BD4QoL

Big Data Models and Intelligent tools for Quality of life monitoring and participatory empowerment of head and neck cancer survivors

D10.6 – Data Protection Impact Assessment (DPIA)

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0	03-Jun-2021	Carlo Resteghini (INT); Stefano Cavalieri (INT)	ToC
1	08-Jun-2021	Elena Martinelli (UMIL)	Revised the ToC
2	08-Jun-2021	Stefano Cavalieri (INT)	Updated the text based on the received comments
3	25-Jun-2021	Stefano Cavalieri (INT)	Updated the document after updating the privacy informative module and performing the DPIA with INT DPO
4	29-Jun-2021	Elena Martinelli (UMIL)	Revised the document
5	30-Jun-2021	Luis Ruiz-Ruiz (INETUM); Laura Lopez (UPM)	Peer review
6	01-Jul-2021	Stefano Cavalieri (INT); Elena Martinelli (UMIL)	Finalized the document
7	05-Jul-2021	Francesco Giuliani (CSS); Elena Martinelli (UMIL)	Added DPIA from CSS and finalized the deliverable

Addressees of this document

This document is addressed to the ***BD4QoL*** Consortium. It presents the Data Protection Impacts Assessment for the BD4QoL prospective randomized trial, defined by INT and CSS partners. The DPIA for UoB will be produced based on these documents and on the study protocol and will be made available to the coordinator and to the EU upon request.

This document will be delivered to the European Commission. This deliverable will be public.

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Abbreviations and definitions

CNIL	Commission Nationale de l'Informatique et des Libertés
CRF	Case Report Form
DPIA	Data Protection Impact Assessment
DPO	Data Protection Office
EC	Ethical Committee
eCRF	Electronic Case Report Form
EORTC	European Organisation for Research and Treatment of Cancer
GDPR	General Data Protection Regulation
INT	Istituto Nazionale dei Tumori of Milan, Italy
IRCCS	Istituto di Ricovero e Cura a Carattere Scientifico
PI	Principal Investigator
PoC	Point of Care
QoL	Quality of Life
WP	Work Package

1 ABOUT THIS DOCUMENT

As reported by the European Commission, in compliance with the GDPR, a data protection impact assessment (DPIA) is required whenever processing is likely to result in a high risk to the rights and freedoms of individuals. A DPIA is required at least in the following cases:

- a systematic and extensive evaluation of the personal aspects of an individual, including profiling;
- processing of sensitive data on a large scale;
- systematic monitoring of public areas on a large scale.

Further details are included in the guidelines on DPIA, which are publicly available online on the European Commission website (https://ec.europa.eu/newsroom/article29/items/611236).

This deliverable provides details about the DPIA performed in the context of the BD4QoL prospective clinical study.

2 STUDY SUMMARY AND LIST OF PARTICIPATING CENTERS

2.1 Study summary

2.1.1 Study objective and endpoints

As reported in the study protocol, the primary objective of the clinical study is to reduce the proportion of HNC subjects experiencing a clinically meaningful deterioration of QoL between at least 2 visits during post-treatment follow-up. Secondary endpoints are:

- To delay the time to the first clinically meaningful deterioration of QoL between at least 2 visits during post-treatment follow-up.
- To reduce the proportion of HNC subjects experiencing a clinically meaningful deterioration in pre-specified EORTC QLQ-C30 and QLQ-HN43 scales and in EQ-5D-5L domains between at least 2 visits during post-treatment follow-up.

To reach these endpoints, eligible patients will be randomized in a 2:1 fashion to receive the BD4QoL platform or not. All the randomized patients (intervention and control arms) will fill in the aforementioned QoL questionnaires.

2.1.2 Main technologies involved in the project

As reported in annex 7 of the prospective study protocol, the main technologies involved in the project will be:

- **The BD4QoL Data Hub** that acts as a master data repository for the project (details in WP3 deliverables, especially D3.6 and D3.7)
- **The mobile application** that collects data from the patient's smartphones and allows interaction with different metrics and results (details in WP3 deliverables, especially D3.5)
- **The Point of Care application**, a tool for health and social care professionals in the different Point of Care (PoC) engaged in patient's monitoring and follow-up (details in WP4 deliverables)
- **Questionnaires' data collection**, a web form for collecting QoL, PREM and PROM data from patients (details about which PROMs/PREMs will be collected are included in D2.4. Further details about the technical aspects are included in WP3 deliverables)

- **The Patient Empowerment Platform** enables patients to hold two-way conversation interactions with a chatbot service providing non-clinical advice, the ability to send personalised notifications and collecting affective trait data (details in WP5 deliverables, especially D5.1)
- **The Behaviour Recognition System** is a set of algorithms and processes that analyse the data available from the patient and infer the activities realised and their importance in assessing the quality of life (details in WP2 and WP5 deliverables)
- **The advanced QoL prediction application** generates predictive models that, by analysing the different information available from patients and retrospective studies, enable the forecast of what the QoL will be like in the future and, therefore, allow caretakers to adopt corrective measures that can help to improve it (details in WP6 and WP7 deliverables).

Details about data management infrastructure and data security are included in D3.6.

2.1.3 Ethical considerations and reasons for having a DPIA

As reported in the study protocol, the BD4QoL randomized controlled trial will be initiated only after all required legal documentation has been reviewed and approved by the responsible independent ethical committee (EC) of the center according to all applying national and international regulations. As a first step, the study sponsor (INT) will submit the study to its EC. After this approval, the remaining clinical partners of the Consortium joining the prospective study will submit the protocol and the INT EC approval to their ECs.

Details about the ethical requirements and framework of the project are reported in the two deliverables of WP1 and in D10.3.

Due to the sensitiveness of the data that will be collected, both health-related and smartphone-related, the BD4QoL consortium paid a special attention to the ethical and legal implications of data management. This refers especially to patients' safety, wellbeing and privacy and the idea of unobtrusive monitoring technologies. In addition to what is foreseen by the national and international laws, these are the essential reasons for providing a DPIA.

2.2 List of participating centers needing a DPIA during the project

The following consortium partners are expected to share sensitive data within the project, and will prepare a DPIA with their respective DPOs:

- Fondazione IRCCS Istituto Nazionale dei Tumori di Milano. Via Venezian 1, 20133 Milan. Italy
- Casa Sollievo della Sofferenza. Viale Cappuccini 1, 71013 San Giovanni Rotondo (FG). Italy
- University Hospitals Bristol NHS Foundation Trust. Bristol Dental Hospital. Bristol BS1 2LY. United Kingdom
- Regione Lombardia. Piazza Città di Lombardia 1, 20124 Milano. Italy (limited to the task T7.5, in the frame of the relevant deliverables)
- Any further subcontractor that will enroll participants in the randomized trial.

3 DATA PROTECTION IMPACT ASSESSMENT (DPIA)

INT is the sponsor of the prospective clinical study. In this research project, the first DPIA of the randomized trial was made at this clinical institution using an internal web-based application (http://dpm.istitutotumori.mi.it/login) that was accessible using institutional credentials.

The final report of the DPIA performed at INT is available (in Italian) in annex 4.5 of this deliverable.

4 ANNEXES

4.1 Informed consent form

Clinical study ID number at Fondaz. IRCCS Istituto Nazionale dei Tumori di Milano: to be assigned by the INT Ethical Committee

Study name:

A multicentre randomised trial for quality of life evaluation by non-invasive intelligent tools during post-curative treatment follow-up for head and neck cancer

Principal investigator: Prof. Lisa Licitra

Form n. 2

INFORMED CONSENT FOR STUDY ENROLMENT

This form must be signed by you only if you decide to participate to the study.
It is important that you have thoroughly discussed with your doctor before signing this consent, also on the basis of the study information sheet (Form 1).
Only patients accepting this study will participate.
The patient may withdraw his consent at any time.

In full possession of my mental faculties,

1) **I declare that I have been fully informed about the aforementioned clinical trial, that I have read the Study information for the Patient form,**

on…../…../…….

I got a copy for my records, and I have discussed adequately with my Doctors involved in this study,

on …../…../…….

at
……..
;

2) I declare to be aware of the advantages and potential disadvantages linked to the object of the study

3) I give my free and informed consent to take part in the aforementioned clinical trial;

3) ☐ **<u>I authorize</u>**

☐ **<u>I do not authorize</u>**

<u>to provide to my general practitioner,</u>

dr. ……...……

<u>news about my participation in this clinical study.</u>

Signature of Patient

…….……

Name of the Patient

…….……

Date: …../…../…….

Signature of the Legal Representative or Guardian *(if appropriate)*

……..……

Name

……..……

Date: …../…../…….

Signature of Witness *(if appropriate)*

……..……

Name

……..……

Date: …../…../…….

Signature of Witness *(if appropriate)*

……..……

Name

……..……

Date: …../…../…….

Researcher Signature

……..……

Name

……..……

Date: …../…../…….

Activities recognized by the BD4QoL platform

This table summarizes all the possible activities to be analyzed in BD4QoL to identify individual behavior. Activities and domains needed for the development of alerts and interventions have been highlighted in color (these data will be constantly collected if you accept to join this trial after signing the informed consent form). You can withdraw your consent to the use of not-highlighted fields whenever you want directly through the App. In case you withdraw from the entire study, none of the following variables will be collected.

Domain	Activity	Detected through	Reliability
Mobility	**Active**	Smartphone step counter	High
	Inactive	Google Activity Recognition for Android phones and iOS	Medium
Physical activity	**Walking**	Smartphone step counter	Medium
	Running	Google Activity Recognition for Android phones and iOS	Medium
	Cycling	Google Activity Recognition for Android phones and iOS	Medium
	Sports	Entering/exiting sports related locations for Android / 15mins intervals with iOS	Medium
	Sleeping	App + accelerometer/light sensor[2]	Low
Activities of Daily Living	**Eating/drinking**	Entering/exiting restaurants/bars, food shops, …	Medium
	Nutrition	Textual exchanges with WP5 chatbot app	Low/Medium
	Staying at home	GPS or Google Activity Recognition for Android phones / 15mins intervals with iOS	Medium
Instrumental Activities of Daily Living	**Shopping**	Entering/exiting various shops for Android / 15mins intervals with iOS	Medium
	Manage medications	Entering/exiting pharmacies for Android / 15mins intervals with iOS	Medium
	Using telephone	Incoming / outgoing / missed calls and incoming / outgoing messages for Android / unavailable with iOS	High
	Travelling	Google Activity Recognition for participant inside a car, or train, or bus (android and IOS)	High
	Managing finances	Entering/exiting banks, ATMs, … for Android / 15mins intervals with iOS	Medium
Socialization	**Visiting social places**	Entering/exiting social restaurants, clubs, … for Android / 15mins intervals with iOS	Medium
	Using telephone	Incoming / outgoing / missed calls and incoming / outgoing messages unavailable with iOS	High

Domain	Activity	Detected through	Reliability
	Using social networks	Smartphone app usage logs unavailable with iOS	Medium
Cognitive function	**Visiting cultural places**	Entering/exiting cinemas, museums, …for Android / 15mins intervals with iOS	Medium
	Self-care	Entering/exiting spa, gyms, hairdresser, …for Android / 15mins intervals with iOS	Medium
	Spirituality	Entering/exiting church, synagogue, mosque, …for Android / 15mins intervals with iOS	Medium
	Education	Entering/exiting school, university, …for Android / 15mins intervals with iOS	Medium
Affections	**Sentiment**	Textual exchanges with WP5 chatbot app	Medium
	Depression	Textual exchanges with WP5 chatbot app	Medium
Health related	**Visit heath related places**	Entering/exiting GP practice, hospital, … for Android / 15mins intervals with iOS	Medium

4.2 Patient information sheet

A multicentre randomised trial for quality of life evaluation by non-invasive intelligent tools during post-curative treatment follow-up for head and neck cancer (The BD4QoL Study)

PARTICIPANT INFORMATION LEAFLET

Invitation to take part in a research study

- We'd like to invite you to take part in our research study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it involves.
- Please take time to read the following information carefully. Please feel free to talk to others about the study if you wish.
- You are free to decide whether or not to take part in this study. Whether or not you choose to take part will not affect the care that you receive.
- Please ask us if there is anything that is unclear or if you have any questions.

The first part of this Participant Information Leaflet gives an overview of the purpose of the study and what will happen to you if you take part.

The second part gives more detailed information about the study and the study app.

PART ONE:

What is the BD4 QoL study and why is it being done?

This study is looking to find out whether a smartphone-based electronic tool (an App) is able to reduce or to predict a reduction in the quality of life of people treated for head and neck cancer. The study will also find out if the app can provide support to address quality of life issues.

People treated for head and neck cancer often have a reduction in their quality of life; this can be due to the side effects of treatment with problems such as dry mouth, hearing loss, etc. At the moment we do not have a way to predict who will suffer from the side effects of treatment. The only way to find out if someone has poor long-term quality of life is to administer repeated questionnaires at follow-up clinics. Smartphones can collect a lot of data that could detect quality of life deterioration by looking at changes in daily life activities. They can record when people are less active (for example reduced step count) or when people have less social activity (for example fewer phone calls, messages, less time on social media). An automated 'chatbot' could help people by enabling them to ask health related questions.

If the study is successful it could mean that people with head and neck cancer would receive immediate support and advice on how to manage problems occurring after treatment through an app on their phone. It is hoped that this would reduce the impact on their quality of life. The head and neck cancer team would have more precise and continuous monitoring of their patients' health and quality of life.

Why am I eligible to join the study?

We are inviting people aged 18 years or over who have received treatment for head and neck cancer, and are now clear of the cancer, to take part in the study.

