REBECCA

Integration of real-world data into clinical data for better personalised treatment of breast-cancer patients

1. OBJECTIVES

REBECCA is a Horizon 2020 project [2021-2025] that aims to **tap into the potential of Real World Data** to provide personalised treatment and care to breast cancer patients or cancer survivors. The ultimate goals of REBECCA are to advance clinical research by moving beyond randomised controlled trials and to **improve post-treatment in breast cancer** to increase patients' quality of life.

REBECCA also aims at the mass adoption of Real-World Data for understanding **complex chronic conditions** and ultimately wishes to establish Real-World Data as a valuable clinical research and patient management tool.

2. BACKGROUND

In Europe, breast cancer is the most frequently occuring cancer type on a yearly basis. In 75% of cases, breast cancer patients and survivors suffer from **comorbidities**, such as hypertension, chronic obstructive pulmonary disease, rheumatologic disease, and/or diabetes mellitus. Understanding chronic diseases that appear during or after the breast cancer diagnosis can therefore help facilitate therapeutical decision-making.

Currently, **randomised controlled trials** (RCT) are the gold standard in clinical research to establish causal relationships. However, there are several limitations of using RCTs for complex chronic conditions such as breast cancer. Some of these can be overcome by using real-world, observational data.

Limitations of RCTs for complex chronic conditions	Advantages of Real-World Data use in REBECCA
Expensive and time-consuming	Data already exists in large volumes and can be accessed relatively easily and at a lower cost
Small population sample with only a subset of relevant variables	Large number of subjects and can include population samples with various characteristics
No control over independent variables	Uncontrolled conditions thus increasing generalisability and ecological validity

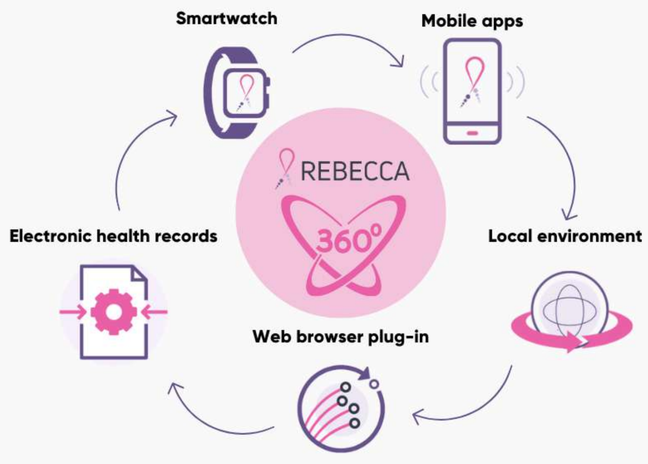
3. METHODOLOGY

The REBECCA 360° platform was designed to collect Real-World Data and therefore support detailed and continous monitoring of breast cancer patients.

The **REBECCA 360° platform** will record data on the patient's:

- behaviour, including diet, physical activity, sleep
- online interactions conveying their cognitive and emotional state
- living environment indicators, including home environment and socio-economic context
- medical history and medical outcomes from electronic health records (EHR)
- Patient-Reported Outcome Measures (PROMs)

This **Real-World Data** is collected through sensor and log data retrieved via electronic health records and innovative technical tools such as mobile apps and wearable devices (e.g. smartwatches or fitness bands).

