

### The Power of Living Well

One Solution

For Psycho-Oncological Care and Cost Savings.



### **Foreword**



When Patients get a cancer diagnosis, their world changes in an instant. They often stop hearing anything the Doctor says. They say, "After I heard the word "cancer," everything sort of went blank." Living Well can help Patients by having them do something every day that helps them remember who they are. You are not just a cancer Patient. You are someone who can practice gratitude and breathe and meditate and move. And you are still the wife, and you are still the mom. So I think it brings them back to themselves. I think the App allows professionals to offer Patients another tool that can support them around the clock. We are not with them every minute, but everyone has their phone with them.

Mary, nurse, assisted cancer Patients in a Living Well's clinical trial at MemorialCare Cancer Institute, Long Beach Medical Center, US.

### Coping with a cancer diagnosis and undergoing treatment can be overwhelming and emotionally challenging for Patients.

They may face a number of mental health challenges, including cancer-related distress, anxiety, depression, and a sense of loss of control over their lives. These can then significantly contribute to a decline in their quality of life and, consequently, their overall health and treatment outcomes.

Unfortunately, although the incidence of cancer is increasing worldwide, healthcare systems remain inefficient in terms of delivering relevant psychological support. This is due to the lack of resources or finances, geographic or psychological barriers, or simply an insufficient number of trained specialists.

Consequently, the stress of the massive cost of oncology care is further exacerbated by Patients' unsupported cancer-related





68%

Percentage of users with a clinically significant decrease in anxietv<sup>1</sup>

**62%** 

Percentage of users with a clinically significant decrease in depression<sup>1</sup>

\$4.7M

of savings for a Provider implementing Living Well (for every 1000 engaged users²)

¹ See the chapter: "Real-World-Data Validation" for more information

<sup>2</sup>Source: Reduced-cost and cost-avoidance ROI model; internal calculations by Prosoma psychiatric distress, which negatively impacts their treatment adherence and engagement, as well as their overall outcomes. These Patients may have a higher risk of treatment complications, a reduced tolerance for side effects, or even require additional consultations or prolonged hospital stays. This pattern leads to escalated healthcare resource utilization and an **increased economic burden on the entire system**.

**Living Well by Prosoma** provides relevant psychological support to cancer Patients from the moment of diagnosis that helps them regain control over their well-being. It relieves cancer-related stress, anxiety, and depressive symptoms and, thus, improves their quality of life, and overall outcomes. By bridging the gaps and breaking barriers to accessing respective care, it delivers cost-effective and comprehensive **support instantly and reliably**.

With its well-defined, therapeutic, Cognitive Behavioral Therapy Program (CBT), Living Well provides one of the most effective, evidence-based approaches in today's psycho-oncology. The way that each Patient responds to that distress is highly subjective, and their negative emotional and behavioral responses are more related to illness perception than their objective medical state. CBT interventions target such maladaptive thinking to improve Patients' cognitive picture of the disease and, therefore, their behavior and quality of life.

Living Well combines world-leading expertise in psycho-oncology, digitalization, mobile device usage trends, and advanced mobile tech developments, making for a state-of-the-art Solution that provides just the support needed. In this document, we will introduce more of Living Well's capabilities, thus, highlighting its potential to **scale the value delivered**.

By addressing Patient needs early on in the intervention, Living Well manages to support not only the Patient needs, but also those of Therapists, Doctors, and Providers. All stakeholders involved in the treatment are benefiting from Living Well's multitude of functionalities and features, while also unlocking substantial value from this **highly scalable Solution**. We estimate that the savings of Providers who integrate Living Well into their care amounted to \$4.7M for every 1000 engaged Program users<sup>1</sup>.

Furthermore, although this paper highlights the value for Patients, Physicians, and Providers, Living Well benefits stakeholders across the entire system, including Pharmaceutical Companies, Healthcare Insurers, and others, in both tangible and intangible ways.





