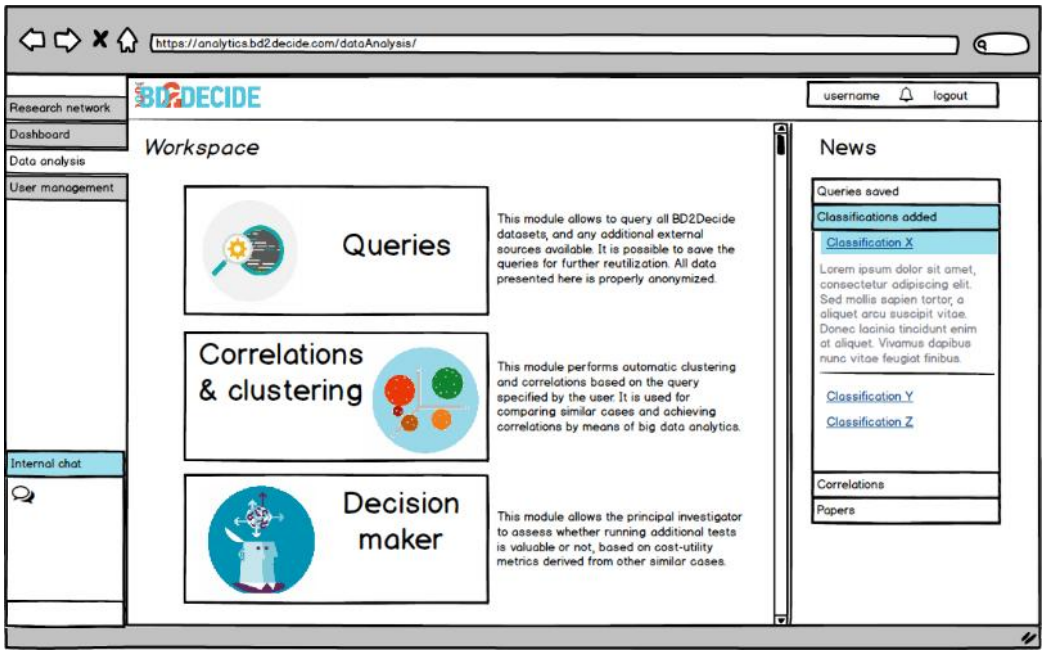
3	Save custom overview preferences (clicking Save) to be reused later (clicking Predefined overview)
4	Export all data clicking Export
Example	

After step 4, the following pop-up appears:

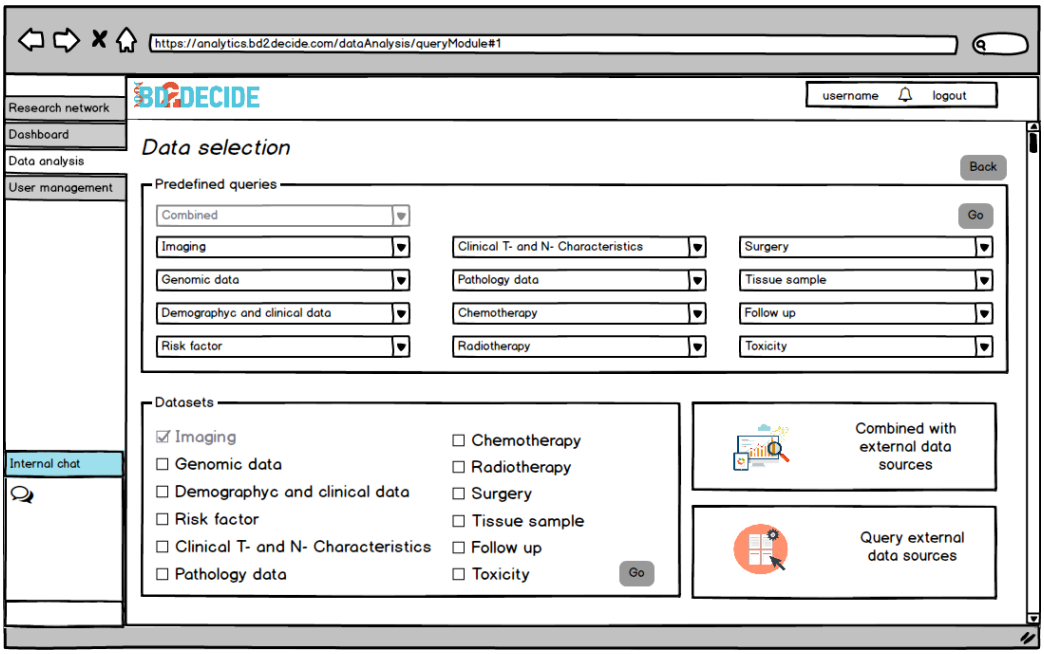


Precondition	PR.0
Description	The user should be logged in (UC#1)
PostCondition	PO.0
Description	The user is able to start the data exploration by clicking the 'Data analysis' tab (UC#6)
Alternative flow	Users who have no permissions for user management do not have the 'User management' tab on the left side of the tool