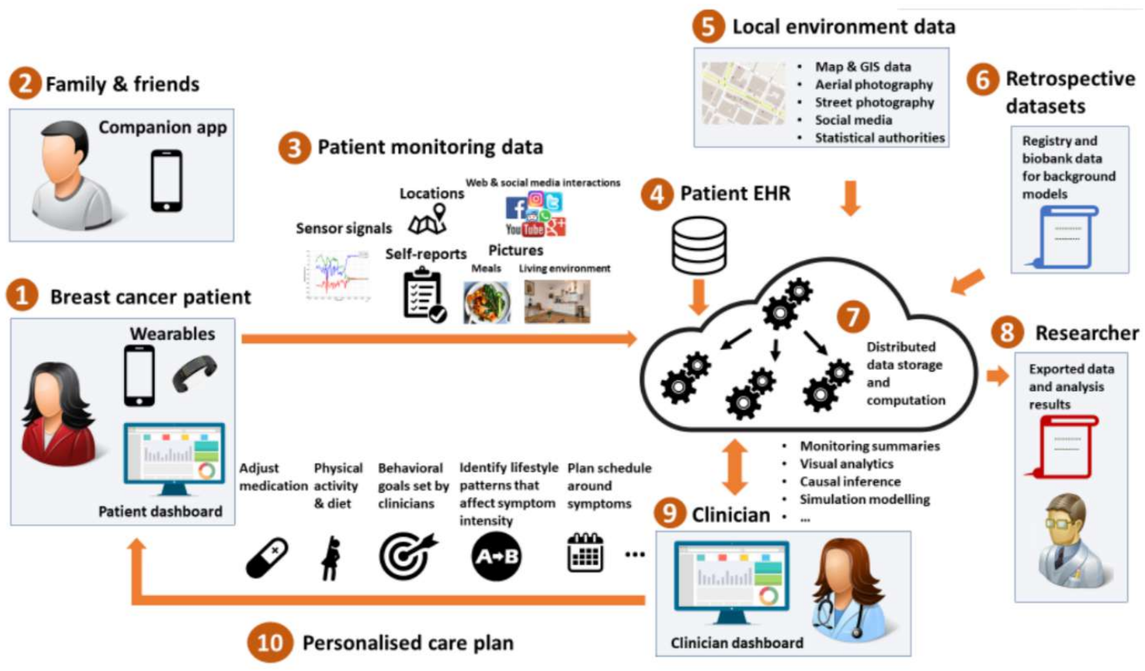


Real World Data in REBECCA

Once collected, the real-world data is then processed by the REBECCA 360° monitoring platform to extract **indicators**, such as clinical status, emotional status or lifestyle. The indicators can then be used in research to establish **causal relationships** with Patient-reported outcomes measures (PROMs) and complex chronic conditions, as well as shed light on confounders.

4. THE REBECCA SYSTEM

REBECCA collects Real-World data to ultimately provide breast cancer patients and survivors with personalised treatment plans through the following process: Breast cancer patients are monitored though mobile and wearable applications, and browser plugins (1). Patients can also authorise family and friends to provide data about their physical and mental health, through a companion app (2). Data from apps (3), clinical data (4), and data from the local urban environment (5) are processed by the system to produce explainable causal models (6)(7), which are shared with clinical researchers (8). This will support improved patient management through data-driven decision making (9), and help clinicians provide **personalised and improved care plans** for patients (10).



The REBECCA system

5. BENEFITS OF REBECCA

1. Enable health managers and practicioners to measure the satefy and effectiveness of breast cancer treatment
2. Improve clinical outcomes and patient-reported outcomes measures
3. Help develop personalised recommendations and treatments by taking into consideration the living circumstances, the ongoing emotional state and the pharmacological treatment profile of each patient
4. Patients benefit from improved care plans, more effective treatment, reduced side effects, faster recovery, and improved quality of life.
5. New knowledge available on clinical management of cancer patients and use of Real-World Data that can inform guidelines and practices for post-cancer treatments.

6. CONCLUSION

The REBECCA project is currently in its 2nd year of development. Learning so far is that having a strong co-creation process in place, and involving breast cancer patient at all stages of the REBECCA 360° platform development, is crucial to enhance patient acceptability and trust in this innovation. It has also resulted in increased active engagement in healthcare decisions.

By using real-world data, combined with the advanced REBECCA 360° monitoring platform and innovative causal data modelling methodologies, REBECCA will **close the gap** between clinical research and practice in the management of patients who have undergone or are still in primary cancer treatment.

*Interested in joining the **REBECCA stakeholder network** to collaborate with us and receive access to the latest findings on breast-cancer-related clinical endpoints and on the practical use of Real-World Data and its benefits?*
Sign up through the QR code to engage with us.

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