### **Table of Contents:**

Foreword	
Delivering Mental Health Care for Cancer Patients	05
Rising Cancer Cases, Escalating Costs   06 Cancer as a Challenge to Patients' Mental Health   07 Cognitive-Behavioral Approach Driving Psycho-Oncology   08 Bridging The Gap for Accessible Mental Health Care   09 Digital Healthcare. The Future of Cancer Mental Care   10	
The Power of Living Well by Prosoma	11
Empowering Capabilities   13  Providing Support Throughout the Patient Journey   14  Tested and Approved. Patients Tell Their Stories   15  Solid Support Rooted in Science   17  Global Certification to Scale the Support   18	
Scientific Validation. Proof of Effectiveness	20
About Our Clinical Studies   20 About Our Real-World-Data Analyses   24 About Patients' Retention   27	
Scaling the Value of Living Well	27
Supporting Patients, Empowering Providers   29 Reducing Healthcare Costs. ROI Calculation   30 Scaling the Value for Partners. Case Studies   32	
Closing Remarks	34





### Delivering Mental Health Care to Cancer Patients Today's Landscape



People still fear stigmatization when they seek psychological help and therapeutic services. At the same time, those seeking help face the challenge of finding a suitable therapist because the range of psychological support available is not sufficient. There is a lack of the necessary care structure to meet the existing and growing demand - even in cities, but especially and quite massively in rural areas. In Europe and worldwide, cancer patients lack access to psychological support and behavioral therapy.

Dipl.-Psych. Christa Diegelmann, Psycho-oncologist, researcher, author, ID Institute for Innovative Health Concepts, Germany

### Rising Cancer Cases, Escalating Costs

Over

**30M** 

estimated cancer cases in 2040

Ove

\$25TN

estimated global economic cancer cost in 2050 Cancer is the leading cause of death worldwide<sup>3</sup>. According to WHO, with nearly 10 million deaths alone in 2020<sup>3</sup>, the estimated number of cancer cases will grow further, from 19.3 million globally in 2020 to 30.2 million in 2040<sup>4</sup>. WHO reports that around one in five people will develop cancer before the age of 75<sup>5</sup>.

With the rising incidence of cancer, there come substantial costs. A study from 2018 revealed that the total cost of cancer in Europe that year amounted to 199 billion euros, with 103 billion euros being spent on cancer care alone<sup>6</sup>.

The estimated global economic cost of cancers from 2020 to 2050 is expected to reach 25.2 trillion international dollars<sup>6</sup> when taking into account factors such as premature mortality and reduced productivity<sup>7</sup>.

Clearly, cancer and its associated costs pose a significant challenge to economies worldwide. However, the negative impact of the disease extends beyond direct care expenses and workforce consequences. Less commonly addressed is the profound effect cancer has on the mental health of Patients.

<sup>3</sup>https://www.who.int/news-room/fact-sheets/detail/cancer, <sup>4</sup>https://gco.iarc.fr/tomorrow/en/dataviz/isotype; <sup>5</sup>https://apps.who.int/iris/bitstream/handle/10665/330745/9789240001299-eng.pdf; https://www.ejcancer.com/article/S0959-8049(20)30026-5/fulltext; <sup>7</sup>https://jamanetwork.com/journals/jamaoncology/fullarticle/2801798



A person's mental and physical health are interrelated. Thus, psychological stressors can strongly impact the medical course of the disease. The particularity of cancer is that the diagnosis is perceived as a threat to life. Massive, existential fears arise. The stress is so high that the brain literally blocks. Our task is to help Patients regain the ability to use their own resources to cope with the disease.

Dipl.-Psych. Margarete Isermann, Psycho-oncologist, researcher, author, ID Institute for Innovative Health Concepts, Germany

### Cancer as a Challenge to Patients' Mental Health

+113%

### increase in costs<sup>8</sup> of care

for cancer Patients suffering from depression

Up to

**50%** 

of cancer
Patients suffer
from
depression
and/or
anxiety°

### Depression leads to:

prolonged hospital stays<sup>10</sup>, physical distress<sup>10</sup>, poorer treatment compliance<sup>11</sup>, lower quality of life<sup>12</sup>, increased desire for hastened death<sup>13</sup> Coping with a cancer diagnosis and undergoing treatment can be overwhelming and emotionally challenging for Patients.

They may face various mental health challenges, including cancer-related distress, which often disrupts their ability to cope with the illness, the physical symptoms that come with it, and their treatment<sup>14</sup>. However, as distress is subjective, some Patients are able to manage the stress of diagnosis and treatment<sup>15</sup>, while others experience more complications in illness adjustment, as well as **anxiety and depressive symptoms**. The numbers state that as many as **half of Patients** undergoing treatments for cancer suffer from at least one of these symptoms<sup>16</sup>. Moreover, the rates of major depressive disorder are up to three times higher for them than for that of the general population<sup>17</sup>.