Flow ID	**UC#6**
Title	**Data analysis workspace**
Actor	**All researchers and administrators**
Description	This module contains the modules to work with the data depending on the goal of the analysis
Steps	
1	By selecting 'Queries' module, the user can look up any data of interest
2	'Correlations & clustering' button opens a module which allows the user to compare between similar cases and to achieve correlations and clusters automatically
3	'Decision maker' modules allows principal investigator to get a cost-utility analysis of additional tests for a specific user/cluster
4	'News' section (in the right side) shows any change of interest for the current user based on his profile and active projects
Example	

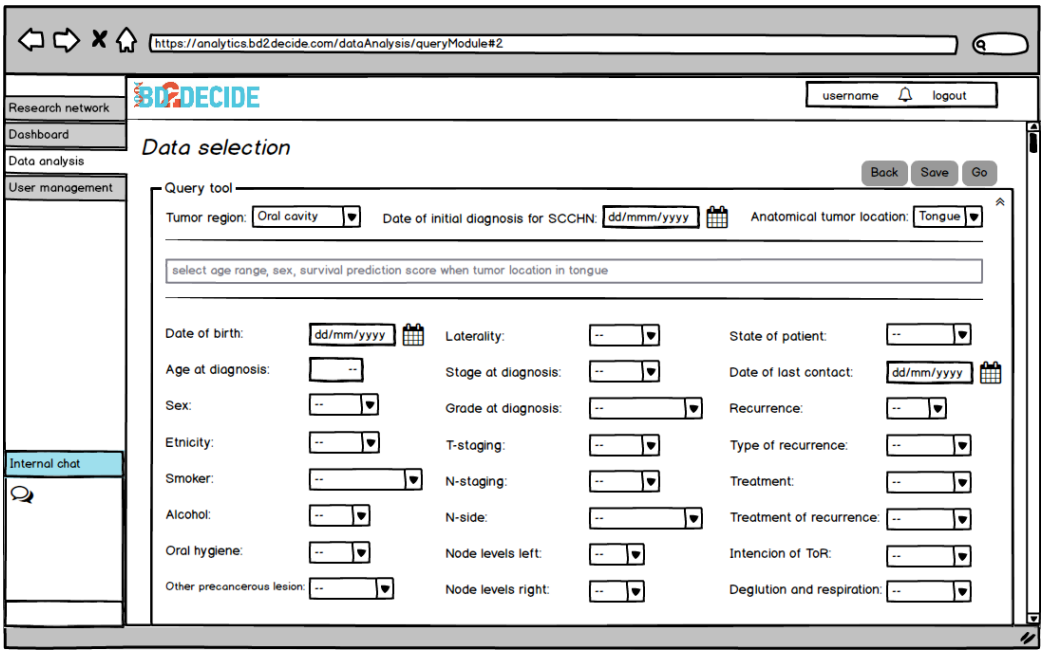
	
Precondition	PR.0
Description	The user should have opened a project
Postcondition	PO.0
Description	The user is able to start the data exploration by clicking one of the three modules (UC#7, UC#14 and UC#15)
Alternative flow #1	Users who have no permissions for user management do not have the 'User management' tab on the left side of the tool
Alternative flow #2	Users who have no permissions to use 'Decision maker' will not see that button

