PATIENT INFORMATION SHEET

PROJECT TITLE: REBECCA - REsearch on BrEast Cancer induced chronic conditions supported by Causal Analysis of multi-source data **STUDY TITLE:** *REBECCA-INCLIVA-Inter-QoL*: *Quality of Life during treatment, Intervention trial*. https://rebeccaproject.eu/	
PRINCIPAL INVESTIGATOR	Dr. Cristina Hernando Melià
SERVICE	Medical oncology
CENTER	University Clinical Hospital of Valencia

We are writing to inform you about a research study in which you are invited to participate. The study has been approved by the Research Ethics Committee of its center, in accordance with current legislation, Law 14/2007, of July 3, on Biomedical Research. Our intention is that you receive the correct and sufficient information so that you can decide whether or not to agree to participate in this study. Read this information sheet carefully and we will clarify any doubts that may arise. In addition, you can consult with the people you consider appropriate.
Likewise, you can request any explanation you want about any aspect of the study and its implications throughout it by contacting the principal investigator of the project, Dr. Hernando, on the phone 96 197 35 17.

1. Voluntary participation

We invite you to participate in the study because you have been prescribed treatment with chemotherapy or radiotherapy, or you have started it in the last six months, following the usual clinical practice in the management of your disease.

You should know that your participation in this study is voluntary and that you may CHOOSE NOT to participate. If you choose to participate, you can change your decision and withdraw consent at any time, without altering your relationship with your doctor or causing any harm to your health care.

2. Justification and Objective of the study

This study aims to explore the potential of "real-world data" as a tool for monitoring patients undergoing chemotherapy or radiotherapy. Real-world data informs about people's behaviors and routines, and is collected through mobile devices and apps.
The objective of this study is to evaluate improvements in patient quality of life, derived from flexible treatment planning based onthe use of real-world data, compared to conventional care.

3. Description of the study

This study will be carried out at the University Clinical Hospital of Valencia, and it is expected that 110 patients aged **between 18 and 75 years**, **diagnosed with breast cancer** (stages I, II or III), and who are going to start or have started in the last 6 months, treatment with **chemotherapy or radiotherapy**, within routine clinical practice.

The study aims to **compare** the **quality of life of** patients and their **satisfaction with treatment**, in three countries who use **a mobile device and an application (App)** to provide data from the real world (lifestyle habits, Internet use, emotional state ...), and patients who do not make use of such a system.

The patients will be distributed into two groups (55 patients in each) randomly, that is, randomly:

1. **Control Group**: patients included in this group will receive **usual health care** (the same as they would receive if they did not participate in the study) and, in addition, they will be offeredthree **supportive telephone consultations**, providing general advice on recommended lifestyle habits.
2. **Intervention Group**: in addition to the **standard treatment**, patients in this group, as well as a companion of their choice, will use the **REBECCA system** throughout the study, facilitating the collection of **real-world data**. In this group, **three telephone support consultations** will be scheduled based on the information collected through this system, in the event of deterioration in quality of life or emotional state predicted by the system (or in the event of a possible decrease in compliance with treatment).

The REBECCA system, which will be used by patients in the intervention group, collects information through:

- an activity bracelet, also called a smartwatch;
- a computer application designed for the patient (pApp);
- optionally, a computer application designed for the figure ofthe partner[1] (cApp).
- A complementary program of the patient's Internet browser.

What information will each of these devices collect?

The **activity tracker** or smartwatch captures, through sensors, data from: acceleration, heart rate, heart rate variation, heart rate during sleep, blood oxygen saturation level, number of steps, stress (based on heart rate information and heart rate variation), sleep time and quality, intensity of movement/physical activity... This activity bracelet connects exclusively and directly, via *Bluetooth* technology, with the patient's computer application (pApp), installed on your mobile phone, to transfer the recorded data.

The **patient computing application (pApp):**

- connects with the activity tracker and recovers the captured data;
- collects the location signal (GPS) of the mobile phone;
- samples and makes available to the patient brief questionnaires (approximately 2-8 questions) to collect information on fatigue, mood, lifestyle habits;

[1] The partner is a **person chosen by the patient** to provide information on his activity environment and state, belonging to the closest environment of The patient.