To take part you will need to have a smartphone with the following characteristics:

- for Android: operating system APK 21 Android version 5 or later
- all mobile phones need to have minimum of 2 GB RAM and minimum of 512 MB free storage and sufficient mobile data connectivity

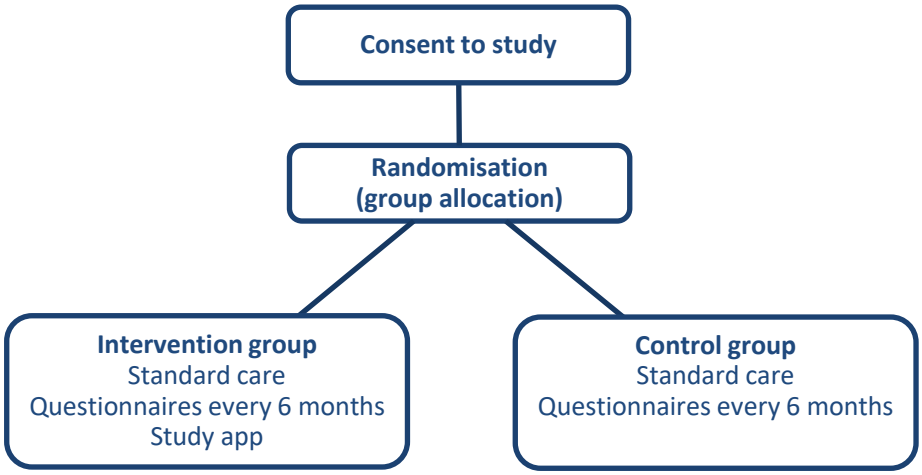
What will happen if I take part?

This study does not involve taking any medication and joining the study will not alter the standard care that you receive.

Study participants will be allocated to one of two groups: the intervention group and the control group. All study participants, regardless of which group they are in, will receive standard follow-up care and will be asked to complete a set of questionnaires every six months for two years. Questionnaires will be completed at randomisation, and at 6, 12, 18 and 24 months after randomisation.

The intervention group will also have the study app installed on their personal smartphone.

The allocation to the two groups is done at random by a computer so you are unable to choose which group you join.



People in the intervention group who have the app installed on their mobile phone will be asked to keep the app activated for the duration of the study. The app will collect data on physical activity (e.g. step count), non-sleep rate (time awake during night) and socialization (e.g. number of phone calls, number of messages made/received). Participants may ask questions electronically through an automated interactive messaging app that will provide advice on how to manage any quality of life problems. Should the app find issues such as reduced physical activity or sleep problems it will offer suggestions to improve health.

The study questionnaires will be given out at your follow up clinic appointments with the head and neck team. The questionnaires need to be completed at the clinic visit but they should not take longer than 20 minutes to do.

How are the study groups decided?

People taking part in the study will be put in to one of the two study groups at random (a bit like tossing a coin). A computer program will allocate people either to the group receiving standard care plus questionnaires (the control arm), or to the group that will receive standard care plus questionnaires and also receive the App (the intervention arm). The allocation to each group cannot be altered by the study team.

How many people will take part in the study?

A total of 195 people will take part in the BD4QoL study. Two thirds of the people taking part (130 people) will have the study app installed on their own mobile phone and will complete

questionnaires every six months. One third of the study participants (65 people) will only complete the questionnaires.

How long does the study last?

Recruitment will start in January 2022 and end in December 2023. Each person will be asked to take part in the study for two years so follow-up of the last participants will be in December 2025.

What happens after the study ends?

All participants will continue as planned with follow-up by the head and neck team. They will no longer need to fill in study questionnaires. Participants included in the intervention arm will have the study app uninstalled from their mobile phone.

Part Two:

The Study App

People randomised to the intervention arm will have the study App installed on their mobile phone and will receive personalized support and recommendations through the App. The recommendations have been written by head and neck doctors and follow head and neck cancer guidelines.

The study app will:

- have a chatbot (a 'chatbot' is software that can have a text conversation with the person using the phone) that can be activated on demand, whenever the participant wishes
- collect data from the participant's mobile phone (see below and annex 4.2 for details on which data will be collected)
- detect major alterations in the participants' usual behaviour (e.g., a reduction in physical activity or in sleeping) and will alert participants about this
- where there has been a significant alteration in usual behaviour the chatbot can provide recommendations (e.g. how to improve physical activity)
- the chatbot can send participants positive messages if it records substantial improvement in behaviour after a period of deterioration
- not disturb the participant if no major variations in usual behaviour are recorded
- provide the head and neck team at your hospital with automated alerts when major behaviour alterations are suspected to be relevant to health-related issues.

Participants may choose to stop the use of the App at any time.

How will the study app be installed on my phone?

If you are randomised to the intervention arm of the study you will be sent a link to download the study app. You do not have to pay to download the app.

What data does the study app collect?

The app will be installed on your personal mobile phone. Participants must keep the App and their mobile phone activated so that the app can record data.

The following information will be collected:

- Behavioural mobile phone-based data that will be monitored to detect any health and quality of life issues:
  - Mobility/physical activity: smartphone step count, mobility from google activity recognition
  - Social contact: The number of phone calls and text messages made and received will be collected. Your phone calls will not be listened to or recorded and your text messages will not be read.
  - Non-sleep rate: time awake during nights based on use / activation of mobile phone
- Optional information (this will only be collected if you consent to this):
  - Sport: Entering and exiting sport related locations (via GPS-Google)
  - Daily life-social activities (via GPS-Google): going to restaurants, theatres, cinema, church etc., shopping, travelling in car, train, bus etc.
  - Further social contact (via mobile phone): the app will record how long you spend on social networks such as Facebook and Instagram. Your interactions on social media, for example your posts and likes, dislikes etc, will not be recorded.
  - Health-related activities (via GPS-Google): going to a location that the phone recognises as a pharmacy, doctor, hospital.

The following information will <u>not</u> be looked at or collected:

- The app will never record or access recordings of your conversations or messages. The app will not have access to the microphone on your phone.
- The app will never use video or have access to the camera on your phone.
- The app will never look at your messages
- The app will never look at your social media content

What happens to the data collected by the app?

The data collected will be sent by the app to the BD4QoL data hub for storage and subsequent analysis.

The app will transfer data to the BD4QoL Cloud in Spain using your home Wi-Fi or mobile data plan. If the Wi-Fi connection is unstable at your home, the research team may be able to lend you a Wi-Fi router for the duration of the study. You will need to return the mobile router after study ends. However please note that you may need to check with your internet provider as they may not agree to the use of a router that has not been provided by them.

How will my data be kept confidential?

For this research project we will use information collected from you, from your medical records, and for those in the intervention arm we will also use information collected from your mobile phone.

The hospital where you join the study will keep a record of your name, your hospital number and your contact details. This information will be kept in order to do the research and to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name, hospital number or your contact details. All of your data will be stored under a code number called your 'study number'.

We will keep all information about you safe and secure. All data collected from the app will be encrypted and will be stored in a secure cloud for the duration of the project.

Some of your information will be sent to members of the BD4QoL study research team in Italy, Spain and Norway. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so that we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Will what I write in the chatbot remain confidential?

Messages written in the chatbot will be analysed by a computer program. The content of the messages in the chatbot will not be shared with the research team or with your clinical team.

Your head and neck clinical team at the hospital will be notified if the app finds a reduction in quality of life but your messages to the app will not be sent to the hospital team.

What do I do if I the app stops working?

In the event of any technical issues, you can find initial support through the Participant Portal where you will find user manuals for the app, frequently asked questions, and common technical issues and their solutions. The contact details to receive support from a technician can be also found in the Participant Portal.

An application tutorial and manual will be available through the App in your mobile phone. If the app is not working please contact the technical team through the Participant Portal.

What data will be collected for the study by the hospital team?

The nurses and doctors working on the study at your local hospital will collect the following information about you from your medical notes:

- age, gender, marital status, education, smoking status and habits, alcohol consumption, a brief medical history, weight, height, details about your head and neck cancer, blood test results that are relevant to head and neck cancer, details of head and neck cancer treatments, any significant medical events that take place during the study. Information on any cancer recurrence.
- The quality of life questionnaires (the study staff will tell you how and when you will be asked to fill in the questionnaires)

The information collected from your medical notes and from your completed questionnaires will be entered in to the study database so that the study researchers can analyse the data. The study researchers who will be analysing the data are based in Italy, Spain and Norway. The information in the database will contain your study number, your initials and date of birth but will not contain any other identifiers.

The study team will not ask other organisations for data that they hold.

What are the potential benefits of taking part in the study?

Participants allocated to the intervention arm may benefit from having the mobile app but we cannot guarantee that this will be the case. For participants included in the intervention arm (2/3 of subjects) the expected benefits are the potential avoidance of the reduction in terms of quality of life during post-treatment follow-up. For people included in the control arm (1/3 of subjects): neither specific benefits nor potential risks, inconveniences or restrictions are expected.

What are the potential risks / inconveniences of taking part in the study?

Some people may find answering the study questionnaires to be inconvenient.

You may find that the app takes up storage space on your mobile phone or that your data limits may be exceeded. Please check your phone contract before joining the study.

Throughout the study, you will be asked to provide information regarding your health status, quality of life, symptoms, and lifestyles, in terms of physical activity, sleeping, and social activity. If you are uncomfortable using the app and responding to its questions, you may discontinue its use and/or withdraw from the study anytime without any consequences.

Your name, hospital number and contact details will not be sent to the study sponsor or to the study collaborators. Instead, to reduce the risk of you being identified, we will use a code number known as your 'study number'.

Will my data be shared with other researchers?

Data from your questionnaires, medical notes and from the app will be shared with the study collaborators who work on the BD4QoL Study. The BD4QoL study is an international collaboration so data could be shared with study collaborators both within and outside of the EU. We will only use your study number as the identifier on your data in order to protect confidentiality. The link between the study number and your identity will only be available to the study team at the hospital where you signed your consent form. The link file will be kept securely in either a locked cabinet in a restricted access room or on a password protected file in a restricted access drive on the hospital system.

All research in the NHS is subject to inspection by the ethics committee and / or by the study sponsor in order to make sure that the research is being performed properly.

Will data from this study be used for other research?

- Data sharing with other researchers is important in clinical research to make the most use of good quality research data and to support policy and other decision-making.
- Researchers working on this study may use anonymised data collected during this study for other research studies.
- Even in future studies your privacy will be always protected according to national and international laws about data protection.

Can I access my data?

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Will I receive any money or compensation for taking part in this study?

No financial compensation will be given to study participants, and the study will not provide expenses (e.g. travel costs, meals, child-care, etc) to participants and / or others who might accompany them.

Please note that the study does not pay towards the cost of your mobile phone or your data or call usage.

Will the participation in this study have an impact on any insurance cover that I may have?

Participation in this study should not affect any insurance cover that you have, e.g. travel insurance, life insurance or private medical insurance. However, please check with your insurance company to make sure.

Which hospitals are taking part in the study?

The study is taking place at: University Hospitals Bristol and Weston (UK), Casa Sollievo della Sofferenza (S. Giovanni Rotondo, Italy), Istituto Nazionale dei Tumori di Milano (Italy). Other centres may be added to this study.

When and how will participants find out the results of the study?

We will write to everyone who takes part in the study to let them know the study outcome. Please note that this is likely to be around 2026 / 2027 as we will need to wait until all participants have completed study follow up and all of the study data has been analysed. Please let us know if you would prefer us not to contact you with the study results.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the study team who will do their best to answer your questions; their contact number can be found at the end of this leaflet. If you remain unhappy and wish to complain formally, you can do this by contacting the study staff.

What will happen if I don't want to carry on with the study?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected. If you decide to withdraw from the study this will not affect the care that you receive. To withdraw from the study please contact the research team on the email address or the telephone number given at the end of this leaflet. To ensure the right treatment of your data the research team will ask you whether you wish to withdraw from all of the study or just from a part of it.

There are several options for withdrawing from the study:

- You may choose to withdraw from using the app but remain in the study and carry on completing the questionnaires

- You may choose to withdraw from questionnaires and / or the app but allow the researchers to use the data already collected for future analysis.

- You may choose to withdraw from the whole study. In this case the study researchers will not be allowed to use your data for future analysis but they will keep the data that has already been collected.

If the head and neck cancer comes back, or if a new cancer is diagnosed during the study, participants will be asked to stop taking part. You will no longer need to fill in study questionnaires and the app will be uninstalled from your mobile phone.

Who is organising and funding this study?

- The study is sponsored by Fondazione IRCCS Istituto Nazionale dei Tumori (Milan, Italy)
- Funding is provided by the European Commission within the call H2020-SC1-DTH-2018-2020 (Digital transformation in Health and Care), topic SC1-DTH-01-2019 (Proposal number 875192)
- No pharmaceutical company is involved in the conduct of this study.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Research Ethics Committee of this Institution.

For more information

You can find more information on the BD4QoL study here:

- https://www.bd4qol.eu/wps/portal/site/big-data-for-quality-of-life/for-patients
- https://www.bd4qol.eu/wps/wcm/connect/9bc518ed-9dae-47a1-8e0a-1dbf8cb279ff/BD4QoL_Leaflet_v13.pdf?MOD=AJPERES
- The Participant Portal contains a tutorial on the app, frequently asked questions, common technical issues, and contact details.
- A demonstration video of the mobile app is available at the link reported above
- You can find general information on taking part in research at:
- www.hra.nhs.uk/information-about-patients/
- www.hra.nhs.uk/patientdataandresearch

What happens next?

If, after having read and understood this information sheet and having received answers to any questions that you have, you agree to take part in this study, we will ask you to sign a consent form. You will be given a copy of the consent and participant information materials to take home with you.

