

Cultural differences and individual preferences have a significant impact on healthcare and clinical trial experience. Solutions exist in attempt to **reduce these disparities, but often rely solely on healthcare providers and industry stakeholders to develop flexible approaches to take all variables into consideration. How are we then efficiently incorporating the patients' voice into drug development? Have we learned enough about the reality of what it means to be a patient living with a chronic disease? Having open discussions with patients has become necessary for the scientific community to deepen its understanding of the reality of patients' day to day lives, and to be able to consider their various experiences throughout the steps of drug development.**

At Kayentis we collaborate with several patient experts and associations. We recently invited Carine, Cecilia, and other fellow members from a cancer patient association which aims to enable women facing breast cancer to perform mountain activities as a reprieve from the heavy healthcare environment, and to find energy and self confidence that can often be lost following long periods of treatment or illness.

Their testimonies confirm the value that listening to patients can bring to clinical research.

The essential need to increase patient feedback in cancer research

Cancer cases are rising, and every year 20 million people are diagnosed with cancer around the globe. Cancer can unfortunately touch many different organs, but among the 50 million people currently living with cancer, 15% of them have breast cancer, which makes it the **most widespread of all types**. Despite these figures, cancer treatment and diagnosis have benefited from great scientific progress in the last two decades. Patients can now receive innovative treatments, more adapted and personalized treatment protocols, and many countries have now access to advanced screening techniques.

In addition to developing screening procedures and treatments, cancer research has also tackled deciphering patients' quality of life through collecting outcomes directly from patients during clinical trials. Oncology trial protocols are increasingly integrating electronic patient reported outcomes (ePROs) and electronic diaries (eDiaries) as endpoints. With patients' wellbeing at the forefront of the regulators' consideration **and the rising number of PROs in drug labels** over the past two decades, the EMA and the FDA both recognize guidance and **flexible approaches** are needed as PROs are used more and more in oncology research.

Current PROs in oncology research center around collecting data related to symptomatic reactions, side effect impact, functional impairment or pain, which does allow for direct patients' feedback in clinical research. However, this information does not sufficiently consider or fully understand what it means to be a patient. We must draw a better picture of the burden that both the disease and the clinical trial procedures place on patients.

1. Perceiving the specific context of the pandemic differently

Through moving and rewarding exchanges we learned more about the day-to-day lives of these young women fighting against breast cancer. The healthcare context of these last years played a very specific role in their journey. Some mentioned the positive impact of the lockdown period, which brought the opportunity to spend time with family and step away from the hospital setting in an unforeseen way. Others described deep feelings of loneliness, especially when undergoing post-surgery recovery alone at the hospital whilst no visitors were permitted for several long weeks. All agreed social interactions are more than a necessary support to face the disease.

2. "There are as many cancers as people who have it"

Each individual person will have their own experience regarding cancer treatment and/or participation in a clinical

trial. This leads to extremely variable impacts of a cancer diagnosis. Being diagnosed with the same disease even at approximately the same age, does not indicate the same treatment or experience of a clinical trial. Our invitees explained receiving part or all of the complete set of cures that can contain chemotherapy, hormone therapy, radiotherapy, and surgery can severely impact self-confidence and self-image, as well as the capacity to maintain social relationships.

Reflecting on how the announcement of her illness happened, Carine told how “rude it was and how hard it has been to be confronted to such a specific and unknown vocabulary”.

On top of the disease and the treatments, taking part of a clinical trial can also affect the capacity to continue to work and or to maintain social and physical activity. What this looks like though and the lasting impact it will have varies depending on the individual.

One of the women recounted the intense, heavy pain associated with cancer, its presence as a reminder of the disease “when the pain is back, the feeling of not being cured surfaces”.

Another woman, Cecilia, focused on her experience after the treatment period ended.

She explained that the fight continues because the threat of cancer will always be there and the time after can “be even more impactful because you feel more alone after the treatments”.

3. Facing cancer creates a shift in the way time is perceived



“I enjoy the little things even more, but at the same time, I find it very difficult to imagine and plan for the future” highlighted Carine.

Fabienne mentioned the speed of the process right after diagnosis, emphasizing that *“procedures and treatments follow one another, the notion of time is completely disturbed”*.

Cecilia, a breast cancer patient and a hospital nurse herself, referred to the time needed from healthcare professionals *“taking the necessary time and adapting the tone and the behavior to the patient, when announcing such a hard news or when explaining the treatment or the trial’s journey to a patient, is paramount”*.

Through multiple precious testimonies, different feelings and experiences were expressed, even though all suffered from the same disease at approximately the same age, in the same geographical area. However, they all agreed that healthcare providers and industry stakeholders should try to consider patients as individuals, and adapt their behavior, care, services, and systems to these individual people.

Despite heavy workload or structural challenges, healthcare providers and industry stakeholders must rethink how they approach the individual patients and spend the adequate time that conveying such news requires. To do this, there is no other option than working with and giving a voice to patients to fully understand their lives. Flexible systems and solutions must be adopted to respond to their various needs. Every patient is a potential user of a digital solution. Being able to adapt and accommodate patients’ individualized needs is essential to reduce the burden of their disease.

Key Words:

- eCOA
- ePRO
- eDiary
- cancer patients
 - oncology
- data collection
- clinical trial

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