- It allows the patient, if desired, to take photographs from the application itself[2] and make annotations about them (thus providing information, for example, about their diet or their environment).

The **partner's computer application (cApp)** has brief questionnaires on quality of life, symptoms or close environment of the patient, to which the colleague responds. The use of this application is optional, always in the event that the patient wishes to designate a person she trusts with whom she shares her environment.

The **browser add-on program** is installed on the patient's computer and collects data on Internet usage. **At any time, the patient can stop and resume monitoring her activity**. Likewise, you **can delete any data that you do not want to provide**. In any case, all data will be pseudonymised, since [3]**no personally identifiable information is collected** (name, IP ...) and patients are characterized by a unique code. The data captured by this browser add-on is:

- Web pages visited: address, page name, user, time of visit.
- Search terms entered in Internet search engines.
- Activity on platforms and social networks (Facebook, Youtube, Instagram ...) including: shortcuts, pages and titles of conversations, search terms, visits made (user, time of visit in profiles or groups of a certain social network or platform), comments, reactions to comments from third parties (like, dislike, emoticons, etc.).

4. Study activities

The present study lasts approximately **18 months**. All study participants will be treated according to standard clinical practice; in addition, all may receive up to **3 supportive telephone consultations**. Those included in the Intervention Group will complement throughout the study, through the use of the REBECCA system, the data collected during routine medical visits. To do this, the participants of the **Intervention Group**, as well as a person from their freely chosen environment, will be trained in the **use of the REBECCA system**, which includes mobile devices and applications, and an online tracking platform. **Each participant will provide through this system information of interest about their daily lives, which requires an approximate dedication of between 15 and 30 minutes a day** to **respond to application notices and questionnaires**. The REBECCA system will allow the **collection of information** throughout the study about their **lifestyle habits**, the **use they make of the Internet**, as well as their **mood** and **quality of life**.

5. Risks and inconvenience arising from your participation in the study

Your participation in the study involves regular use of mobile devices and apps that allow the collection of data on their lifestyle habits, Internet use, mood and quality of life.

[2] Only the **Photographs that the patient wants to take from the application** (Papp) will be used in the study. This excludes photos taken from outside the app (e.g. from your mobile phone's camera).

[3] The datos ppseudonymised do not allow identify directly to the individuals from whom they come.

The mobile device that will be used during the study is an activity bracelet, such as those commonly used during sports. The use of these bracelets does not pose any risk. However, it should be borne in mind that the use of applications requires interaction time (answering notices, answering questionnaires) and that the use of the mobile device involves wearing the bracelet correctly placed around the wrist.

6. Possible benefits

Itis quite possible that you will not get any benefit in the prognosis and treatment of breast cancer by participating in this study, however, it could help improve future patients' quality of life and satisfaction with treatment.

7. Protection of personal data

The researcher and the center are respectively responsible for the processing of their data and undertake to comply with the data protection regulations in force, Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights and Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (RGPD).

The data collected for the study will be identified by a code, so that it does not include information that can identify you, and only your doctor/collaborators will be able to relate such data to you and your medical history. Therefore, your identity will not be revealed to any person except for exceptions in case of medical emergency or legal requirement.

Access to your personally identified information will be restricted to the study physician/collaborators, competent authorities, the Research Ethics Committee and personnel authorized by the sponsor (study monitors, auditors), when they need it to verify the data and procedures of the study, but always maintaining the confidentiality of the same in accordance with current legislation.

In accordance with the provisions of data protection legislation, you can exercise the rights of access, modification, opposition and cancellation of data, for which you must contact your study doctor. If you decide to withdraw consent to participate in this study, no new data will be added to the database, but those that have already been collected will be used.

In addition, you can limit the processing of data that is incorrect, request a copy or that the data you have provided for the study is transferred to a third party (portability). To exercise your rights, contact the principal investigator of the study or the Data Protection Officer of the center/institution in dpd@gva.es. You also have the right to contact the Data Protection Agency if you are not satisfied.