Cancer-related distress may contribute to reduced quality of life, meaning Patients may experience a decline in their physical, emotional, social, and spiritual functioning<sup>18</sup>. Numerous studies demonstrate that suffering from a mental health condition can worsen the outcomes of cancer treatment. For example, in a group of breast cancer Patients, depression and anxiety were associated with disease recurrence and higher mortality<sup>19</sup>. Moreover, depressed Patients are less likely to comply with Doctor's instructions<sup>20</sup> or to exercise regularly, and they have a tendency to abuse tobacco or alcohol<sup>21</sup>.

Therefore, in order to properly or even prevent the various challenging consequences of mental health problems, it is **essential** to offer cancer Patients sufficient mental health support in addition to their regular cancer therapy.





<sup>8</sup> https://pubmed.ncbi.nlm.nih.gov/29601657/, 9 https://pubmed.ncbi.nlm.nih.gov/12118028/

<sup>&</sup>lt;sup>10</sup>https://spcare.bmj.com/content/bmjspcare/5/4/381.full.pdf, <sup>11</sup>https://www.sciencedirect.com/science/article/pii/S014067360002821X.,

<sup>&</sup>lt;sup>12</sup>https://pdf.sciencedirectassets.com/271242/1-s2.0-\$0885392400X00188/1-s2.0-\$0885392496001819/main.pdf,

<sup>&</sup>lt;sup>13</sup>https://www.sciencedirect.com/science/article/pii/S0885392407002072 <sup>14</sup>The NCCN 2020 Virtual Annual Conference,

<sup>&</sup>lt;sup>15</sup>https://www.hindawi.com/journals/tswj/2019/9750940/ <sup>16</sup> https://pubmed.ncbi.nlm.nih.gov/12118028/

<sup>&</sup>lt;sup>17</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4356432/, https://pubmed.ncbi.nlm.nih.gov/22727334/

<sup>&</sup>lt;sup>18</sup>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2935927/<sup>19</sup>https://www.nature.com/articles/s41380-019-0595-x.;

<sup>&</sup>lt;sup>20</sup> https://pubmed.ncbi.nlm.nih.gov/8433390/ <sup>2</sup>1https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2935927/

### Cognitive-Behavioral Approach Driving Psycho-Oncology

Studies reveal that **psychotherapeutic** interventions significantly reduce psychosocial problems in cancer Patients, leading to improved quality of life as well as social and emotional functioning during and after oncological treatment<sup>22</sup>. Furthermore, Patients' emotional and behavioral responses are found to be closely related to their perception of the illness rather than their objective medical state and diagnosis<sup>23</sup>.

As a result, CBT has emerged as one of the most frequently used and most effective evidence-based approaches in psycho-oncology. This approach is based on the understanding that one's mood and behavior can be modified by addressing maladaptive thinking. Then, by targeting Patients' dysfunctional thought patterns, CBT helps to improve their cognitive understanding of the disease and, thus, to manage anxiety and enhance their overall state of mind, behavior, and quality of life<sup>24</sup>.

<sup>22</sup>https://pubmed.ncbi.nlm.nih.gov/32496507/; <sup>23</sup>https://onlinelibrary.wiley.com/doi/pdf/10.1111/ppc.12265, https://pubmed.ncbi.nlm.nih.gov/16731240/; <sup>24</sup>e.g., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6457819/, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008529.pub3/full#0



Every night before I went to bed, I started to have more anxiety than I did any other time during the day. It was because, for so long, things were happening late at night that would land me in the ER. So I had this rational and irrational thought of, ok, tonight if I feel this or this, I have to wake up my husband so he will drop me off at the ER. I would start to fantasize in a way, what's the worst thing that is gonna happen. Oh! Now this is going to happen, and then this is going to happen. I had a narrative in my head. But one of the lessons in Living Well was about where your thinking is coming from. I had to stop myself and go what you're thinking now, Jamie, is destructive, but also it's not true. You're coming up with a storyline in your head of what could happen.