4.3 Privacy module (original version in Italian)

Informativa sul trattamento dei dati personali

ex Regolamento EU 2016/679 redatta il 24/06/2021

Il presente documento ha lo scopo di informare l'interessato su come vengono utilizzati i dati che lo riguardano nell'ambito dell'attività di trattamento

BD4QoL studio prospettico	Studio multicentrico, internazionale, a due bracci, randomizzato (2:1), in aperto, per ridurre il deterioramento della qualità della vita di pazienti in follow-up dopo il trattamento per un tumore del distretto testa-collo. Lo studio utilizza un ecosistema di applicativi tecnologici integrati (in CLOUD, con server localizzati in Spagna): - APP per paziente: che raccoglie dati relativi allo stile di vita / comportamentale - Data Hub: unico repository per i dati raccolti - Point of Care: sistema di supporto decisionale e di gestione del flusso di lavoro per i professionisti dedicati al follow-up, che raccoglie i dati tramite l'APP e dai questionari compilati dai pazienti. Inoltre una delle funzionalità dello strumento PoC è la raccolta di dati clinici dai pazienti. Questa funzionalità viene implementata attraverso una serie di interfacce collegate a REDCap (strumento per implementare le eCRF) - Piattaforma di empowerment del paziente: applicazione per la gestione dei sintomi e suggerimenti per l'autogestione comportamentale. Attraverso il chatbot stabilisce un'interfaccia di comunicazione diretta con il paziente al fine di conoscere in prima persona il suo stato, rilevando cambiamenti comportamentali rilevanti che potrebbero essere indicativi . Questo strumento consente di responsabilizzare e supportare il paziente nella gestione dei sintomi verso il miglioramento della qualità della vita. - Il Behavior Recognition System: insieme di algoritmi e processi che analizzano i dati disponibili dal paziente e ne deducono le attività realizzate e la sua importanza nella valutazione della qualità della vita. Le attività quotidiane sono un modo comune per conoscere la qualità della vita di un paziente. Un cambiamento nella routine può significare qualche variazione nella qualità della vita che deve essere monitorata. - Applicazione di previsione avanzata della qualità di vita: calcola la qualità della vita di un paziente dai diversi dati raccolti. Tale valore viene confrontato con i valori ottenuti in precedenza e, al verificarsi di una qualsiasi delle condizioni definite, segnala l'allerta per rischio di calo della qualità della vita. Dunque genera modelli predittivi che consentono di prevedere come sarà la qualità di vita e consentire ai caregiver di adottare misure correttive che possono aiutare a migliorarla - portale della documentazione: spazio comune di collaborazione e documentazione ad uso dei partner coinvolti nell'iniziativa

Ai sensi degli articoli 13 e 14 del regolamento EU 2016/679 si informa l'interessato che i suoi dati saranno trattati dal Titolare del trattamento definito nella sezione **Soggetti** il quale tratta i dati per le finalità menzionate nella sezione **Finalità**, per un determinato periodo di tempo definito nella sezione **Periodo di conservazione** e potrebbero essere comunicati a soggetti definiti nella sezione **Comunicazione**.

Si informa altresì l'interessato che può esercitare numerosi diritti con riguardo ai suoi dati personali, un'elencazione dei diritti è fornita in calce alla presente informativa nella sezione **Diritti dell'interessato.** I diritti dell'interessato possono essere esercitati in qualsiasi momento contattando il Responsabile della protezione dei dati (RPD) o in sua assenza il Titolare.

Soggetti – Chi tratta i miei dati e a chi mi posso rivolgere per avere informazioni ed esercitare i miei diritti?

Qualifica	Denominazione	Dati di contatto
Titolare	Fondazione IRCCS Istituto Nazionale dei Tumori	Tel: 0223901
		E-Mail: direzione.generale@pec.istitutotumori.mi.it
		Indirizzo: via Giacomo Venezian, 1
Responsabile della protezione dei dati (RPD)	Anna Roli	Tel: 0223903098
		E-Mail: dpo@istitutotumori.mi.it
		Indirizzo: Via Giacomo Venezian, 1 20133 Milano

Finalità – Perché vengono trattati i dati?

Finalità del trattamento	Base giuridica del trattamento
Finalità di ricerca per ridurre il deterioramento della qualità di vita nei sopravviventi a tumori testa-collo in corso di follow-up.	Consenso libero e informato art. 9, comma 2, lettera a); art. 6, comma 1, lettera a);

Trasferimenti – A chi vengono comunicati i miei dati?

Destinatari	Posizione geografica	Legittimazione in caso di trasferimento extra UE
Partner clinici del progetto BD4qOL prospettico - Partner tecnici del consorzio BD4QoL	Intra UE	

Diffusione

Il trattamento comporta la diffusione dei dati
No

Periodo di conservazione

Periodo di conservazione dei dati o criterio per determinarlo
10 anni Descrizione: 10 anni a partire dal termine dello studio clinico (last-patient out)

Origine dei dati

I dati vengono raccolti presso:
Raccolta presso l'interessato, Comunicati da terzi Partner clinici del progetto BD4qOL prospettico

Categorie di dati trattati

Categorie di dati	
Personali	Dati personali di identificazione
	Dati di contatto
	Dati comportamentali - Ad esempio: posizione; abitudini di acquisto
Categorie particolari di dati personali	Dati relativi alla salute

Processo decisionale automatizzato e profilazione – I dati che mi riguardano vengono utilizzati per profilarmi e vengono prese decisioni in maniera automatica sulla base della profilazione?

Profilazione	Processo decisionale automatizzato
Si	Si
Descrizione del processo decisionale	
Attività dei pazienti monitorata tramite app: se riduzione, paziente riceve consigli tramite chatbot; se riduzione grave, medici sono contattati tramite dashboard. Il paziente può attivare autonomamente H24 7/7 la chatbot per riferire eventuali sintomi	

Diritti dell'interessato

L'interessato ha diritto a chiedere al Responsabile della protezione dei dati o al Titolare:

(Accesso)

l'accesso ai dati personali che lo riguardano

(Portabilità)

ricevere in un formato strutturato, di uso comune e leggibile da dispositivo automatico

i dati personali che lo riguardano.

(Rettifica)

la rettifica dei dati personali che lo riguardano

(*Oblio*)

la cancellazione dei dati personali che lo riguardano

(Limitazione)

la limitazione del trattamento dati personali che lo riguardano

(Opposizione)

opposizione al trattamento per determinate finalità

L'interessato può altresì ritirare il consenso espresso in qualsiasi momento senza pregiudicare la liceità del trattamento basata sul consenso prestato prima della revoca.

Per esercitare i sopracitati diritti l'interessato può rivolgersi al Responsabile della protezione dei dati o al Titolare. L'interessato ha il diritto di proporre reclamo a un'autorità di controllo, scrivendo a garante@gpdp.it, oppure protocollo@pec.gpdp.it.

4.4 Privacy module (English translation)

Information sheet on data processing

From EU law 2016/679. Version 24/06/2021

This document is aimed at informing the study participant about how his data will be processed within the context of the research project.

BD4QoL prospective study	Multicenter, international, two-arm, randomized (2: 1), open label study aimed at reducing the treatment of patients' quality of life during follow-up after curative treatment for head and neck cancer. The study uses an ecosystem of integrated technological applications (in CLOUD, with servers located in Spain): - APP for patient: which collects lifestyle / behavioral data - Data Hub: single repository for the collected data - Point of Care: decision support and workflow management system for professionals dedicated to follow-up, which collects data through the APP and from questionnaires filled out by patients. Also a feature of the PoC tool is the collection of clinical data from patients. This functionality is implemented through a series of interfaces connected to REDCap (tool for implementing the eCRF) - Patient empowerment platform: application for symptom management and applied for behavioral self-management. The chatbot will be the direct communication interface with the patient in order to know his state, noting relevant behavioral changes that could be indicative of health-related quality of life deterioration. This tool allows the empowerment and the support of the patient in managing symptoms towards improving the quality of life. - The Behavior Recognition System: set of algorithms and processes that analyze the data available from the patient and deduce the activities carried out and its importance in assessing the quality of life. Daily activities are a common way to learn about a patient's quality of life. A change in routine may mean some change being in the quality of life that needs to be monitored. - Advanced quality of life prediction application: calculate a patient's quality of life from the various data collected. This value is compared with the values obtained previously and, upon the occurrence of any of the defined conditionns, it signals the alert for the risk of a decline in quality of life. Therefore, generate predictive models that allow you to predict what the quality of life will be and allow caregivers to obtain corrective measures - documentation portal of the: joint collaboration and documentation for the use of the partners involved in the initiative

Pursuant to articles 13 and 14 of EU regulation 2016/679 we inform the study participant that his/her data will be processed by the Data Controller defined in the **Subjects** section who processes the data for the purposes mentioned in the **Purpose** section, for a specific period of time defined in the **Retention** period section and could be communicated to subjects defined in the **Communication** section.

The study participant is also informed that he can exercise numerous rights with regard to his personal data, a list of rights is provided at the bottom of this information in the **Rights of the study participant**. The rights of the interested party can be exercised at any time by contacting the Data Protection Officer (DPO) or, in his absence, the Data Controller.

Subjects – Who will process my data and to whom may I ask for information and to exert my rights?

Position	Name	Contacts
Controller	Fondazione IRCCS Istituto Nazionale dei Tumori	Tel: 0223901
		E-Mail: direzione.generale@pec.istitutotumori.mi.it
		Address: via Giacomo Venezian, 1
Data protection responsible (DPR)	Anna Roli	Tel: 0223903098
		E-Mail: dpo@istitutotumori.mi.it
		Address: Via Giacomo Venezian, 1 20133 Milano

Purpose – Why are you processing my data?

Purpose for data processing	Juridical basis for data processing
Research purpose to reduce the quality of life deterioration in head and neck cancer survivors during follow-up.	Informed consent art. 9, comma 2, letter a); art. 6, comma 1, letter a);

Data transfer – To whom my data are transferred?

Data receiver	Geographical position	Reason for transfering data outside the EU
Clinical partners of the BD4QoL prospective study Technical partners of the BD4QoL consortium	Within EU	

Dissemination

Data processing implies data dissemination
No

Retention

How long data will be stored
10 years Description: 10 years from the conclusion of the clinical prospective study (last-patient out)

Data origin

Where data will be collected
At study participant level, Communicated by third parties, Clinical partner of the BD4QoL prospective study

Types of data

Data categories	
Personal	Personal identification data
	Contact data
	Behavioral data – e.g., GPS position
Particular categories of personal data	Health-related data

Automated decision process and profiling – Will my data be used for profiling? Will decisions be made automatically on the basis of profiling?

Pofiling	Automated decision process
Yes	Yes
Description of the automated process	
Study participant activity will be monitored through the app: in case of deterioration of daily activities, the participant will receive tips and recommendations throught the chatbot; in case of severe deterioration, the clinical researchers are contacted through the PoC dashboard. The study participant can activate the chatbot whenever desired (H24 7/7) to report symptoms.	

Rights of the study participant

The study participant has the right to ask the Responsible of data protection or the Data controller:

(Access)

the access to personal data that refer to him/her

(Portability)

receive personal data that refer to him/her in a structured format, of common use and easily readable from an automated tool

(Change)

the correction of personal data that refer to him/her

(*Cancellation*)

the deletion of personal data that refer to him/her

(Limitation)

the limitation of the processing of personal data that refer to him/her

(Opposition)

the op position to the processing of personal data that refer to him/her with a specific purpose.

The study participant may also withdraw the consent expressed at any time without prejudice to the lawfulness of the processing based on the consent given before the revocation.

To exercise the aforementioned rights, the study participant can contact the Data Protection Officer or the Data Controller. The interested party has the right to lodge a complaint with a supervisory authority, by writing to garante@gpdp.it, or protocol@pec.gpdp.it.

4.5 INT DPIA

Attached file made of 43 pages (in Italian language)

4.6 CSS DPIA

Attached file made of 13 pages (in English language)

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI
VIA GIACOMO VENEZIAN, 1
MILANO

C.F.- P.IVA 80018230153

T. 0223901
F.
W. WWW.ISTITUTOTUMORI.MI.IT
DIREZIONE.GENERALE@PEC.ISTITUTOTUMORI.MI.IT

Valutazione d'impatto sulla protezione dei dati

Valutazione d'impatto BD4QoL studio prospettico

25/06/2021

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI
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1 Introduzione

Il presente documento "Valutazione d'impatto BD4QoL studio prospettico" ha lo scopo di valutare l'impatto sulla protezione dei dati dell'attività di trattamento "BD4QoL studio prospettico", l'impatto è valutato con particolare attenzione ai diritti e alle libertà degli interessati ed ha come obiettivo DPIA per deliverable D10.6.

2 Informazioni essenziali:

Data creazione analisi: 24/06/2021
Data generazione documento: 25/06/2021
Status: in corso
Titolare: Fondazione IRCCS Istituto Nazionale dei Tumori
DPO: Anna Roli
Reporter: CARLO RESTEGHINI

3 Pre-assessment

A seguito di una prima analisi, basata sui dodici criteri individuati nell'allegato 1 al provvedimento n. 467 dell'11 ottobre 2018, "Elenco delle tipologie di trattamenti, soggetti al meccanismo di coerenza, da sottoporre a valutazione d'impatto" risulta che il nel trattamento preso in esame sono presenti i seguenti criteri:

- **Trattamenti valutativi o di scoring**
  Trattamenti valutativi o di scoring su larga scala, nonché trattamenti che comportano la profilazione degli interessati nonché lo svolgimento di attività predittive effettuate anche on-line o attraverso app, relativi ad aspetti riguardanti il rendimento professionale, la situazione economica, la salute, le preferenze o gli interessi personali, l'affidabilità o il comportamento, l'ubicazione o gli spostamenti dell'interessato.

- **Monitoraggio sistematico**
  Trattamenti che prevedono un utilizzo sistematico di dati per l'osservazione, il monitoraggio o il controllo degli interessati, compresa la raccolta di dati attraverso reti, effettuati anche on-line o attraverso app, nonché il trattamento di identificativi univoci in grado di identificare gli utenti di servizi della società dell'informazione inclusi servizi web, tv interattiva, ecc. rispetto alle abitudini d'uso e ai dati di visione per periodi prolungati. Rientrano in tale previsione anche i trattamenti di metadati ad es. in ambito telecomunicazioni, banche, ecc. effettuati non soltanto per profilazione, ma più in generale per ragioni organizzative, di previsioni di budget, di upgrade tecnologico, miglioramento reti, offerta di servizi antifrode, antispam, sicurezza etc.

