WESHARE

INFRASTRUCTURE

OPERATING CHARTER

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1. Purpose of this Charter

The purpose of this charter is to describe the functioning of the WeShare Infrastructure.

It is intended for research sponsors (academic, private) and oncology researchers wishing to conduct studies or research involving a theme associated with Quality of Life (QoL) and/or Social and Human Sciences (SHS).

These studies or research can be conducted prospectively using the data collection tools offered by WeShare or retrospectively using data already collected and stored in a Health Data Warehouse (HDW).

2. What is the WeShare Program ?

2.1 The WeShare Program

2.1.1 Rationality and ambitions

There are currently more than 18 million individuals diagnosed with cancer worldwide/year, and this number is expected to increase to more than 26 million by 2040 (Shapiro, 2019). Over the past few decades, research focused on cancer treatments has been productive and has led to fundamental advances that enable the use of personalized, biologically driven approaches. As a result of improved management and prolonged life or reduced mortality for some cancers, it is expected that an increasing number of people diagnosed with malignancies will become part of a new community of "cancer survivors. These "cancer survivors", living with or beyond their disease, face persistent problems as well as the after-effects of their previous or ongoing treatments.

In 2006, Rowland defined a "cancer survivor" as "anyone with a history of cancer, from the time of diagnosis and for the rest of their lives" (Rowland, 2006). This increasingly long lifespan of cancer survivors has led to the emergence of new research priorities and needs. In particular, in addition to continuing to find therapies that will prevent or stop the disease, we must now focus on reducing the medical, psychological, and social burdens of cancer and improving QOL (Mullan, 1985). (Ganz, 2006). Recent and disturbing figures attest to the magnitude of this problem. Data from a contemporary cohort of over 12,000 French breast cancer survivors (CANcer TOxicities [CANTO]), in particular, identified problems that persist for several years after diagnosis. More than 50% of patients suffer from at least one severe chronic symptom after treatment, more than 30% report significant emotional or social dysfunction, and post-cancer unemployment is high: approximately 20% of women who were employed before their cancer stopped working 2 years after their breast cancer diagnosis (Ferreira, 2019; Dumas, 2019; Pistilli, 2020). Data also suggest that this post-treatment functional decline correlates with a higher rate of noncompliance with hormone therapy, a treatment administered to prevent cancer recurrence (Pistilli, 2020).

The definition of management with a transformative impact on the medical and social burden of cancer can only occur if we initiate a process of integration between classical clinical research on drug development and SHS, while using disciplines such as psychology, sociology, economics, ethics and communication sciences as catalysts. This process will allow: 1) to acquire a fine and thorough understanding of i) the combined medical and social hazard of cancer, by defining complex and multifactorial models and ii) the societal and economic impact of new innovative guidelines for cancer care management; 2) to propose multidimensional interventions, taking into account biomedical, psychological, socio-economic and ethical determinants.

In part, this process has begun in recent years, marking the beginning of a new way of thinking about cancer research. However, although we have seen an increase in the number of funded studies and published articles characterizing the impact of these lines of research on cancer, the field is still very small. The cancer research budget is primarily allocated to research addressing basic science, translational research, or drug development, while less than 10% of the budgets are devoted to survivorship research, research that incorporates the SHS component (Harrop, 2011). Of the current studies, 60% of research is observational and uses primarily descriptive methodology without integration of medical, behavioral, social, and biological data. Qualitative studies are important in cancer survivorship research because they identify problems faced by survivors and interventions to address or counteract them. However, few large-scale interventional studies are available to date. In addition, there are no research programs with national or international coverage (Harrop, 2011). As a result, this translates into a lack of Type I/1a evidence in the majority of research in this area.

In order to provide answers to all of the above problems, the WeShare program was created (Figure 1). This program offers tools to implement :

1) innovative observational, qualitative or interventional studies in the field of QOL and SHS in oncology,