Jamie, cancer Patient taking part in a Living Well's clinical trial at MemorialCare Cancer Institute, Long Beach Medical Center, US.

### **Bridging the Gap for Accessible Mental Health Care**

Although psycho-oncological support is increasingly becoming a standard part of cancer care in various countries, there is still a significant gap in delivering respective care in a sufficient manner. This is mainly due to a lack of trained specialists (psychotherapists, psycho-oncologists), the ongoing stigma around mental health, and financial and geographical barriers. Therefore, the need to find an effective and scalable Solution is urgent, as managing associated cancer symptoms can be overwhelming for both Patients and Providers.

### **Patient Provider**

Due to a lack of psychological support<sup>25</sup>

• Increased Healthcare Utilization, as Patients may seek additional consultations, impacting the hospital's overall flow and straining its resources, resulting in a shortage of skilled personnel to help.

• Increased ED Utilization by Patients experiencing mental health crises or emotional distress, which can further burden the

healthcare system and potentially divert resources from other

+145%

more likely to require

emergency care

critical cases. • Longer Hospital Stays can result from a need for additional mental health support, which can then complicate and delay the recovery process. This leads to increased healthcare costs and

+103%

more likely to be rehospitalized in 30 days

- Reduced Treatment Adherence impacts Patients' tolerance to treatment-related side effects, leading to suboptimal outcomes and increased healthcare utilization.
- Increased Healthcare Costs caused by additional resources required to address the mental health needs of Patients, such as increased staffing and specialized counseling services, can impact the financial stability of hospital systems.
- Healthcare Provider Well-being is negatively impacted as treating Patients with mental health challenges demands emotional energy and resources, which may lead to Provider burnout and reduced job satisfaction.

Currently, no healthcare system in the world offers sufficient mental health support accessible to all cancer Patients post-diagnosis. Digital interventions can make a promising Solution to address the challenge.

impacts bed availability.





<sup>&</sup>lt;sup>25</sup>pubmed.ncbi.nlm.nih.gov/29601657/, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7484454/

### Digital Healthcare. The Future of Cancer Mental Health Care

Digital health combines information and communications technologies in medicine and other health professions to promote wellness and manage illnesses and **health risks**. With such a broad scope, it includes the use of wearable devices, health information technology, mobile health. telemedicine. and telehealth<sup>26</sup>. These can be used independently or alongside medication, devices, or other therapies.

Digital Healthcare Solutions undergo formal reviews by institutions like the FDA in the US and BfArM in Germany to ensure their safety and effectiveness for medical conditions. Accessing the products may require a prescription, and in countries like Germany, they can be reimbursed through statutory health insurance after a thorough assessment.

Medical mobile apps can provide cost-effective and clinically-validated support to Patients. Their capability to

translate medical expertise into digital services allows them to deliver

a low-threshold service that can be utilized by an unlimited number of Patients, regardless of time and location. Digital healthcare products are therefore capable of bridging the gap in cancer-related mental health care, providing a scalable Solution and substantial support to cancer Patients, all while reducing costs.

With this in mind, Prosoma developed a digital healthcare Solution called Living Well, a unique combination of a Digital Program (Mobile App) and Personal Support (Tele-Coach). Its aim is to alleviate Patients' stress, anxiety, and depressive symptoms associated with their cancer diagnosis and treatment. Both features are utilized throughout the various stages of the treatment and, therefore. support their emotional well-being during the entirety of the recovery process.

<sup>&</sup>lt;sup>26</sup> https://www.ncbi.nlm.nih.gov/books/NBK470260/



Many Patients need information about their cancer and the treatment, which may not always be available. The app is packed with it, allowing patients to access and use them at their own pace. Also, when they hear something in the session with a psychotherapist and have the same message in the app, it is the most effective learning. A mobile app is perfect for that because skills require repetition. Living Well can really be helpful to any cancer institution, anywhere.