- **Dati sensibili o dati di natura estremamente personale**
  Trattamenti di categorie particolari di dati ai sensi dell'art. 9 oppure di dati relativi a condanne penali e a reati di cui all'art. 10 Regolamento UE 2016/679 interconnessi con altri dati personali raccolti per finalità

diverse.

- **Trattamento di dati su larga scala**
  Trattamenti su larga scala di dati aventi carattere estremamente personale (v. WP 248, rev. 01): si fa riferimento, fra gli altri, ai dati connessi alla vita familiare o privata (quali i dati relativi alle comunicazioni elettroniche dei quali occorre tutelare la riservatezza), o che incidono sull'esercizio di un diritto fondamentale (quali i dati sull'ubicazione, la cui raccolta mette in gioco la libertà di circolazione) oppure la cui violazione comporta un grave impatto sulla vita quotidiana dell'interessato (quali i dati finanziari che potrebbero essere utilizzati per commettere frodi in materia di pagamenti).

- **Combinazione o raffronto di insiemi di dati**
  Trattamenti di dati personali effettuati mediante interconnessione, combinazione o raffronto di informazioni, compresi i trattamenti che prevedono l'incrocio dei dati di consumo di beni digitali con dati di pagamento (es. mobile payment).

- **Dati relativi a interessati vulnerabili**
  Trattamenti non occasionali di dati relativi a soggetti vulnerabili (minori, disabili, anziani, infermi di mente, pazienti, richiedenti asilo).

- **Utilizzi innovativi o applicazione di nuove soluzioni tecnologiche**
  Trattamenti effettuati attraverso l'uso di tecnologie innovative, anche con particolari misure di carattere organizzativo (es. IoT; sistemi di intelligenza artificiale; utilizzo di assistenti vocali on-line attraverso lo scanning vocale e testuale; monitoraggi effettuati da dispositivi wearable; tracciamenti di prossimità come ad es. il wi-fi tracking) ogni qualvolta ricorra anche almeno un altro dei criteri individuati nel WP 248, rev. 01.

Preso atto che il sopracitato documento asserisce che la valutazione d'impatto sulla protezione dei dati debba essere effettuata ogniqualvolta ricorrano almeno un criterio e tenendo conto che nel trattamento preso in esame ne ricorrono 7, il Titolare del trattamento ha ritenuto opportuno procedere all'esecuzione della valutazione d'impatto.

4 Informazioni sul trattamento

ID	Trattamento	Data Creazione	Data ultima modifica
70	BD4QoL studio prospettico	09/06/2021	23/06/2021

Studio multicentrico, internazionale, a due bracci, randomizzato (2:1), in aperto, per ridurre il deterioramento della qualità della vita di pazienti in follow-up dopo il trattamento per un tumore del distretto testa-collo. Lo studio utilizza un ecosistema di applicativi tecnologici integrati (in CLOUD, con server localizzati in Spagna): - APP per paziente: che raccoglie dati relativi allo stile di vita / comportamentale - Data Hub: unico repository per i dati raccolti - Point of Care: sistema di supporto decisionale e di gestione del flusso di lavoro per i professionisti dedicati al follow-up, che raccoglie i dati tramite l'APP e dai questionari compilati dai pazienti. Inoltre una delle funzionalità dello strumento PoC è la raccolta di dati clinici dai pazienti. Questa funzionalità viene implementata attraverso una serie di interfacce collegate a REDCap (strumento per implementare le eCRF) - Piattaforma di empowerment del paziente: applicazione per la gestione dei sintomi e suggerimenti per l'autogestione comportamentale. Attraverso il chatbot stabilisce un'interfaccia di comunicazione diretta con il paziente al fine di conoscere in prima persona il suo stato, rilevando cambiamenti comportamentali rilevanti che potrebbero essere indicativi . Questo strumento consente di responsabilizzare e supportare il paziente nella gestione dei sintomi verso il miglioramento della qualità della vita. - Il Behavior Recognition System: insieme di algoritmi e processi che analizzano i dati disponibili dal paziente e ne deducono le attività realizzate e la sua importanza nella valutazione della qualità della vita. Le attività quotidiane sono un modo comune per conoscere la qualità della vita di un paziente. Un cambiamento nella routine può significare qualche variazione nella qualità della vita che deve essere monitorata. - Applicazione di previsione avanzata della qualità di vita: calcola la qualità della vita di un paziente dai diversi dati raccolti. Tale valore viene confrontato con i valori ottenuti in precedenza e, al verificarsi di una qualsiasi delle condizioni definite, segnala l'allerta per rischio di calo della qualità della vita. Dunque genera modelli predittivi che consentono di prevedere come sarà la qualità di vita e consentire ai caregiver di adottare misure correttive che possono aiutare a migliorarla - portale della documentazione: spazio comune di collaborazione e documentazione ad uso dei partner coinvolti nell'iniziativa
Modalità di conservazione
cartaceo, informatizzato
Titolare
Fondazione IRCCS Istituto Nazionale dei Tumori
Responsabile Protezione dei Dati
Anna Roli

Origine dei dati	
Raccolta presso l'interessato, Comunicati da terzi - Partner clinici del progetto BD4qOL prospettico	
Finalità	
Finalità di ricerca per ridurre il deterioramento della qualità di vita nei sopravviventi a tumori testa-collo in corso di follow-up.	
Basi giuridiche	
Consenso libero e informato	
Riferimenti normativi	
art. 9, comma 2, lettera a);, art. 6, comma 1, lettera a);	
Categorie di dati	
Personali	Dati personali di identificazione
	Dati di contatto
	Dati comportamentali (Ad esempio: posizione; abitudini di acquisto)
Categorie particolari di dati personali	Dati relativi alla salute
Categorie di interessati	
Pazienti arruolati in studi / sperimentazioni cliniche	
Trasferimento e comunicazione dati	
Partner tecnici del consorzio BD4QoL, Partner clinici del progetto BD4qOL prospettico	
Designati	
s.c. Oncologia medica 3 - Tumori testa collo: LISA FRANCESCA LINDA LICITRA	
Responsabili del trattamento	
INETUM (Spagna)	
Diffusione	
Il Trattamento non comporta attività di diffusione	
Procedimento automatizzato	
Attività dei pazienti monitorata tramite app: se riduzione, paziente riceve consigli tramite chatbot; se riduzione grave, medici sono contattati tramite dashboard. Il paziente può attivare autonomamente H24 7/7 la chatbot per riferire eventuali sintomi	

Periodo di conservazione dei dati	
10 anni	
Descrizione del periodo di conservazione dei dati	
10 anni a partire dal termine dello studio clinico (last-patient out)	
Applicativi	
Ecosistema Applicativi BD4QoL	APP e applicativi utilizzati nel progetto di ricerca prospettico BD4QoL

5 Valutazione proporzionalità in relazione alla finalità

Tenuto conto che l'attività di trattamento BD4QoL studio prospettico comporta il trattamento delle seguenti categorie di dati personali:

- Personali (Dati personali di identificazione, Dati di contatto, Dati comportamentali - Ad esempio: posizione; abitudini di acquisto)
- Categorie particolari di dati personali (Dati relativi alla salute)

con riferimento alle seguenti categorie di interessati
- Pazienti arruolati in studi / sperimentazioni cliniche

Il Titolare ritiene che le categorie di dati trattati siano necessari e proporzionali al perseguimento della finalità: Finalità di ricerca per ridurre il deterioramento della qualità di vita nei sopravviventi a tumori testa-collo in corso di follow-up.

6 Diritti e principi fondamentali

Nel presente capitolo si prendono in considerazione i diritti di accesso, rettifica, cancellazione, portabilità, e opposizione. Lo scopo dell'analisi e evidenziare come ciascuno dei diritti degli interessati rilevi, sia contemplato e lo si pensi implementare nell'attività di di trattamento in analisi.

- **Accesso**
  Possibilità del partecipante di visualizzare i dati generati tramite piattaforma BD4QoL.

  Informativa privacy.
- **Rettifica**
  Possibilità del partecipante di richiedere eventuali variazioni dei dati tramite piattaforma BD4QoL.

Informativa privacy.

Procedura interna PRO-G-2 "privacy e diritti dell'interessato".

- **Cancellazione**
  Possibilità del partecipante di richiedere eventuale cancellazione dei dati tramite piattaforma BD4QoL.

  Informativa privacy.

  Procedura interna PRO-G-2 "privacy e diritti dell'interessato".
- **Opposizione**
  Possibilità del partecipante di opporsi all'utilizzo dei dati tramite piattaforma BD4QoL.

  Informativa privacy.

  Procedura interna PRO-G-2 "privacy e diritti dell'interessato".
- **Liceità, Correttezza e Trasparenza**
  I dati personali sono trattati in modo lecito, corretto e trasparente nei confronti dell'interessato
  Individuazione di base giuridica adeguata.

  Informativa privacy.
- **Limitazione della finalità**
  I dati sono raccolti per finalità determinate, esplicite e legittime, e successivamente trattati in modo che non sia incompatibile con tali finalità
  Finalità individuata e circoscritta, specificata nel protocollo.
- **Limitazione della conservazione**
  I dati sono conservati in una forma che consenta l'identificazione degli interessati per un arco di tempo non superiore al conseguimento delle finalità per le quali sono trattati
  Periodo di conservazione definito.
- **Integrità e riservatezza**
  I dati sono trattati in maniera da garantire un'adeguata sicurezza dei dati personali
  Sicurezza informatica adeguata a garantire l'integrità e la riservatezza del dato mediante pseudonimizzazione, crittografia e accesso controllato al sistema.

  Formazione in ambito privacy dei ricercatori che trattano i dati.

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7 Valutazione del rischio

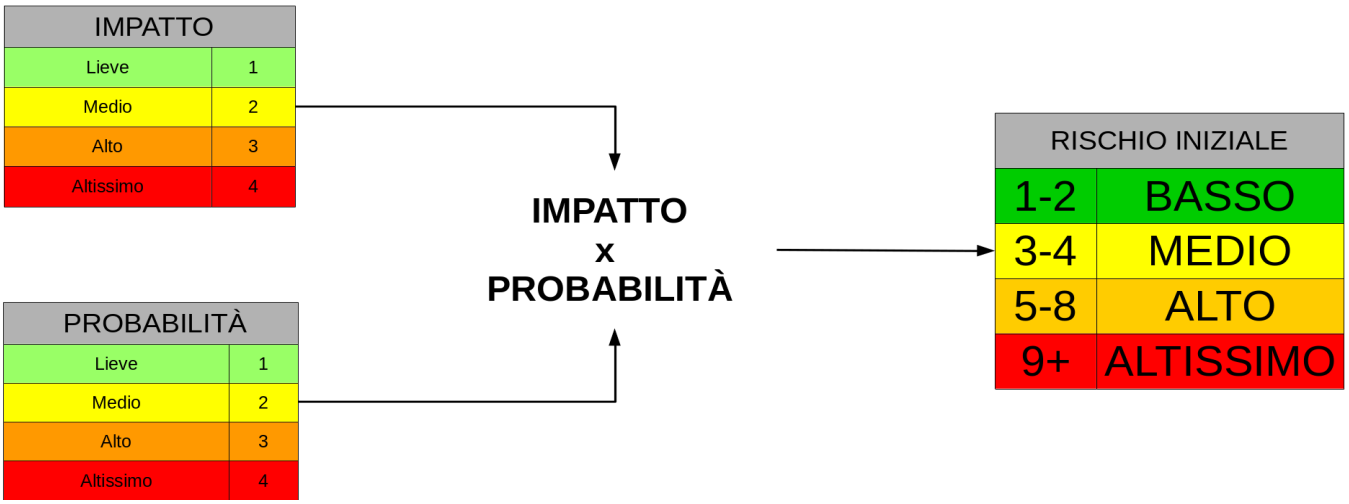
In termini generali la metodologia adottata per la valutazione e gestione del rischio è basata sullo standard ISO31000. Sono state prese in considerazione una serie di ulteriori linee guida e documenti al fine di realizzare una valutazione del rischio calata nel contesto dei rischi per i diritti e le libertà delle persone fisiche con riguardo al trattamento dei loro dati personali.

Nello specifico, gli ulteriori documenti presi in considerazione per effettuare la presente valutazione sono:

- WP29/EDPB – "valutare la particolare probabilità e gravità del rischio";
- CNIL – severity represents the magnitude of a risk;
- Enisa – Handbook on Security of Personal Data Processing
- NIST – Privacy Risk Management for Federal Information Systems;

Al fine di calcolare la magnitudo di un rischio e si adotta una formula del tipo:

$$R_1 = f(M, p)$$



dove:

- **R** : magnitudo del rischio non mitigato
- **M** (Impatto per i diritti e le libertà degli interessati): viene calcolato assegnando un valore su una scala da uno a quattro secondo la seguente scala:

Lieve	Gli interessati non saranno coinvolti o nella peggiore delle ipotesi potrebbero incontrare alcuni inconvenienti, che supereranno senza alcun problema.

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Medio	Gli interessati potrebbero incontrare degli inconvenienti, che saranno in grado di superare nonostante alcune difficoltà
Grave	Gli interessati potrebbero incontrare conseguenze significative, che dovrebbero essere in grado di far fronte seppur con gravi difficoltà
Gravissimo	Gli interessati potrebbero confrontarsi con conseguenze significative o irreversibili.