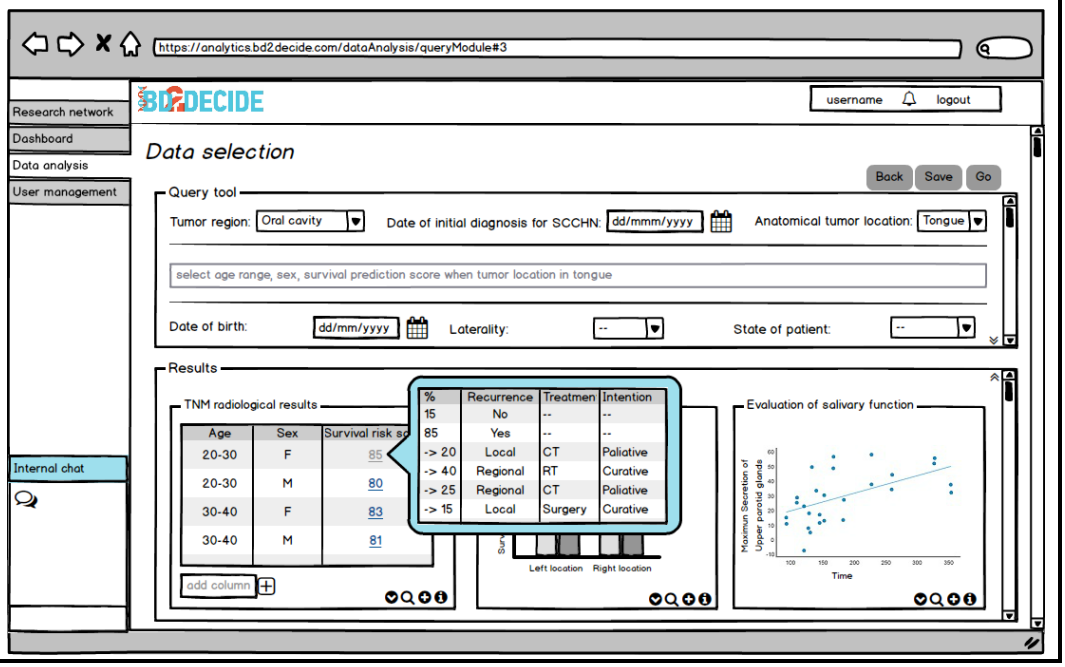
Flow ID	**UC#7**
Title	**Queries module**
Actor	**All researchers and administrators**
Description	This module has all data (internal and external) available to start data exploration
Steps **1**	'Predefined queries' section contains queries stored by the user classified by data type or for a combination of some types of data. By selecting one query in the drop-down menu and clicking Go, the query fields and results appears (UC#9) By selecting one or more of the data types in 'Dataset' section and clicking Go, the query

2	option fields appear in order to filter the data to be analysed (UC#8)
3	Clicking 'Combined with external data sources' button, a set of external sources can be selected with the purpose of adding that information to the analysis (UC#10)
4	Clicking 'Query external data sources' button, a set of external data sources are available to explore (UC#11)
5	Clicking Back the user return to Data analysis workspace (UC#6)
Example	

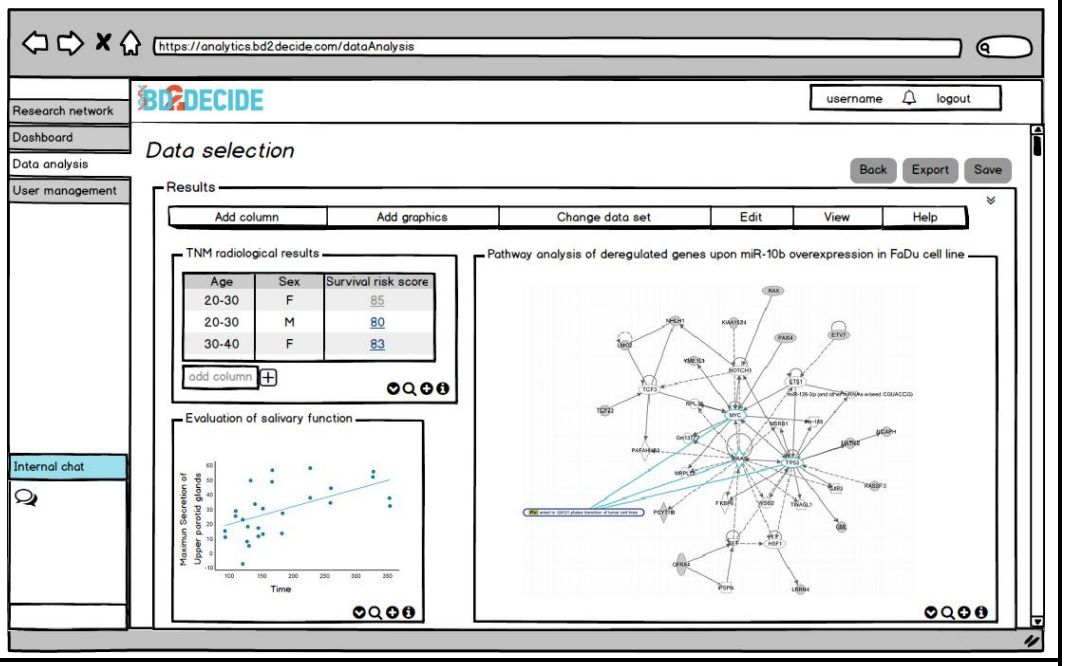
Precondition	PR.0
Description	The user should have opened a project and select 'Query' module in UC#6
Postcondition	PO.0
Description	The user is able to start the data analysis
Alternative flow #1	Users who have no permissions for user management do not have the 'User management' tab on the left side of the tool