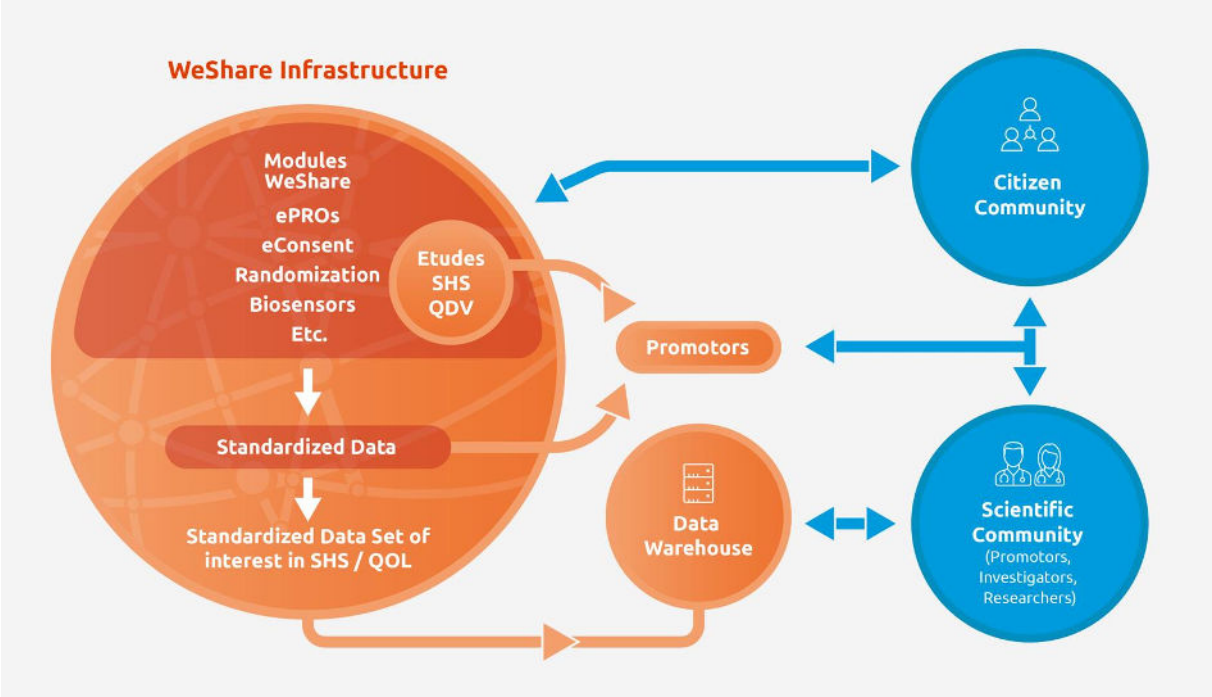
2) a Health Data Warehouse (HDW) that will allow, by pooling data from these studies, the conduct of large-scale cross-sectional studies. Indeed, researchers do not currently have massive, longitudinal and standardized data, allowing the evaluation of essential questions related to the QOL and the SHS. Such data will facilitate understanding of how these factors interact and influence the survival experience.

Beyond the tools outlined above, two communities are created through the WeShare program:

- An active community of researchers fostering the development of transformative cancer research with a strong SHS and QoL component via the WeShare Infrastructure

- An active community of patients, users and citizens contributing to the development of patient-user-citizen oriented research

Figure 1: Concept of the WeShare program



2.1.2 Funding method and term

To create the WeShare infrastructure, a multidisciplinary consortium was set up. It brings together seven partners, including Unicancer (coordinating institution), Gustave Roussy, the François Baclesse Center, the Léon Bérard Center, the Ecole Polytechnique, the National Quality of Life and Cancer Platform and the Seintinelles association. This program is funded by the ANR, Equipements Structurants pour la Recherche (ESR / EquipEx+) for 10.9 million euros.

This funding covers the development and implementation phases of the infrastructure over a period of 6 years. WeShare's business model takes into account pricing adapted to the status of the study/research promoter and to demand (type of module, HDW sharing, HDW access).

2.2 The WeShare Program : Phases, Modules and Health Data Warehouse (HDW)

2.2.1 The different phases of the WeShare program

The WeShare program includes a 6-year development phase (from 2021 to 2026) and includes

- An implementation and interconnection phase during 3 years (from 2021 to 2023): the WeShare platform is built from pre-existing functionalities or modules, to be consolidated and improved or from modules available on the market. These modules are interconnected and optimized in

WeShare according to the needs of the WeShare consortium. Pilot projects are selected to implement and validate the modules.

- An expansion stage during 3 years (from 2024 to 2026): the objective is to continue the development of new modules, more and more functionalities are added according to the specific needs of the pilot projects emanating from the scientific community insofar as these can serve future projects.

Researchers can access the modules as soon as they are validated by the WeShare partner(s) who developed the module.
This 6-year development phase will be followed by a 2-year consolidation and exploitation phase (from 2027 to 2028).

2.2.2 Proposed and upcoming modules

The modules that the WeShare consortium wishes to develop and offer to the scientific community are detailed in the Access Guide to the WeShare Platform and on the WeShare website http://weshare.unicancer.com

The implementation of these modules takes into account the fact that the tool for collecting, managing and making available the data collected during the various studies/research is developed in compliance with security standards and regulations.

2.2.3 The Health Data Warehouse

A Health Data Warehouse (HDW) will allow for large-scale cross-sectional studies by pooling standardized data sets from studies/research (using FAIR standards).