- **p** probabilità di accadimento del rischio: viene calcolato assegnando un valore su una scala da uno a quattro secondo la seguente scala:

Improbabile	L'avverarsi della minaccia non sembra possibile
Poco Probabile	L'avverarsi della minaccia sembra difficile
Probabile	L'avverarsi della minaccia sembra possibile
Altamente Probabile	L'avverarsi della minaccia sembra probabile

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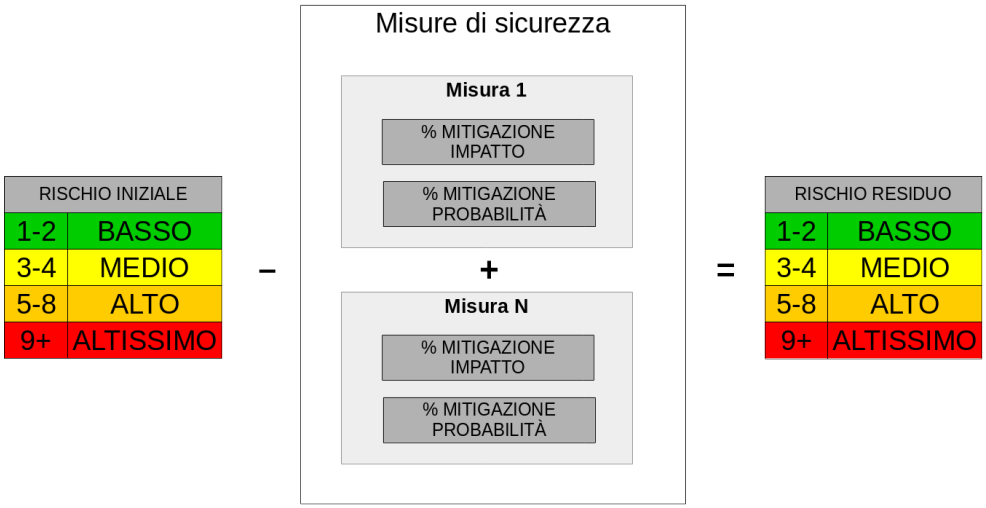
Un controllo di sicurezza può agire sulla probabilità o l'impatto di una Minaccia utilizzate per calcolare il rischio secondo la seguente logica:

$$R_2 = R_1 - (M_1 + M_2 + M_3)$$

dove:

- R_2= rischio finale è il rischio a valle dell'inserimento dei controlli di sicurezza
- R_1= rischio iniziale come definito nel paragrafo precedente
- M_n= controllo di sicurezza adottato



Allo scopo di rendere quanto più chiara la valutazione dei rischi effettuata in questo capitolo saranno esposte in ordine:

1. Le misure di sicurezza adottate divise in tecniche ed organizzative. Le prime sono suddivise su due livelli categoria di misure e tipo di misura e sono correlate all'attività di trattamento presa in esame. Le seconde, anch'esse, divise su due livelli ma correlate agli applicativo o alla natura informatizzata dell'attività di trattamento.
2. Elenco dei rischi con indicazione:
   - Nome della minaccia
   - Fonte della minaccia, che può essere:
     - Umano: soggetto appartenente all'organizzazione del soggetto che effettua la valutazione d'impatto (dipendenti, collaboratori, utenti);
     - Contesto: soggetto esterno all'organizzazione del soggetto che effettua la valutazione d'impatto (concorrenti, agenzie pubbliche, subappaltatori);
     - Strumenti: soggetto non umano (sensori non claibrati, software bug, rottura hardware, disastro naturale);
   - Area d'impatto della minaccia: Disponibilità e/o Integrità e/o riservatezza.
   - Valore dell'impatto e della probabilità. Con possibile motivazione delle scelte.
   - Valore complessivo del rischio non mitigato.
3. Controlli di sicurezza applicati e incidenza di questi su probabilità ed impatto della minaccia. Le misure di sicurezza sono pesate sommando l'incidenza delle singole misure.${QUALITATIVE} Le misure di sicurezza sono pesate come descritto qui: https://doc.privacymanager.eu/manuale/valutazione_impatto.html#valutazione-del-rischio-qualitativa ${/QUALITATIVE}
4. Rischio residuo (mitigato).

7.1 Misure di sicurezza

Misure di sicurezza sui trattamenti

MISURE ORGANIZZATIVE GENERALI
Nomina formale dei delegati con relative istruzioni generali
Nomina formale del DPO (Responsabile Protezione Dati)
Formazione generale
Privacy by Design
Nomina del Responsabile e istruzioni
Staff del DPO
Nomina formale del RSI (Responsabile della Sicurezza delle Informazioni)

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Istruzioni generali delle persone autorizzate
Istruzioni specifiche delle persone autorizzate
Privilegi di accesso ad archivi cartacei o cartelle elettroniche di struttura
Policy generale
Prassi consolidate e/o buone pratiche
Informative
Privacy by default
Granularità dei dati raccolti
MISURE ORGANIZZATIVE PARTICOLARI
Accesso fisico protetto (es: locale chiuso a chiave, accesso non libero, sorveglianza continua da parte del personale)
Sistema di anti intrusione
Cancellazione e distruzione dei dati a seguito di richiesta di esercizio dei diritti da parte dell'interessato
Configurazione adeguata degli strumenti informatici
Consenso specifico ove previsto

Misure di sicurezza sugli asset

Ecosistema Applicativi BD4QoL	
Misure tecniche	Autenticazione
	Autorizzazione
	Firewall
	Disaster recovery
	Pseudonimizzazione
	Minimizzazione per impostazione predefinita (Privacy By Default)
	Interoperabilità
	Canale cifrato
Server fisico	

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7.2 Valutazione del rischio

Categoria: Minacce comuni alla sicurezza
Minaccia: Attacco basato su chiave compromessa
Area Impatto: Riservatezza
Fonti di rischio: Umano

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	2	1
Probabilità	2	1
Livello di rischio	4	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Canale cifrato

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
90%	90%

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Categoria: Minacce comuni alla sicurezza
Minaccia: Attacco Denial-of-Service di rete
Area Impatto: Disponibilità
Fonti di rischio: Umano, Strumenti

Dettagli minaccia

	Rischio iniziale	**Rischio residuo**
Impatto	2	1
Probabilità	3	2
Livello di rischio	6	2

Rischio residuo

2 BASSO

Misure di sicurezza
Misure tecniche
Autenticazione

Mitigazione Impatto	**Mitigazione probabilità**
90%	50%

Totale mitigazione del rischio

Mitigazione Impatto	**Mitigazione probabilità**
90%	50%

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Categoria: Minacce comuni alla sicurezza
Minaccia: Intercettazione
Area Impatto: Riservatezza
Fonti di rischio: Umano, Strumenti

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	3	1
Probabilità	2	1
Livello di rischio	6	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Canale cifrato

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
90%	90%

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Categoria: Minacce comuni alla sicurezza
Minaccia: Spoofing d'identità (spoofing dell'indirizzo IP)
Area Impatto: Riservatezza
Fonti di rischio: Umano, Strumenti

Dettagli minaccia

	Rischio iniziale	**Rischio residuo**
Impatto	2	1
Probabilità	2	1
Livello di rischio	4	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Canale cifrato

Mitigazione Impatto	**Mitigazione probabilità**
90%	50%

Totale mitigazione del rischio

Mitigazione Impatto	**Mitigazione probabilità**
90%	50%

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Categoria: Minacce comuni alla sicurezza
Minaccia: Attacco man-in-the-middle
Area Impatto: Riservatezza
Fonti di rischio: Umano, Strumenti

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	3	1
Probabilità	2	1
Livello di rischio	6	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Canale cifrato

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
90%	90%

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Categoria: Minacce comuni alla sicurezza
Minaccia: Attacco di riproduzione RTP
Area Impatto: Riservatezza
Fonti di rischio: Umano, Strumenti

Dettagli minaccia

	Rischio iniziale	**Rischio residuo**
Impatto	3	1
Probabilità	2	1
Livello di rischio	6	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Canale cifrato

Mitigazione Impatto	**Mitigazione probabilità**
90%	90%

Misure tecniche
Autenticazione

Mitigazione Impatto	**Mitigazione probabilità**
90%	50%

Totale mitigazione del rischio

Mitigazione Impatto	**Mitigazione probabilità**
100%	100%

Categoria: Minacce comuni alla sicurezza
Minaccia: Messaggi istantanei indesiderati
Area Impatto: Riservatezza
Fonti di rischio: Umano, Strumenti

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	1	1
Probabilità	1	1
Livello di rischio	1	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Autorizzazione

Mitigazione Impatto	Mitigazione probabilità
90%	50%

Misure tecniche
Autenticazione

Mitigazione Impatto	Mitigazione probabilità
90%	50%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
100%	100%

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Categoria: Minacce comuni alla sicurezza
Minaccia: Virus e worm
Area Impatto: Disponibilità, Riservatezza, Integrità
Fonti di rischio: Umano, Strumenti

Dettagli minaccia

	Rischio iniziale	**Rischio residuo**
Impatto	2	1
Probabilità	3	2
Livello di rischio	6	2

Rischio residuo

2 BASSO

Misure di sicurezza
Misure tecniche
Firewall

Mitigazione Impatto	**Mitigazione probabilità**
50%	50%

Totale mitigazione del rischio

Mitigazione Impatto	**Mitigazione probabilità**
50%	50%

Categoria: SET PREDEFINITO MINACCE
Minaccia: Locale lasciato aperto o incustodito
Area Impatto: Disponibilità, Riservatezza, Integrità
Fonti di rischio: Umano

Dettagli minaccia

	Rischio iniziale	**Rischio residuo**
Impatto	1	1
Probabilità	1	1
Livello di rischio	1	1

Rischio residuo

1 BASSO

Misure di sicurezza
MISURE ORGANIZZATIVE PARTICOLARI
Sistema di anti intrusione

Mitigazione Impatto	**Mitigazione probabilità**
90%	90%

MISURE ORGANIZZATIVE PARTICOLARI
Accesso fisico protetto (es: locale chiuso a chiave, accesso non libero, sorveglianza continua da parte del personale)

Mitigazione Impatto	**Mitigazione probabilità**
90%	90%

MISURE ORGANIZZATIVE GENERALI
Istruzioni generali delle persone autorizzate
- Allegate al contratto dei neoassunti

- Allegate alle autorizzazioni di frequenza a vario titolo

Mitigazione Impatto	**Mitigazione probabilità**
90%	90%

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MISURE ORGANIZZATIVE GENERALI
Privilegi di accesso ad archivi cartacei o cartelle elettroniche di struttura

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Formazione generale

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Formazione specifica

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Training sullo studio

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
100%	100%

Categoria: SET PREDEFINITO MINACCE
Minaccia: Armadio/cassetto lasciato aperto
Area Impatto: Disponibilità, Riservatezza, Integrità
Fonti di rischio: Umano

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	1	1
Probabilità	1	1
Livello di rischio	1	1

Rischio residuo

1 BASSO

Misure di sicurezza
MISURE ORGANIZZATIVE GENERALI
Istruzioni generali delle persone autorizzate
- Allegate al contratto dei neoassunti

- Allegate alle autorizzazioni di frequenza a vario titolo

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Istruzioni specifiche delle persone autorizzate
Assegnate dal Delegato del Titolare

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Privilegi di accesso ad archivi cartacei o cartelle elettroniche di struttura

Mitigazione Impatto	Mitigazione probabilità
90%	90%

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MISURE ORGANIZZATIVE PARTICOLARI
Accesso fisico protetto (es: locale chiuso a chiave, accesso non libero, sorveglianza continua da parte del personale)

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Formazione generale

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
100%	100%

Categoria: SET PREDEFINITO MINACCE
Minaccia: Accesso e o trattamento dei dati personali per finalità diverse da quelle autorizzate
Area Impatto: Disponibilità, Riservatezza, Integrità
Fonti di rischio: Umano, Contesto

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	4	1
Probabilità	1	1
Livello di rischio	4	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Autenticazione

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Misure tecniche
Autorizzazione

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Privilegi di accesso ad archivi cartacei o cartelle elettroniche di struttura

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Istruzioni generali delle persone autorizzate

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- Allegate al contratto dei neoassunti

- Allegate alle autorizzazioni di frequenza a vario titolo

Mitigazione Impatto	**Mitigazione probabilità**
90%	90%

MISURE ORGANIZZATIVE GENERALI
Istruzioni specifiche delle persone autorizzate
Assegnate dal Delegato del Titolare

Mitigazione Impatto	**Mitigazione probabilità**
90%	90%

MISURE ORGANIZZATIVE GENERALI
Informative

Mitigazione Impatto	**Mitigazione probabilità**
100%	100%

MISURE ORGANIZZATIVE PARTICOLARI
Consenso specifico ove previsto

Mitigazione Impatto	**Mitigazione probabilità**
100%	100%

Totale mitigazione del rischio

Mitigazione Impatto	**Mitigazione probabilità**
100%	100%

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Categoria: SET PREDEFINITO MINACCE
Minaccia: Allontanarsi dalla propria postazione lasciando il PC connesso
Area Impatto: Disponibilità, Riservatezza, Integrità
Fonti di rischio: Umano

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	1	1
Probabilità	2	1
Livello di rischio	2	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Log out / disconnessione automatica temporizzata

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
90%	90%

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Categoria: SET PREDEFINITO MINACCE
Minaccia: Fornire le credenziali individuali ad altro collega
Area Impatto: Disponibilità, Riservatezza, Integrità
Fonti di rischio: Umano

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	2	1
Probabilità	1	1
Livello di rischio	2	1

Rischio residuo

1 BASSO

Misure di sicurezza
MISURE ORGANIZZATIVE GENERALI
Istruzioni generali delle persone autorizzate
- Allegate al contratto dei neoassunti

- Allegate alle autorizzazioni di frequenza a vario titolo

Mitigazione Impatto	Mitigazione probabilità
80%	80%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
80%	80%

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Categoria: SET PREDEFINITO MINACCE
Minaccia: Copiare i dati su dispositivi removibili (es: pen drive, hard disk esterni) non custoditi
Area Impatto: Riservatezza
Fonti di rischio: Umano

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	4	1
Probabilità	1	1
Livello di rischio	4	1

Rischio residuo

1 BASSO

Misure di sicurezza
MISURE ORGANIZZATIVE GENERALI
Formazione generale

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Istruzioni generali delle persone autorizzate
- Allegate al contratto dei neoassunti