Flow ID	**UC#8**
Title	**Queries module. Data selection**

Actor	**All researchers and administrators**
Description	This section presents the data selection fields available. Additionally a free text input is available to search for the data of interest
Steps **1** **2** **3** **Example**	By selecting in drop-down menus and/or typing in the input-text fields, or typing a query in free text field, and then clicking Go, the results of the query appear (UC#9) By clicking Back the user returns to the 'Query' module (UC#7) By clicking Save, the query performed can be saved for later use. This query is also stored in the project section mentioned in UC#3 
Precondition	PR.0
Description	The user should have opened a project, select 'Query' module in UC#6 and 'Dataset' options in UC#7
Postcondition	PO.0
Description	The user is able to get results for the data selected (UC#9)
Alternative flow #1	Users who have no permissions for user management do not have the 'User management' tab on the left side of the tool

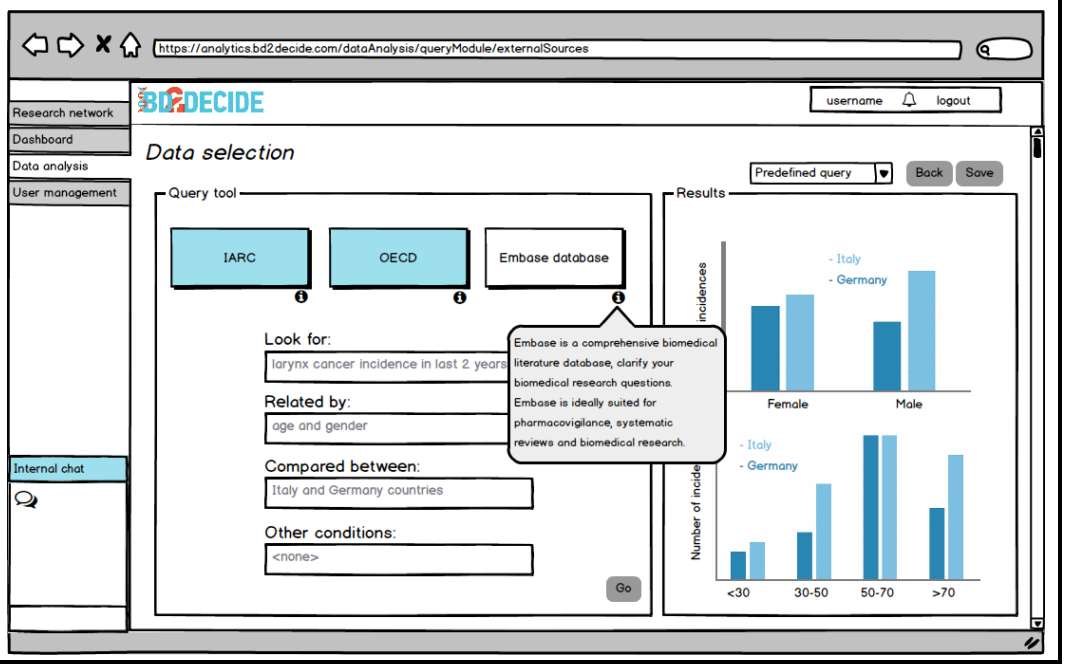
Flow ID	UC#9
Title	**Queries module. Data selection and results**
Actor	**All researchers and administrators**
Description	This section shows the outcomes of the query performed
Steps	
1	By changing the data selected and then clicking Go, the results are refreshed
2	Clicking Back or the user returns to 'Queries module. Data selection' (UC#8) to edit the query
3	Clicking Save, the query performed can be save for later use. This query is also stored in the project section mentioned in UC#3
4	Clicking the data available in the tables, more details are shown Click icons for each graph to export, search for papers related to the data, review data that generates the graph or get information about the data
5	Clicking , a more detailed results section appears, allowing the user to customize the outcomes
6	
Example	

After step 6, the following view appears allowing the user to add information, add more graphics, change data representation, edit the results and change the visualization. Export button shows a similar pop-up like in UC#5.