The WeShare website http://weshare.unicancer.com plans to integrate a "Studies and Features" section that will allow you to know the studies for which sponsors have agreed to contribute data and the type of data corresponding to the WeShare HDW.

3. Using the WeShare Infrastructure Modules

3.1 Development of a study via the WeShare platform - Access process

You wish to conduct studies or research in oncology, particularly on topics related to Quality of Life (QOL) and/or Social and Human Sciences (SHS) and use one or more of the WeShare platform modules described in paragraph 2.2.2. As a research actor, you can access the modules of the platform as soon as they are validated by the WeShare partner(s) who developed the module. **The process of accessing the WeShare platform is detailed in the Access Guide to the WeShare Platform (available soon).**

3.2 Pricing

A fee for access and use is applied according to different criteria:

- The status of the promoter/researcher: partner/collaborator/non-partner, academic or private
- The need or not to carry out specific developments
- The number of research projects/studies that the sponsor/researcher wishes to conduct via the WeShare platform per year
- The possibility of uploading standardized data (clinical, socio-economic, ePROs, etc.) collected through your research/study projects into a health data warehouse. The purpose of the data upload is to support future research projects in SHS and QDV.

3.3 Contract

The contractual phase begins as soon as you agree with the pricing conditions and the proposed schedule. A contract is then proposed to you. This contract includes the following elements :

- the legal status of the parties,
- the needs, deadlines and delivery,
- the rules for using the platform, including the information to be provided to patients/citizens/study users regarding the use of the WeShare infrastructure
- for the concerned study, the data to be stored in the WeShare Data Warehouse once it has been used by the sponsor, in order to allow data reuse for new or secondary data researches
- the financial terms and conditions and the related developments planned within the framework of the project
- the distribution of data protection obligations,
- in the event that standardized data is included in the WeShare Data Warehouse, Unicancer's commitment to inform the sponsor of any subsequent research carried out using the data it has agreed to include in WeShare and the sponsor's right to object, as well as the rules of access to the Data Warehouse to be respected by any project leader
- the rules of publication to be respected by the promoter in the framework of his study.
- the importance of making the results of your research available to the public and the possibility of doing so via the services of the WeShare platform

3.4 Data management, hosting and protection of personal data

As an infrastructure, WeShare hosts the data of studies/research that will rely on the collection modules offered by the platform. Thus, it is the responsibility of the sponsor/researcher of each study/research using these modules to ensure that the processing of the data collected complies with the regulations on personal data.

The servers that will host the study data collected via the WeShare modules will be stored in AZNetwork's Datacenter in a Health Data Hosting (HDS) environment.

An access account to the WeShare platform is created for each patient/participant. This account is used to disseminate the results of the study in which the patients/participants are participating and/or to inform of the start of new studies (clinical trials but also quality of life and/or human and social science surveys) using the WeShare platform in which the patients/participants are likely to participate.

For clinical trial studies, sponsors issue a dedicated study information and consent form to each patient/participant. This information note must contain a mention of the use of the various WeShare modules and the payment of standardized data into the health data warehouse. The standard statements to be added to the information note and the protocol are provided to the sponsor during the contractual phase.

A trusted third party stores the correspondence between the patient's study identifiers, participants and their identity. The trusted third party selected is HDS certified. Unicancer never accesses the patient's or participant's directly identifying data. Patients' rights will be exercised with the sponsor as indicated in the information note with the help of Unicancer if necessary.

4. Research using data of the WeShare HDW

You want to conduct studies or research and need to use data from the WeShare HDW. **The process of accessing the HDW is detailed in the WeShare HDW Access Guide (available soon).**

A fee for access and use is applied according to different criteria:

- The status of the sponsor/researcher: partner/collaborator/non-partner, academic or private
- The volume of data requested

The contractual phase begins as soon as you agree with the pricing conditions and the proposed schedule.

5. Publication rules

The sponsor/researcher undertakes to expressly cite UNICANCER as the coordinator of WeShare in any publication, communication or presentation related to the Study or Research.

In addition, the promoter/researcher undertakes to mention the support provided by the ANR under the "Investissements d'avenir" program, by indicating the number of the Grant Awarding Agreement, in their own communication actions on the "WESHARE" Project (ANR-21-ESRE-0017), its results and in their publications (for example: "This work uses the WeShare infrastructure which benefits from a state grant managed by the National Research Agency under the France 2030 integrated future investment program, bearing the reference "ANR-21-ESRE-0017"). Oral communication materials, poster communications and websites must also display the "France 2030" logos. The promoter/researcher undertakes to deposit the scientific publications (full text) resulting from the research, development or innovation project in an open archive, either directly in HAL or through a local institutional archive.