### The Power of Living Well by Prosoma

- ▶ The only digital healthcare Solution delivering clinically validated behavioral and psychological support to cancer Patients instantly, reliably, and cost-effectively.
- ➤ Designed with a defined CBT-based Program, it leads Patients from the moment of a diagnosis to **relieve cancer-related anxiety and depressive symptoms** and **improve well-being, quality of life**, and overall outcomes.
- ➤ Not only allows constant access to therapeutic content that forms its Program but also connects with a **Tele-Coach** trained **psychologist** who ensures support, motivates Patients, and **enhances their engagement**.
- ▶ By bridging the gaps and breaking barriers for accessible care, it addresses **Stakeholders'** needs and challenges across the system, allowing them to **unlock substantial** value that is fully scalable.

### The Team

### Top experts in the fields of CBT, psycho-oncology, user experience, data science, and the Patients themselves.

### **The Solution**

Living Well is an innovative digital healthcare Solution developed to fill the gap in the insufficient behavioral and psychological care of cancer Patients. It is a unique combination of a Digital Program (mobile App) and Personal Support (Tele-Coach) to deliver the care the Patients need at a cost-effective and convenient manner, instantly and reliably.

### The Design

## Highly intuitive, interactive, encouraging, and fully animated. Experts in user experience and game developers introduced best practices and techniques from their fields to provide Living Well users with the most engaging and accessible experience.

### **The Support**

By directly addressing Patients' mental health needs via a 90-day CBT-based course using mindfulness interventions, healthy habit-building techniques, and Health-Coach support, it relieves cancer-related anxiety and symptoms of depression to improve Patients' quality of life, and overall outcomes.

### The Proof

# The App's Program effectiveness is continuously assessed through clinical trials, real-world data, and user experience analyses to ensure it delivers the support needed. The Program is derived from CBT, one of the most effective, scientifically validated approaches in today's psycho-oncology.

### The Scale

Combining world-leading medical expertise in psycho-oncology, digitalization, and advanced mobile tech makes Living Well a powerful, scalable Solution. By addressing the needs gap of Patients first, it is capable of addressing the needs and challenges of Stakeholders' across the system, including Doctors, Therapists, Providers, Insurers, Pharma Companies, and others, benefiting them all from its variety of functionalities while allowing to unlock substantial value from the powerful synergy that is created.





### **Empowering Capabilities**

Living Well is geared toward adult Patients and cancer survivors of all cancer types. It can be used in conjunction with other psychological interventions or on its own. It is a **self-care medical device that empowers Patients in a variety of dimensions**.

Tailored CBT-Based Intervention:
Patient support, resources, and
strategies adapted to individual
circumstances.



On-Demand Care Availability and Accessibility: ability to use the Solution at will, alleviating the constraints of traditional; appointment-based care and extending it beyond hospital walls.



22 Highly Engaging Sessions based on available comparative studies for CBT, covering various content areas, i.e., regulating emotions, cognitive work on negative thoughts, behavioral activation, etc.



A Range of Exercises, i.e., breathing techniques, work with imagination, mindfulness, and gratitude, all designed to support Patients in different challenges they may encounter during their treatment.



Emotion and Stress
Monitoring Tools:
measure emotional well-being
and symptoms, report data on

and symptoms, report data on Patient progress, and allow for early interventions, care planning, and improved Patient-Provider collaboration.



Therapy combined with live, online support from Health Coaches who assist with education, and ongoing motivation, behavioral change support, adherence, and progress monitoring; available throughout the journey.



### **Broad Accessibility.**

Addresses Patients of diverse languages, genders, cultural backgrounds, literacy levels, visual impairments, motor skills, and coping mechanisms related to anxiety or depression.



Practical Information and Tips, including many relevant articles, Q&As, podcasts, and other Patients' Stories to boost Patients' motivation.

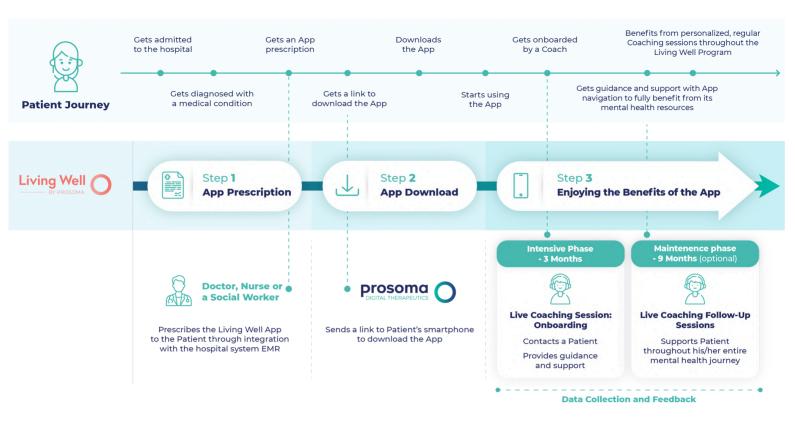






### Providing Support Throughout the Patient Journey

Living Well **supports care in many ways**, from early Patient engagement to improved, long-term overall outcomes, providing Patients and their Clinicians with the necessary tools to get the support they need.