- Allegate alle autorizzazioni di frequenza a vario titolo

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
100%	100%

Categoria: SET PREDEFINITO MINACCE
Minaccia: Copiare i dati su dispositivi removibili (es: pen drive, hard disk esterni) e trasportarli all'esterno senza autorizzazione
Area Impatto: Riservatezza
Fonti di rischio: Umano

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	4	1
Probabilità	1	1
Livello di rischio	4	1

Rischio residuo

1 BASSO

Misure di sicurezza
MISURE ORGANIZZATIVE GENERALI
Formazione generale

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Istruzioni generali delle persone autorizzate
- Allegate al contratto dei neoassunti

- Allegate alle autorizzazioni di frequenza a vario titolo

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
100%	100%

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Categoria: SET PREDEFINITO MINACCE
Minaccia: Modifica accidentale dei dati
Area Impatto: Integrità
Fonti di rischio: Umano, Contesto

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	1	1
Probabilità	1	1
Livello di rischio	1	1

Rischio residuo

1 BASSO

Misure di sicurezza
MISURE ORGANIZZATIVE GENERALI
Istruzioni generali delle persone autorizzate
- Allegate al contratto dei neoassunti

- Allegate alle autorizzazioni di frequenza a vario titolo

Mitigazione Impatto	Mitigazione probabilità
80%	80%

MISURE ORGANIZZATIVE GENERALI
Privilegi di accesso ad archivi cartacei o cartelle elettroniche di struttura

Mitigazione Impatto	Mitigazione probabilità
80%	80%

MISURE ORGANIZZATIVE GENERALI
Istruzioni specifiche delle persone autorizzate
Assegnate dal Delegato del Titolare

Mitigazione Impatto	Mitigazione probabilità
90%	90%

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MISURE ORGANIZZATIVE GENERALI
Training sullo studio

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
100%	100%

Categoria: SET PREDEFINITO MINACCE
Minaccia: Cancellazione accidentale dei dati
Area Impatto: Disponibilità
Fonti di rischio: Umano, Contesto

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	1	1
Probabilità	1	1
Livello di rischio	1	1

Rischio residuo

1 BASSO

Misure di sicurezza
MISURE ORGANIZZATIVE GENERALI
Privilegi di accesso ad archivi cartacei o cartelle elettroniche di struttura

Mitigazione Impatto	Mitigazione probabilità
80%	80%

MISURE ORGANIZZATIVE GENERALI
Istruzioni generali delle persone autorizzate
- Allegate al contratto dei neoassunti

- Allegate alle autorizzazioni di frequenza a vario titolo

Mitigazione Impatto	Mitigazione probabilità
80%	80%

MISURE ORGANIZZATIVE GENERALI
Formazione generale

Mitigazione Impatto	Mitigazione probabilità
80%	80%

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MISURE ORGANIZZATIVE GENERALI
Istruzioni specifiche delle persone autorizzate
Assegnate dal Delegato del Titolare

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Training sullo studio

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
100%	100%

Categoria: SET PREDEFINITO MINACCE
Minaccia: Mancato aggiornamento dei dati
Area Impatto: Integrità
Fonti di rischio: Umano, Contesto

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	1	1
Probabilità	1	1
Livello di rischio	1	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Interoperabilità

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Istruzioni generali delle persone autorizzate
- Allegate al contratto dei neoassunti

- Allegate alle autorizzazioni di frequenza a vario titolo

Mitigazione Impatto	Mitigazione probabilità
80%	80%

MISURE ORGANIZZATIVE GENERALI
Formazione generale

Mitigazione Impatto	Mitigazione probabilità
80%	80%

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MISURE ORGANIZZATIVE GENERALI
Istruzioni specifiche delle persone autorizzate
Assegnate dal Delegato del Titolare

Mitigazione Impatto	Mitigazione probabilità
90%	90%

MISURE ORGANIZZATIVE GENERALI
Training sullo studio

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
100%	100%

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Categoria: SET PREDEFINITO MINACCE
Minaccia: Trasmissione informatica di dati personali a soggetti non autorizzati per difetto degli strumenti
Area Impatto: Riservatezza
Fonti di rischio: Strumenti

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	2	1
Probabilità	1	1
Livello di rischio	2	1

Rischio residuo

1 BASSO

Misure di sicurezza
MISURE ORGANIZZATIVE PARTICOLARI
Configurazione adeguata degli strumenti informatici

Mitigazione Impatto	Mitigazione probabilità
90%	90%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
90%	90%

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Categoria: SET PREDEFINITO MINACCE
Minaccia: Cyber Crime
Area Impatto: Disponibilità, Riservatezza, Integrità
Fonti di rischio: Contesto, Strumenti

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	1	1
Probabilità	1	1
Livello di rischio	1	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Firewall

Mitigazione Impatto	Mitigazione probabilità
80%	80%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
80%	80%

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Categoria: SET PREDEFINITO MINACCE
Minaccia: Emergenza non sanitaria con impatto sul sistema informativo
Descrizione: (Ad esempio: incendio, alluvione, terremoto)
Area Impatto: Disponibilità, Riservatezza, Integrità
Fonti di rischio: Contesto

Dettagli minaccia

	Rischio iniziale	**Rischio residuo**
Impatto	4	1
Probabilità	1	1
Livello di rischio	4	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Back-up

Mitigazione Impatto	**Mitigazione probabilità**
80%	80%

Misure tecniche
Disaster recovery

Mitigazione Impatto	**Mitigazione probabilità**
80%	80%

Totale mitigazione del rischio

Mitigazione Impatto	**Mitigazione probabilità**
100%	100%

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Categoria: SET PREDEFINITO MINACCE
Minaccia: Guasto tecnologico
Area Impatto: Disponibilità, Riservatezza, Integrità
Fonti di rischio: Strumenti

Dettagli minaccia

	Rischio iniziale	Rischio residuo
Impatto	2	1
Probabilità	2	1
Livello di rischio	4	1

Rischio residuo

1 BASSO

Misure di sicurezza
Misure tecniche
Disaster recovery

Mitigazione Impatto	Mitigazione probabilità
80%	80%

Misure tecniche
Back-up

Mitigazione Impatto	Mitigazione probabilità
80%	80%

Totale mitigazione del rischio

Mitigazione Impatto	Mitigazione probabilità
100%	100%

8 Coinvolgimento delle parti interessate

- **Sono state raccolte le opinioni degli interessati o dei loro rappresentanti?**
  Survey preliminare con un campione di pazienti sulla accettabilità e fattibilità dello studio clinico.
  Coinvolgimento dello staff di ricerca per beta-testing.
- **È stato coinvolto il Responsabile della Protezione dei Dati?**
  Coinvolgimento dello staff del DPO. Privacy by design e DPIA.

9 Note

Misure di sicurezza informatiche in fase di aggiornamento.

Il Titolare del trattamento

➢ CONTEXT

OVERVIEW

- Which is the processing under consideration?

The processing under consideration relates to the European H2020 BD4QoL (Call: H2020-SC1-DTH-2018-2020 – Digital transformation in Health and Care). Topic: SC1-DTH-01-2019), Grant Agreement n. 875192.

Primary objective of the BD4QoL H2020 Project
To reduce the proportion of HNC subjects experiencing a clinically meaningful deterioration of QoL between at least 2 visits during post-treatment follow-up.

Secondary objectives of the BD4QoL H2020 Project
- To delay the time to the first clinically meaningful deterioration of QoL between at least 2 visits during post-treatment follow-up.
- To reduce the proportion of HNC subjects experiencing a clinically meaningful deterioration in pre-specified EORTC QLQ-C30 scales between at least 2 visits during post-treatment follow-up.
- To reduce the proportion of HNC subjects experiencing a clinically meaningful deterioration in pre-specified EORTC QLQ-HN43 scales between at least 2 visits during post-treatment follow-up.
- To reduce the proportion of HNC subjects experiencing a clinically meaningful deterioration in pre-specified EQ-5D-5L domains between at least 2 visits during post-treatment follow-up.

Exploratory objectives
- To assess the association of clinically relevant variations in QoL (EORTC QLQ-C30 and HN43 global scores, 11,12) with disease recurrence and survival in HNC survivors within the study observation (up to 24 months) period during post-treatment follow-up.
- To analyse time-dependent variations of QoL (EORTC QLQ-C30 and HN43 scores) within the study observation (up to 24 months) period during post-treatment follow-up in HNC survivors assessing their association with recurrence and survival.
- To analyse QoL scores (EORTC QLQ-C30 and HN43 scores) within the study observation (up to 24 months) period during post-treatment follow-up in nasopharyngeal cancer patients assessing their association with recurrence and survival.
- To reduce the proportion of HNC subjects experiencing a clinically meaningful deterioration in pre-specified EORTC QLQ-HN43 scales (not included in secondary endpoints) between at least 2 visits during post-treatment follow-up.
- For HNC survivors randomized in the BD4QoL platform group, using artificial intelligence techniques to build models (Annex 17) to predict a QoL deterioration (EORTC QLQ-C30 and HN43 scores, EQ-5D-5L as defined in 11,12) between at least 2 visits during within the study observation (up to 24 months) period during post-treatment follow-up.
- To assess the association of clinically relevant variations of QoL (EORTC QLQ-C30 and HN43 global scores, 11,12) with self-efficacy for coping with cancer in HNC survivors within the study observation (up to 24 months) period during post-treatment follow-up.
- To reduce the proportion of HNC subjects experiencing a clinically meaningful deterioration of QoL between at least 2 visits during post-treatment follow-up, stratifying according to patients completing treatment within 12 months vs after 12 months.
- To assess the economic impact on HNC survivor care and the viability, usability and trust of using the BD4QoL platform (Health Technology Assessment, HTA).

Study Design
This is a multicentre, international, two-arm, randomised (2:1 ratio), open label, superiority trial, designed to evaluate the proportion of HNC survivors experiencing a clinically meaningful QoL deterioration (reduction of at least 10 points in EORTC QLQ-C30 global health status 11,12) between at least 2 visits during post-treatment follow-up (up to 24 months from randomization) with the use of the BD4QoL platform installed on the study subject's mobile phone in comparison to those without the BD4QoL platform ("standard FU").

Patients will be followed up as per clinical practice:

a. All subjects will be asked to fill in validated questionnaires (QLQ-C30, QLQ-HN43, EQ-5D-5L, CBI-B) on up to 5 occasions over a 2-year period, at randomization (0-month FU), then once every 6 months ± 2 months (after 6, 12, 18, 24 months from randomisation).

b. Participants in both arms will be offered routine standard of care and asked to complete validated QoL questionnaire at regular intervals (described above). In addition those in the intervention arm will be offered the device-generated data collection platform (BD4QoL device *plus* QoL validated questionnaires *plus* counseling and physician contact [early intervention] *plus* possible psychological effect of the whole activities in the interventional arm). A 2:1 randomization will be used (2/3 of subjects with BD4QoL platform vs 1/3 of subjects without).

Inclusion Criteria

1.Effectively cured histologically defined head and neck squamous cell carcinoma (HNSCC) from one of these subsites: oral cavity, nasopharyngeal, hypopharynx, larynx, HPV-positive or negative oropharynx (ICD codes in Annex 12). Non-metastatic salivary gland cancer (SGC) of any histological type can be included only if curative or postoperative radiotherapy included the neck:

1a. For p16-negative or p16-unknown HNSCC, stage I, II, III, IVa or IVb (no IVc) according to UICC/AJCC 8th ed 19. Regional neck metastases from squamous cell carcinoma from unknown primary head and neck site are allowed.

1b. For nasopharyngeal cancer (NPC), stage I, II, III, IVa (no IVb) according to UICC/AJCC 8th ed 19. Regional neck metastases from EBV-positive carcinoma from unknown primary head and neck site are allowed.

1c. For SGCs, stage III, IVa or IVb according to UICC/AJCC 8th ed 19 treated with radiotherapy that included the neck (either post-operative radiation or radical treatment in case of unresectable disease).

1d. For p16-positive oropharyngeal squamous cell carcinoma, stage I, II or III according to UICC/AJCC 8th ed 19. Regional neck metastases from p16-positive squamous cell carcinoma from unknown primary head and neck site are allowed.

2. Patients having completed treatment with curative intent (including any multimodal approach) within 5 years.

3. Patients being disease free at time of accrual. Patients will be deemed in complete remission if clinical examination is negative for recurrence; clinical examination should be preferably, but not mandatorily, integrated with unequivocal radiological imaging that shows absence of disease (in case of doubt, a further radiological imaging should be performed or integrated with cyto/histological samples of the area with suspected disease persistence and the exams will have to be consistently negative) after at least three months after treatment completion.

4. Ability to fill in questionnaires as per protocol.

5. Geographical accessibility and willingness to be followed-up for up to 2 years with IT devices in addition to questionnaires.

6. Age ≥ 18 years.

7. Signed informed consent.

8. Willingness to use their smartphone and their Internet access for the study.

9. Smartphone having the following minimum characteristics:

- RAM: Minimum of 2 GB

- Storage: Minimum of 512 MB free storage

- Operating system: Android APK 21 Android version 5 or more recent

Exclusion Criteria

1. Distant metastases (the following populations are excluded: stage IVc HPV-negative HNSCC and SGC, stage IV p16-positive oropharyngeal squamous cell carcinoma, stage IVb NPC).

2. Paranasal carcinomas, thyroid cancers, neuroendocrine tumors and non-epithelial HNC (e.g. melanoma, sarcoma, etc.) are excluded.

3. Any previous HNC unrelated to the primary HNC for which the patient was treated; premalignant lesions (e.g. leukoplakia, erythroplakia, lichen etc.) are allowed.

4. Subjects with previous malignancies (except localized non-melanoma skin cancers, and the following in situ cancers: bladder, gastric, colon, esophageal endometrial, cervical/dysplasia, melanoma, or breast) unless a complete remission was achieved at least 5 years prior to study entry AND no additional therapy is required during the study period.

5. Participation in clinical trials with other experimental agents within 30 days of study entry or concomitant treatment with experimental drugs.