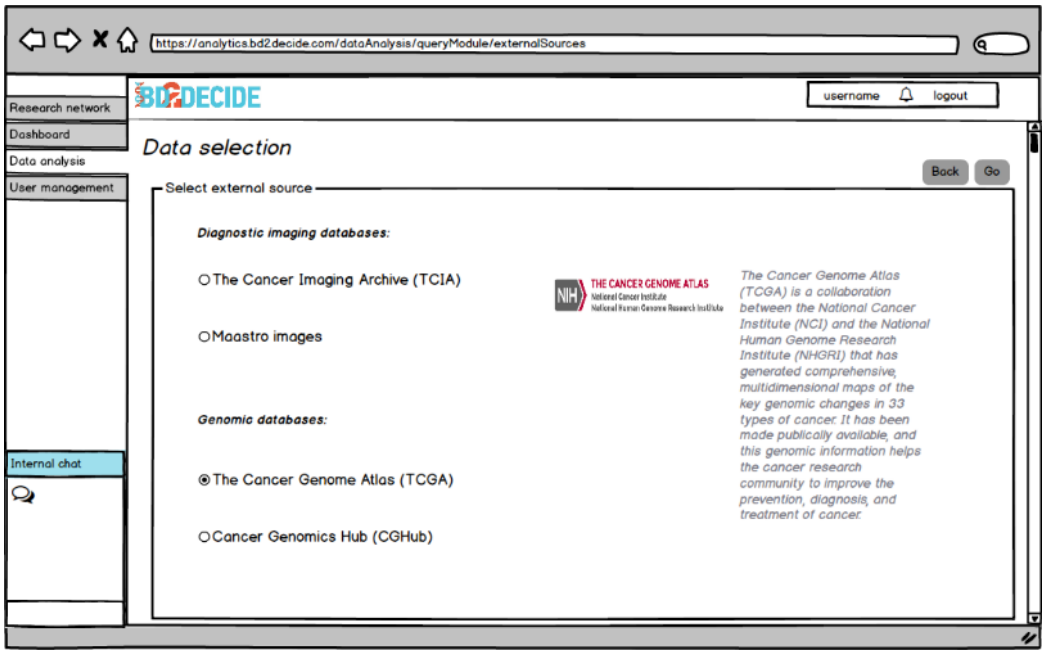
Precondition	PR.0
Description	The user should have opened a project, select 'Query' module in UC#6, 'Dataset' options in UC#7 and select the data to be analysed in UC#8
Postcondition	PO.0
Description	The user is able to work with the results and to change to other data analysis

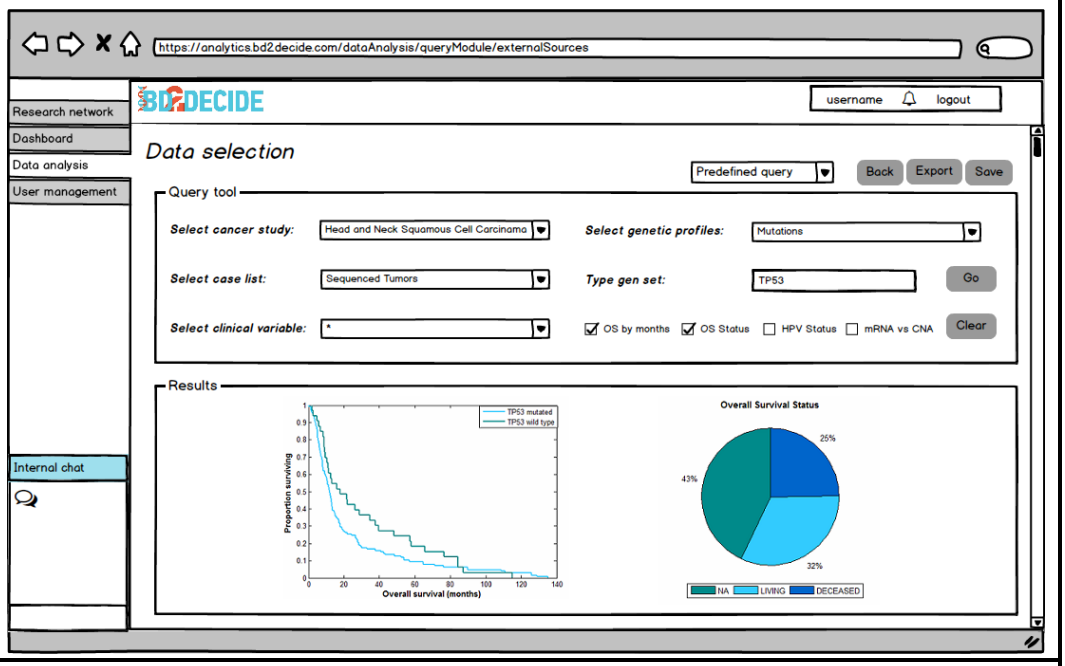
Alternative flow #1	Users who have no permissions for user management do not have the 'User management' tab on the left side of the tool