When the Patients are using this app, they feel better, and I think their attitude, in general, is better and the outcome is better. The professional support behind this is really important for them. The App helps me do my job because they are calmer and more receptive. They are able to learn new coping skills and ask appropriate questions that we are able to handle throughout the treatment.

Deneen, nurse, assisted cancer Patients in a Living Well's clinical trial at MemorialCare Cancer Institute, Long Beach Medical Center, US.

### Tested and Approved. Patients Tell Their Stories

Over

90%

of Patients
found
the Program
successful
in improving
their
well-being.

To ensure the delivery of the best possible support for Patients, we actively involve them in the development process of our Solution.

Consequently, we regularly conduct thorough user experience evaluations, which involve surveys, interviews, and data usage analyses which helps us to understand **how Patients use the Solution and to gather valuable feedback and insights on how to enhance it**. By seeking Patients' input and hearing their voices, it creates a tailored and Patient-centered **overwhelmingly** approach.

Living Well regularly receives positive feedback from Patients.

92%

of Patients positively rate the Solution.

92%

of Patients would recommend the Solution to a friend.

Over

800

**Patients**were eager to share
their Feedback.

3

**Countries** in User Testing, incl. Poland, Germany, and the US.



The App turned out to be a true friend who was by my side every day during difficult times; supportive, always available, wise, and kind. The App includes a lot of essential knowledge and exercises. It's a great tool in psychotherapy, and it helps you feel more comfortable. I recommend it to all women struggling with breast cancer, their relatives, and healthcare professionals. It is an important support tool in the recovery process.



I like the App very much. It is both informative and empathetic. It helps me to structure my day. I think the App is good for people who don't reject conventional medicine but want to expand it a bit. My family life has improved over time using the App- my family understands me better, and they see that the App is helpful.

Eva, Patient, supported her cancer treatment with Living Well, Germany.



[On Patients' Testimonials feature available in the App]

This App will help you because there are people there with the same experience, and it will help you find hope that you can go through this, and you can fight this, because there are real people in the app. I feel like this App will somehow help you go through this difficult journey.

Rowena, Patient, supported her cancer treatment with Living Well, United States.

This is my safe space. Thanks to Living Well, I know how to manage even the hardest moments. Great App - all in one place. I don't have to look for anything, I can easily and effortlessly use what I need at any moment. It is always with me when I can't control my emotions. All I have to do is turn it on.

Ann, Patient, supported her cancer treatment with Living Well, Poland.

### **Solid Support Rooted in Science**

Digital platforms, including web-based programs and mobile apps, can be highly beneficial in providing psychoeducation and training for managing stress and emotions<sup>27</sup>. When combined with CBT, these platforms are able to alleviate symptoms such as anxiety<sup>28</sup>, depression<sup>29</sup>, insomnia<sup>30</sup>, pain<sup>31</sup>, stress<sup>32</sup>, and fatigue<sup>33</sup>, or to support Patients with chronic illnesses<sup>34</sup>.

Studies have proven that using mobile applications delivers favorable results in psycho-oncological care compared to treatments that are provided by traditional means<sup>35</sup>.

In this context, Living Well offers an invaluable Solution to the challenge of limited access to psycho-oncological care by reaching a larger number of Patients. It provides timely, on-demand support, eliminating time spent waiting in lines.

Moreover, communication with Patients, through means of both guided and independent work, supplies them with highly beneficial psychoeducational content without stigmatization. Most existing digital solutions lack significant interaction with Patients, offering just one-way communication. In contrast, Living Well is an interactive tool that evidence-based incorporates psycho-educational personalized content, addressing the respective gap in the market.