6. Patients unable to comply with the protocol, in the opinion of the investigator.

7. Any known or underlying medical conditions that, in the opinion of the investigator, could adversely affect the ability of the participating subject to comply with the study.

8. Having a smartphone operating system other than Android as indicated in inclusion criteria.

- What are the responsibilities linked to the processing?

Data Controller: Fondazione Casa Sollievo della Sofferenza
Other Data Controllers, BD4QoL H2020 Partners: see the Grant Agreement.

- Are there standards applicable to the processing?

The Data Controllers adopts a ISO 9001:2015 quality management system.
All the measures taken are in line with the GDPR and the Grant Agreement of the project.

➢ DATA, PROCESSES AND SUPPORTING ASSETS

- What are the data processed?

Personal Data and Special Categories of Personal Data (e.g. Data Concerning Health) of the participant, having the characteristics specified in the study protocol.
To achieve the study objectives, the BD4QoL platform will use the following sensors embedded in a smartphone to collect data which will be used to infer behavioral and affective traits associated with study outcomes. Sensors at mobile phone used to collect relevant data (details collected in Annex):

• Accelerometer (x,y,z measurements)

• GPS (Lat, Long)

• Ambient light (measurement of light in the room / area where the mobile device is located)

• Screen (daily total time that smartphone screen is ON, OFF, or UNLOCKED)

• Activity (type of activity with which the person engages, such as Walking, Running, etc., with details such as distance covered)

• Steps (total number of steps per day and/or hour)

Data detected from the mobile device's operating system:

• phone usage logs (total counter and only timestamps of three types of events – incoming, outgoing and missed calls – with encrypted (hashed) collection of associated Personal Identifiable Information, such as phone numbers or contact information, as well as total counter and timestamps of incoming and new/replied text messages)

• phone applications usage (identification and seconds or minutes of usage and semantic category of smartphone applications used; for certain specific social media network or communication platforms, more specific information such as duration of app usage per day can be collected; these social applications include facebook, messenger, whatsapp, telegram, viber, signal, skype, etc.; no information about the people with whom communication is made is collected)

• daily connections to wifi networks (counter of wifi names, IDs and connection duration)

The above data will be used to infer activities and behaviors which have a high likelihood of being meaningfully related with participants' QoL trajectories. A list of such activities and behaviors, with an indication of the technical methods to be used for reconstruction as well as an assessment of reliability, is presented in Annex 16.

The BD4QoL App, available for Android and iOS, will be able to collect and store data about the following domains: mobility, physical activity, activities of daily living, instrumental activities of daily living, socialization, cognitive function, affect, health related activities (further details in Annex 16).

A summary of the findings and the supporting data will be available to the patient, clinicians, nurses and to the investigators, through a dashboard available on mobile devices. The data collected by the mobile App will not be available to the technology manufacturer and will be transferred in almost-real-time (real-.time when possible, as soon as data transfer is available) to the central BD4QoL repository (as long there is available storage in the local memory storage of the mobile device).

In the interval between visits, study participants will be able to interact electronically with the platform through a chatbot, which will be part of the BD4QoL platform implementation based on IBM Watson technology. The chatbot is an application to empower patients to manage their QoL and health, under the supervision of clinicians.

The chatbot will have a series of e-coaching functions that include: (i) dialogue management that allows the patient to be counselled by chatting electronically in a structured and effective way; (ii) management of two-way communications with healthcare professionals (e.g. for the patient to request specific support in case of special needs, or for the chatbot to invite the patient for a visit in case of an early detection of HRQoL or health issues ; identified people will have to be in the delegation log by the PI); (iii) detection of affective traits embodied in the e-coach / patient dialogue, through sentiment analysis and emotion analysis technologies to gather data about pts mood (the content of these conversations will not leave the person's phone for processing, only aggregated data will ; this information will be included in the informed consent form). The latter element can be used to both re-adapt the chatbot counselling strategy as well as to provide additional information on subjects mood to clinicians. The adverse events that the chatbot will be able to recognize will be the following: fatigue, malaise, fever, excessive sleepiness,

difficulty sleeping, depression, change in social circumstances, neck swelling, facial pain, difficulty breathing, nose bleeds, difficulty speaking, dry mouth, lost a tooth, muscle weakness, ear pain, difficulty hearing, vertigo / nausea, diarrhea, constipation, difficulty seeing, dry eye, eye pain, nervous eyelid, eye floaters, swollen eye, bleeding eyes, eye watering, sexuality issues, weight loss, difficulty swallowing, mouth sores, appetite loss, difficulty opening mouth, difficulty eating, increased sensitivity to smells, no taste. Further details about adverse events and potential chatbot responses are reported in Annex 8.

The platform will provide to the investigators real time data of device usage (e.g number and type of alerts and chatbot interactions by pts) and it will integrate eCRF data as a study monitoring dashboard.

The BD4QoL platform used in this trial is not to be considered a medical device and is used for experimental assessment only. Tips provided by the chatbot regarding detected symptoms are also not to be considered clinical advice by any means and should not substitute conversations with a member of a trained medical personnel.

The data will be published in clinicaltrials.gov and will be reported to study PIs and to the Funding Authority.

- ## How does the life cycle of data and processes work?

At study entry the following data will be collected and recorded in the eCRF: date of signed informed consent, gender, marital status, education, date of primary tumor diagnosis, comorbidity (ACE27 – Annex 11), baseline body mass index (BMI), age at primary tumor diagnosis, primary tumor site (ICD code – Annex 12), HPV and/or p16 status (mandatory if primary tumor site = oropharynx), Serum plasma EBV-DNA (optional if primary tumor site = nasopharynx), EBER on tumor specimen (optional if primary tumor site = nasopharynx), Baseline (pre-treatment) cTNM staging (AJCC/UICC VIII edition – Annex 13), details about surgery, radiotherapy, systemic therapy, date of treatment completion.

At each follow-up the following data will be collected and recorded in the eCRF: date of consultation, timing after treatment completion (first follow-up; +6 months; +12 months; +18 months; +24 months; other), BMI, disease status (recurrence; date of recurrence; site of recurrence: loco-regional and/or distant and/or second primary tumor), new non-cancer-related medical events (MedDRA), grade of non-cancer-related medical events according to CTCAE version 5 (Annex 14), date of onset and resolution of non-cancer-related medical events, intervention for non-cancer-related medical events (no intervention; surgery; rehabilitation; medical intervention, if yes, to be specified according to Anatomical Therapeutic Chemical Classification System; Psychological intervention; other).
Details about clinical, pathologic and demographic data that will be collected are reported in Annex 10-14.

All data within BDD4QoL shall be handled using tools and processes with 'privacy by design' as the mindset. The project will share data, with applied internal encryption, with subject's local identifier recoded in a hashed ID code. The list matching patient personal data and study ID will be stored off-line in the center which collects the data, which will manage it in compliance with relevant local legislation. The personal data will remain at the recruiting centre and will not be sent in to the BD4QoL team.
Participating hospitals are responsible for maintaining anonymity of participants' data and for safely storing and preventing unnecessary access to any information which may disclose the patient's identity. The provisions of the above mentioned GDPR will be adopted or – if more restrictive – national regulations in matters of personal data protection and privacy. Sensitive data will be used to track health-related data and will not be registered or used for the analysis
Data that leave the participant phone will be (highlighted in blue in Annex 16): walking, sleeping, using telephone.
For those who provide a specific consent the following data will be added to the list of data leaving the phone (not highlighted in blue in Annex 16): activity, inactivity, running, cycling, sports, eating/drinking, nutrition, staying at home, shopping, manage medications, using telephone, travelling, managing finances, visiting social places, using social networks, visiting cultural places, self-care, spirituality, education, sentiment, depression, visit heath related places.
Details about how these data will be recorded by the BD4QoL platform are provided in Annex 16.

- ## What are the data supporting assets?

The communications used for the exchange of messages between the system's applications are done using the HTTPS protocol over TCP. The TCP protocol natively includes features such as error checking and acknowledgement interchange between peers, which means that if data is corrupted or not received, it is resent by the sender to ensure that it is received correctly.BD4QoL Data Hub is deployed in the datacenter that INETUM has located in Murcia, Spain. This datacentre has TIER IV certification, meaning that it

includes capabilities to ensure data safety and availability. The characteristics of this datacentre at different levels are as follows:

a. Facility:
i. Tier IV. 99.999% availability;
ii. Anti-seismic construction with insulated electromagnetic;
iii. Redundant infrastructure for mission environments review;
iv. 1.2 MW of power maximum in datacenter of high density;
v. Double electric ring with 2 UPS and 2 groups generators with 1-week autonomy;
vi. GREEN IT "Base Design", being 50% more efficient in the consumption of energy.

b. Security:
i. Specialized security personnel 24x7;
ii. Intelligent indoor and outdoor video surveillance system with intruder detection;
iii. Access to critical rooms controlled by facial biometrics (TI, MPOE, SOC, NOC, etc.);
iv. Very Early Smoke Detection Air (VESDA);
v. Water extinguishing system mist, avoiding the evacuation of the data center.

c. Operation:
i. Customized 24x7 support backed by technical team of experts with presence onsite IT and Industrial staff;
ii. ITIL, SSAE16, ISO, ICREA standards level 5.

d. Communication:
i. 2N end-to-end redundancy;
ii. Two independent links with diversified access and connection to two neutral points (Telvent and Interxion);
iii. Own public address, balanced between the two links;
iv. Safety equipment Service Provider logic, with protection against DDOS attacks;
v. 2 Multi-Carrier zones (MPOE) for service providers with exterior fingerprint access.

Daily backups of the BD4QoL data repositories will ensure data reconstruction.

The researchers involved in the project will also take advantage of paper based forms regarding the informed consent and the agreement on personal data treatment.

A common file repository of the project documentation is also being used

➢ FUNDAMENTAL PRINCIPLES

PROPORTIONALITY AND NECESSITY

- Are the processing purposes specified, explicit and legitimate?

Personal data collected as part of the study are processed only for the purposes indicated in the project documents, and especially in the study protocol.
The "purpose limitation principle", whereby personal data is collected for specified, explicit and not further processed in a manner that is incompatible with those purposes, is complied with.

- What are the legal basis making the processing lawful?

Explicit consent of the data subject who will sign the paper consent documents, i.e. the consent to participate in the study and consent for the processing of personal data.

- Are the data collected adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')?

Personal data are strictly instrumental to the objectives of the study.

- Are the data accurate and kept up to date?

The Fondazione Casa Sollievo della Sofferenza systematically adapts its organization and updates the tools to protect the data, processed both on paper and electronically, protecting them from destruction, loss, unauthorized access, treatment that is not permitted or does not comply with the purposes of their collection.
Its staff is authorized to collect and record the patients' personal data accessing the systems with the use of a individual "Username" and "Password" credentials.
The EMR system records at any time who (which operator) does what (records, updates, corrects, consults), which data they process and to which patient these data belong.
Each employee is instructed and obliged to maintain confidentiality and office secrecy.
Data discolsure is forbidden execpt in case of explicit authorization.
Finally, each professional of the Fondazione, can manage only the data necessary to perform his/her assigned duties.

- What are the storage duration of the data?

The investigator must retain all study records and source documents for the maximum period required by applicable regulations and guidelines or institution procedures whichever is longer (minimum 5 years). The investigator must contact the coordinator Center prior to destroying any records associated with the study. If an Investigator of a participating Center withdraws from the study (e.g. relocation, retirement), the records shall be transferred to a mutually agreed upon designee (e.g., another investigator, IRB). Such transfer shall be reported in writing and notified to the Coordinating Center and to each Ethical Committee of the participating Centers.
Trial participants assure that the key design elements of this protocol will be posted in a publicly accessible database such as clinicaltrials.gov. In addition, upon study completion and finalization of the study report the results of this study will be either submitted for publication and/or posted in a publicly accessible database of clinical study results. Patients will be informed of this option during the informed consent procedure.

It is the responsibility of the investigator to ensure that the patient-identification sheets are stored for 10 years beyond the end of the clinical study (defined as last patient out). All original patient files must be stored for the longest possible time permitted by the regulations at the hospital, research institute, or practice in question. If archiving can no longer be maintained at the site, the investigator will notify the Sponsor/Representative of the Sponsor.

CONTROLS TO PROTECT THE PERSONAL RIGHTS OF DATA SUBJECTS

- How are the data subjects informed on the processing?

The Data Subjects are adequately informed – orally and in writing – by the by the healthcare professional in charge.

- If applicable, how is the consent of data subjects obtained?

The same healthcare professional administers to the patient - under his own responsibility - the document of informed consent and authorization for the processing of personal data.

- How can data subjects exercise their rights of access and to data portability?

The exercise of the rights by the interested parties can take place according to the processes declared in the document "Information on the protection of your personal data" - MO-PRIVACY-INFO-GENERALE-01, issued by the Data Controller on 24/05/2018; or with the methods indicated in the informed consent and data processing agreement document.

- How can data subjects exercise their rights to rectification and erasure?

The exercise of the rights by the interested parties can take place according to the processes declared in the document "Information on the protection of your personal data" - MO-PRIVACY-INFO-GENERALE-01, issued by the Data Controller on 24/05/2018; or with the methods indicated in the informed consent and data processing agreement document.

- How can data subjects exercise their rights to restriction and to object?

The exercise of the rights by the interested parties can take place according to the processes declared in the document "Information on the protection of your personal data" - MO-PRIVACY-INFO-GENERALE-01, issued by the Data Controller on 24/05/2018; or with the methods indicated in the informed consent and data processing agreement document.

- Are the obligations of the processors clearly identified and governed by a contract?

The setting up of specific Data Processing Agreements between project partners is ongoing.

- In the case of data transfer outside the European Union, are the data adequately protected?

Data transfer ouside the EU is not foreseen.

➢ RISKS

Planned or existing measures

- Encryption

The communications used for the exchange of messages between the system's applications are done using the HTTPS protocol over TCP. The TCP protocol natively includes features such as error checking and acknowledgement interchange between peers, which means that if data is corrupted or not received, it is resent by the sender to ensure that it is received correctly.