The encrypted data may be transmitted to other countries of the European Union, **but in no case will they contain information that can directly identify you**, such as name and surname, initials, address, social security number, etc. In the event that this transfer occurs, it will be for the same **purposes of the study described or for use in scientific publications**, but always maintaining the confidentiality of the same in accordance with current legislation.

The researcher will take the appropriate measures to ensure the protection of your privacy and will not allow your data to cross with other databases that could allow your identification. If the investigator cannot confirm this claim, the patient should be informed of the risk of re-identification arising from the reuse of their data in future studies not defined at this time.

8. INFORMATION CONCERNING BIOLOGICAL SAMPLES

Their participation in this study **does not involve the collection and use of biological samples for research purposes**.

INFORMED CONSENT

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STUDY CODE	
PRINCIPAL INVESTIGATOR	Dr. Cristina Hernando Melià.
SERVICE	Medical oncology.
CENTER	University Clinical Hospital of Valencia

I, ___>><<_
(Handwritten name by the patient)
I have read the information sheet given to me about the study.
I have been able to ask questions about the study.
I have received enough information about the study.
I have spoken to ____>><<_
(Handwritten name by the patient)
I understand that my participation is voluntary.
I understand that I can withdraw from the studio:
-Whenever.
- Without having to give explanations.
- Without this affecting my medical care.
I freely agree to participate in the study.
I consent to the use and processing of my personal data for this investigation under the conditions explained in this information sheet.

I will receive a signed and dated copy of this informed consent document

Participant's signature — Researcher's signature

Date:____/____/____ — Date:____/____/____

(signature and handwritten date by the patient)

INFORMED CONSENT LEGAL REPRESENTATIVE

PROJECT TITLE: REBECCA - REsearch on BrEast Cancer induced chronic conditions supported by Causal Analysis of multi-source data **STUDY TITLE:** *REBECCA-INCLIVA-Inter-QoL*: *Quality of Life during treatment, Intervention trial*.	
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PRINCIPAL INVESTIGATOR	Dr. Cristina Hernando Melià.
SERVICE	Medical oncology.
CENTER	University Clinical Hospital of Valencia

I, ____>><<_
(Handwritten name by representative)
as __>><<__
_____>><<_
(Handwritten name by representative)
I have read the information sheet given to me about the study.
I have been able to ask questions about the study.
I have received enough information about the study.
I have spoken to ____>><<_
(Handwritten name by representative)
I understand that your participation is voluntary.
I understand that you can withdraw from the study:
-Whenever.
- Without having to give explanations.
- Without this affecting your medical care.

I freely consent to your participation in the study
I consent to the use and processing of your personal data for this investigation under the conditions explained in this information sheet.

You will receive a signed and dated copy of this informed consent document

Signature of the legal representative, family member or de facto related person

Researcher's signature

Date:____/____/____
(Signature and handwritten date by the representative)

Date:____/____/____

INFORMED CONSENT TO WITNESSES

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PRINCIPAL INVESTIGATOR	Dr. Cristina Hernando Melià.
SERVICE	Medical oncology.
CENTER	University Clinical Hospital of Valencia

I, ____>><<_
(Handwritten name by witness)
as a witness, I affirm that in my presence D/Dª ____
____>><<_
(Handwritten name by witness)
and the information sheet given to you about the study has been read, so that:

You have been able to ask questions about the study.
You have received enough information about the study.
You have spoken with ____>><<_
(Handwritten name by witness)
You understand that your participation is voluntary.
You understand that you can withdraw from the study:
-Whenever.
- Without having to give explanations.
- Without this affecting your medical care.

He freely consents to his participation in the study.
You consent to the use and processing of your personal data for this investigation under the conditions explained in this information sheet.

You will receive a signed and dated copy of this informed consent document

Signature of the witness — Researcher's signature

Date:____/____/____ — Date:____/____/____

(Signature and handwritten date by the witness