Flow ID	UC#10
Title	**Queries module. External and internal sources**
Actor	**All researchers and administrators**
Description	This section allows to combine BD2Decide data with external sources (IARC, OECD and Embase)
Steps	
1	By clicking icon below the external database button, a brief description of the dataset appears
2	By typing search conditions in the inputs, and then clicking Go, the results appears on the right side
3	By clicking Save, the query performed can be saved for later use. This query is also stored in the project section mentioned in UC#3
4	By clicking Back the user returns to 'Queries module' (UC#6) to change the analysis type
5	
Example	

Precondition	PR.0
Description	The user should have opened a project, select 'Query' module in UC#6 and 'Combined with external data sources' button in UC#7
Postcondition	PO.0
Description	The user is able to switch to other data analysis
Alternative flow #1	Users who have no permissions for user management do not have the 'User management' tab on the left side of the tool

Flow ID	**UC#11**
Title	**Queries module. External sources**
Actor	**All researchers and administrators**
Description	This section allows to explore external sources (TCIA, Maastro images, TCGA and CGHub)
Steps	
1	By selecting an external source, a brief description appears on the right side, and then clicking Go, the data selection options and result section displays in the tool
2	Clicking Back the user return to 'Queries module' (UC#6) to change the analysis type
3	In example 2: Clicking Save, the query performed can be save for later use. This query is also stored in the project section mentioned in UC#3 Clicking Export, export options appears like in UC#5
4	
Example	