- Privacy protection criteria

Patients' names will not be recorded. A sequential identification number will be automatically attributed to each patient registered in the trial. Investigators must guarantee that all personnel involved in this study will respect the confidentiality of any information concerning the trial subject. All parties involved in this clinical trial will maintain strict confidentiality to ensure that neither the person nor the family privacy of the patient participating in the trial is violated; appropriate measures shall be taken to avoid the access of non-authorized persons to the trial data. The processing of the personal data of patients taking part in the trial shall comply with local law on the privacy and with the GDPR.

- Pseudonymisation

At each participating centre the investigators will assign a newly defined unique ID to each enrolled subject (e.g. INT_0001, INT_0002 for INT etc.). All data will be shared and recorded with this ID, and the log file where the ID can be translated in the respective name of the patient will be available only at the participating centre site, and will be preserved locally.

- Logical access control

Clinical investigators will be allowed through an authorization list to access clinical and study generated data from patients recruited at own Center. Access to patient's data both anonymized and for clinical use (identifiable) will only be granted according to each hospital regulations and restrictions (i.e. only authorized personnel that has been granted access by the patient or healthcare operators in charge of emergency interventions), and then local hospital regulations will be applied. Non clinical study investigators will be able to access only pseudonymized data (both clinical and device generated).

- Backup

Daily backups of the BD4QoL data repositories will ensure data reconstruction.

- Physical access control

Data are stored in data centers which can only be accessed by authorized personnel.

Illegitimate access to data

- What could be the main impacts on the data subjects if the risk were to occur?

Illegitimate exploitation of health data, Illegitimate exploitation of the information collected about subjects' behaviors and life styles (mobility, physical activity, activities of daily living, instrumental activities of daily living, socialization, cognitive function, affect, health related activities).

- What are the main threats that could lead to the risk?

Data Breach on the BD4QoL platform infrastructure, Data Breach on the Fondazione Casa Sollievo della Sofferenza Health Information System.

- What are the risk sources?

Social Engineering attacks, Password violation, Disruption of the devices, Man-in-the-middle attacks, Other types of attack which aim at corrupting data integrity ot availability.

- Which of the identified controls contribute to addressing the risk?

Encryption, Pseudonymisation, Logical access control, Privacy protection criteria, Physical access control.

- How do you estimate the risk severity, especially according to potential impacts and planned controls?

Important.

- How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?

Limited.

Unwanted modification of data

- What could be the main impacts on the data subjects if the risk were to occur?

The impacts wouldn't affect severely the study participants but could mine the scientific evidence to be generated.

- What are the main threats that could lead to the risk?

Data Breach on the project's infrastructure, Unintended errors in the software that lead to the modification of data.

- What are the risk sources?

Man-in-the-middle attacks, Social Engineering attacks, Password violation, Disruption of the devices, Man-in-the-middle attacks, Unintended errors in the use of the systems by users with high-level permissions.

- Which of the identified controls contribute to addressing the risk?

Logical access control.

- How do you estimate the risk severity, especially according to potential impacts and planned controls?

Important.

- How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?

Negligible.

- **Data disappearance**

- What could be the main impacts on the data subjects if the risk were to occur?

The impacts wouldn't affect severly the study participants but could mine the scientific evidence to be generated.

- What are the main threats that could lead to the risk?

DOS attacks, Cryptolocker attacks, Other types of attack which aim at corrupting data integrity and availability, Faults or malfunctioning of physical components, Data Breach on the project's infrastructure.

- What are the risk sources?

Social Engineering attacks, Password stealing, Disruption of the devices, Man-in-the-middle attacks, Other type of attacks aimed at data integrity disruption.

- Which of the identified controls contribute to addressing the risk?

Backup, Logical access control.

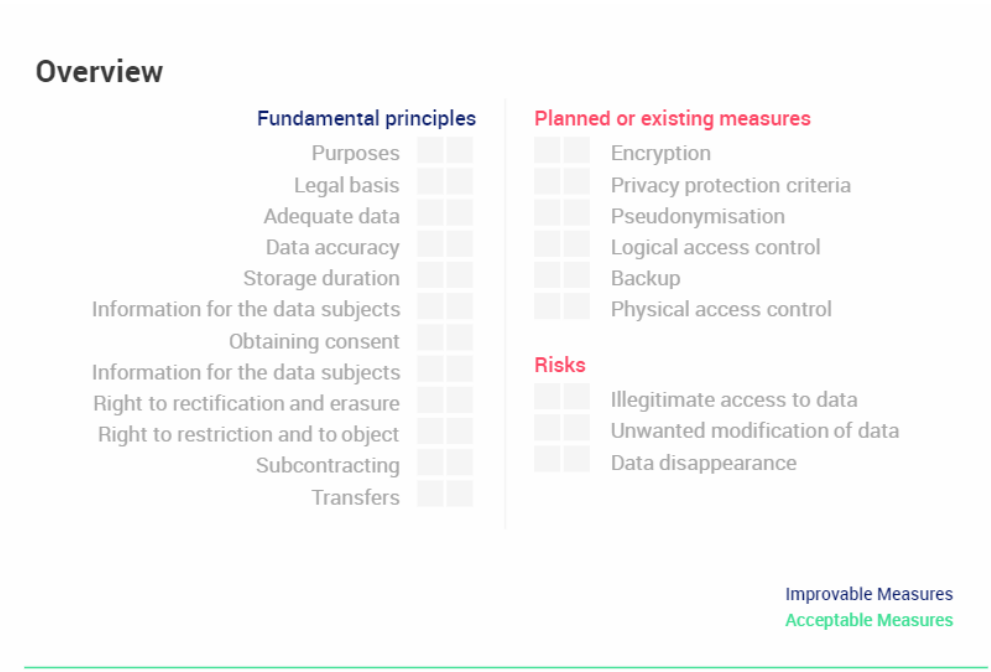
- How do you estimate the risk severity, especially according to potential impacts and planned controls?

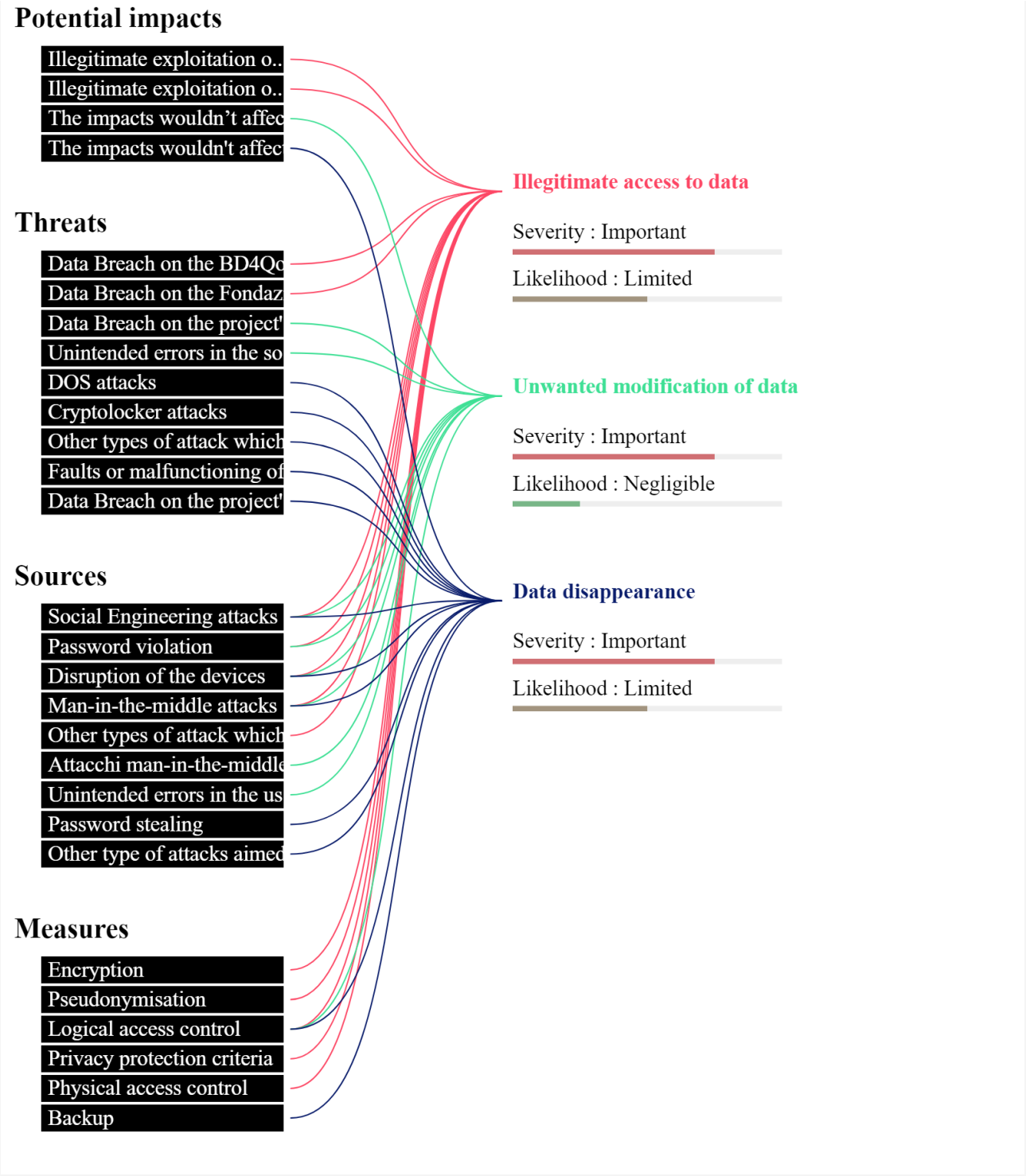
Important

- How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?

Limited

➢ Action plan

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Data disappearance
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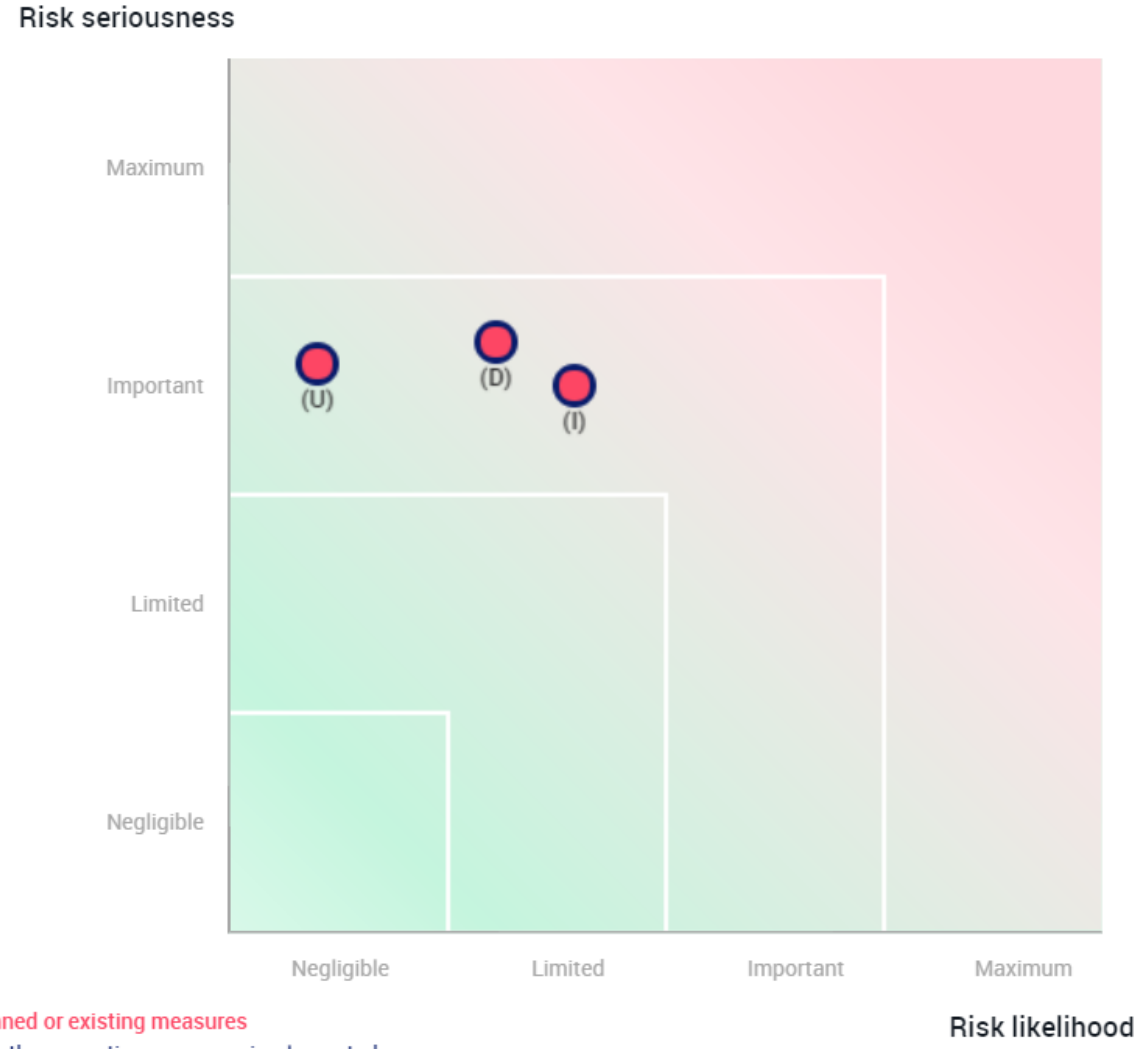

- Planned or existing measures
- With the corrective measures implemented
- (I)llegitimate access to data
- (U)nwanted modification of data
- (D)ata disappearance

08/06/2021

➢ DPO'S OPINION

The DPO of the Fondazione Casa Sollievo della Sofferenza expresses his favorable opinion on this DPIA.

The Data Controller