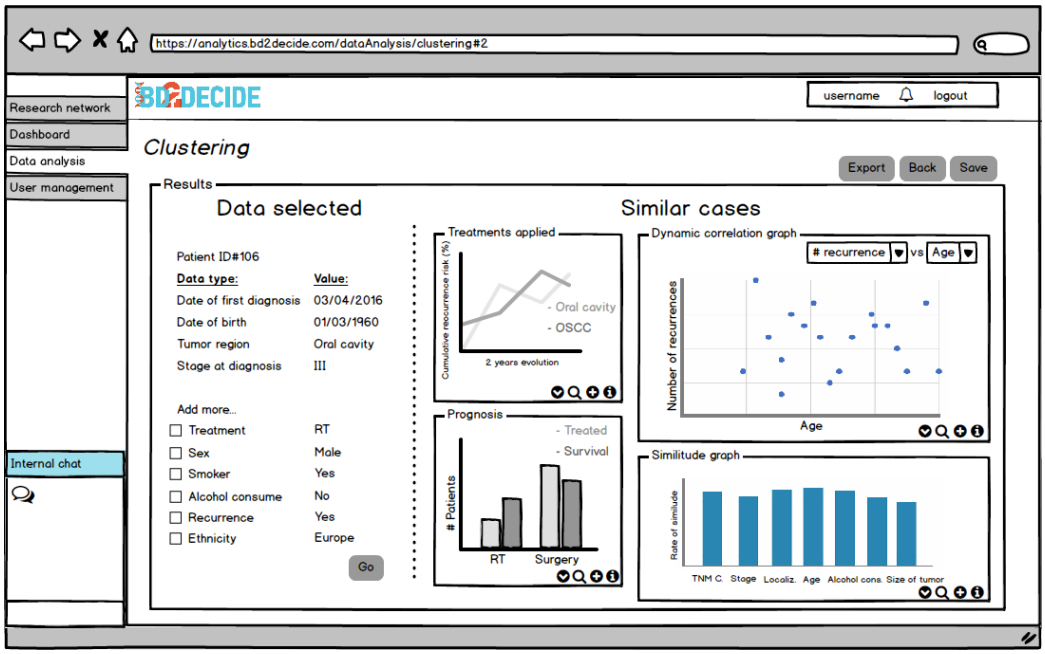




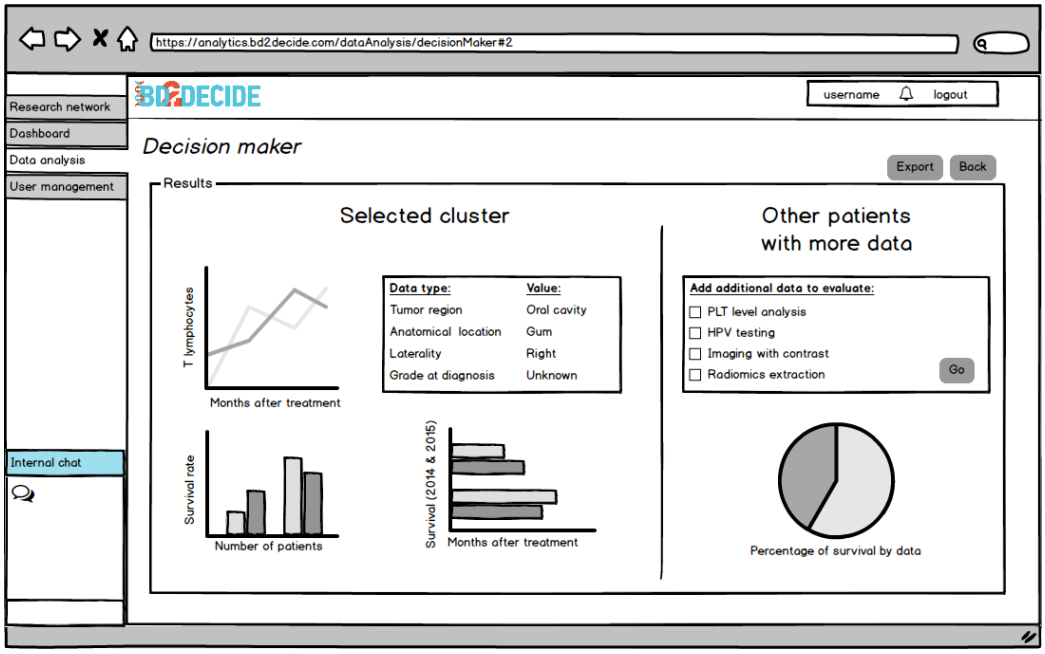
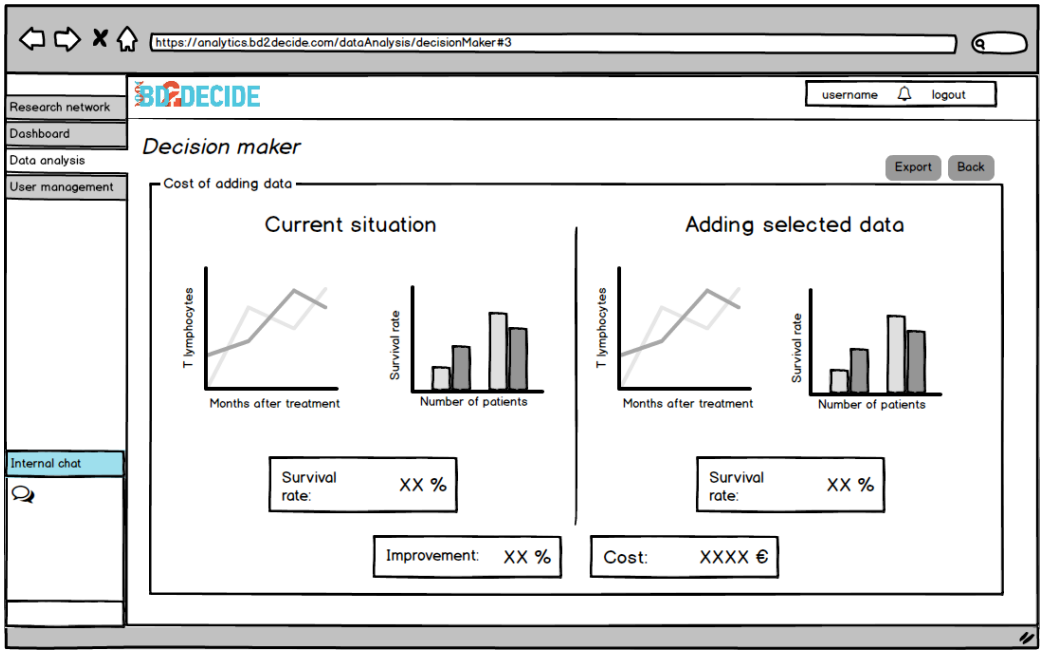
Precondition	PR.0
Description	The user should have opened a project, select ‘Query’ module in UC#6 and ‘Query external data sources’ button in UC#7
Postcondition	PO.0
Description	The user is able to switch to other data analysis
Alternative	Users who have no permissions for user management do not have the ‘User management’ tab

flow #1	on the left side of the tool

Flow ID	UC#12
Title	**Correlations & clustering module**
Actor	**All researchers and administrators**
Description	This section allows to compare a patient's data with other similar cases
Steps	
1	After selecting the data, including patient ID with an interface similar to UC#8, the results appear
2	Clicking Back the user returns to 'Clustering selection' (similar to UC#8) to change the data selected
3	Clicking Save, the query performed (the cluster created) could be saved for later use. This query is also stored in the project section mentioned in UC#3
4	By adding extra information of the patient (in the left side of the results section), and clicking Go, the similar case results are refreshed Clicking Export, export options appear like in UC#5
5	Click the icons in each graph to export, search for papers related to the data, review data that generates the graph or get information about the data
6	
7	Switching between the drop-down menus available in 'Dynamic correlation graph', different data is shown, with the aim of discovering new relationships
8	

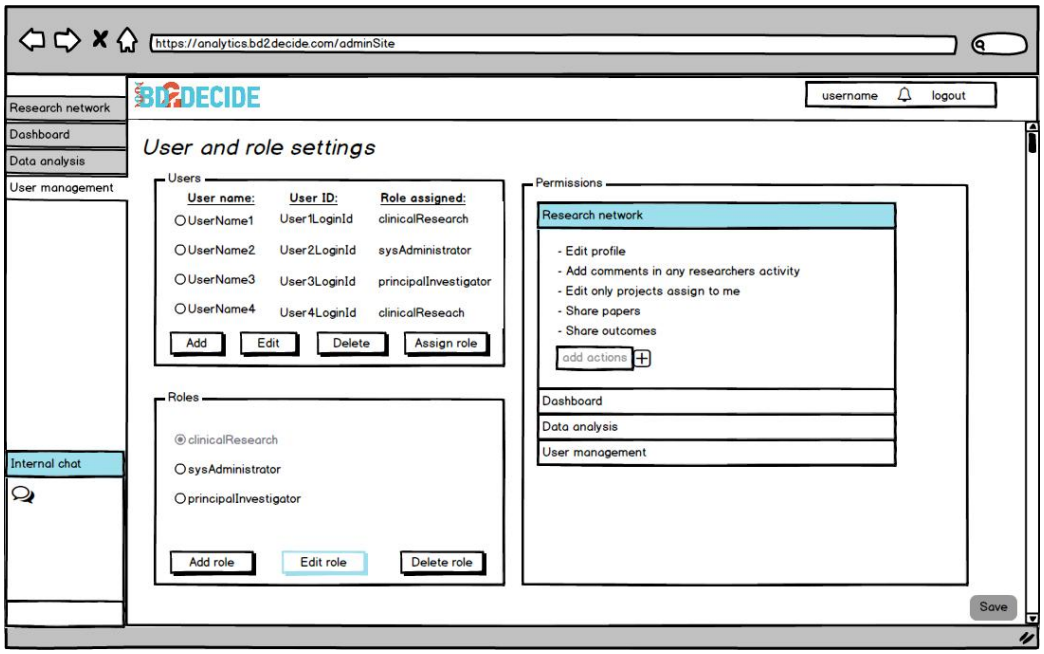
Example	
Precondition	PR.0
Description	The user should have opened a project and select ‘Correlations & clustering’ module in UC#6
Postcondition	PO.0
Description	The user is able to switch to other data analysis
Alternative flow	Users who have no permissions for user management do not have the ‘User management’ tab on the left side of the tool

Flow ID	**UC#13**
Title	**Decision maker module**
Actor	**Principal investigators and administrators**
Description	This section allows to evaluate the cost-utility ratio of adding an extra test comparing between similar cases and other clusters
Steps	
1	After selecting a target cluster, with an interface similar to UC#8, the results appear Clicking Back the user returns to ‘Decision maker selection’ (similar to UC#8) to change the data selected
2	Clicking Export, export options appear like in UC#5 By selecting additional test to evaluate the cost-utility and clicking Go, the second view

3	appears showing the survival rate estimated in both scenarios and the improvement and cost calculated adding the test selected to patients that correspond to the target cluster
4	
Example	 
Precondition	PR.0
Description	The user should have opened a project and select ‘Decision maker’ module in UC#6
Postcondition	PO.0

Description	The user is able to switch to other data analysis
Alternative flow	Users who have no permissions for user management do not have the 'User management' tab on the left side of the tool

Flow ID	**UC#14**
Title	**User management tab**
Actor	**Administrators**
Description	Administrator site allows the researcher to manage users and roles to adapt their permissions according to their needs.
Steps	
1	After accessing to 'User and role settings', the user is able to add new users clicking the 'Add' button and to edit existing users by selecting them and then clicking 'Edit' button. These options allow to fill the user name and the password
2	By selecting one or more users and clicking the 'Delete' button the users selected are erased from the application By clicking a specific user and 'Assign role', one of the roles created before could be assigned to the current user selected
3	To add, edit or delete roles, the procedure is similar. When 'Edit role' or 'Add role' is selected, the roles section becomes active giving the flexibility to add or delete the proper actions in each module to the role selected
4	

Example	
Precondition	PR.0
Description	The user should have administrator permissions