The highly valuable and effective combination of cutting-edge medical expertise in psycho-oncology, extensive industry knowledge, the latest digitalization and mobile device usage trends, and advanced mobile tech makes Living Well a powerful Solution to deliver value to Stakeholders across the system.

<sup>&</sup>lt;sup>32</sup>https://www.sciencedirect.com/science/article/pii/S2214782923000490; <sup>33</sup>https://jigc.bmj.com/content/early/2023/06/14/ijgc-2023-004304.abstract; <sup>34</sup>https://www.sciencedirect.com/science/article/pii/S2589537022001535; <sup>35</sup>https://pubmed.ncbi.nlm.nih.gov/32130181/,https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6693695/.



The Living Well App differs from the other ones because of its therapeutic and resource-oriented approach. The App not only uses the evidence-based approach of cognitive behavioral therapy but goes beyond to include a variety of elements for coping with illness and strengthening personal resources.

Christa Diegelmann, MA, Psycho-oncologist, researcher, author, ID Institute for Innovative Health Concepts, Germany

 $<sup>^{27} \</sup>text{https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6131163//https://formative.jmir.org/2021/5/e25078;}^{28} \text{https://www.jmir.org/2019/6/e12556/,} \\$ 

<sup>&</sup>lt;sup>29</sup>https://www.sciencedirect.com/science/article/pii/S2589537022001535;https://www.jmir.org/2019/6/e12556/;<sup>30</sup>https://www.sciencedirect.com/science/article/pii/S000578942100133,<sup>31</sup>https://www.sciencedirect.com/science/article/pii/S0005796723001171;

### Global Certification to Scale the Support



Prosoma adheres to ISO 13485 (quality management system for medical devices), and designs and develops its products according to the standard.



### CE certified:

a class I medical device in accordance with the European Medical Device Regulations 2017/745 (MDR). The certification ensures adherence to the highest European standards.



### Safe to use and data secure:

Living Well follows the highest data security standards (ISO/IEC 27001, EU GDPR) to ensure Patients' data is safe and only available to authorized users.



### Ongoing DiGA submission in

Germany; aims to be reimbursed in the near future for breast cancer Patients.
DiGA is German health legislation that allows Digital Healthcare applications to be prescribed by Doctors.



### FDA-approved in the US, HIPAA compliant.

Meets the specific requirements for medical devices.



### **DTx Adoption**;

e-Health Solutions have become a part of the psycho-oncology standard of care in Germany (S3 Guideline).



For clinicians, the Living Well App is a huge help. I really hope that it can be incorporated into any healthcare system and that all cancer centers have it. It complements the oncology treatment and allows Patients to pace themselves according to their needs and what they want to learn. I definitely think that using this App is going to revolutionize the way we look at cancer support.

Mariusz Wirga, Medical Director, Psychosocial Oncology, MemorialCare Todd Cancer Institute, US

### Scientific Validation Proof of Effectiveness



When Patients use Living Well, I can see the progress, like how they change and how much better they handle the adversities related to cancer treatment. Living Well promotes scientifically validated behavioral change interventions that help them follow their treatment, enjoy a healthier lifestyle, and improve their quality of life.

Mariusz Wirga, Medical Director, Psychosocial Oncology, MemorialCare Todd Cancer Institute, US

### **Living Well's Clinical Highlights**

Statistically and clinically significant reduction of symptoms of anxiety, depression, and distress in women using Living Well, compared to the control groups

The higher the baseline levels of anxiety, depression, and/or distress were, the more impactful the improvements

**In all clinical trials**, the standout is **reduction of anxiety**, one of the most common symptoms experienced by Patients right after diagnosis.

53%

Percentage of Patients engaged with Living Well with clinical improvement in anxiety

### **About Our Clinical Validation**

Living Well is currently undergoing validation in randomized control trials (RCTs) conducted in the US, Germany, and Poland. Additionally, an intensive pilot study was conducted in Poland on female cancer Patients experiencing high levels of symptoms of depression and/or anxiety. The bioethics committee has approved the protocols.

The primary objective of studies is to evaluate the effectiveness of our digital healthcare Solutions\* in reducing symptoms of anxiety, depression, and distress among cancer Patients.

Country	Poland	Poland	Germany	USA
Study	Pilot RCT	RCT	Pilot RCT	Pilot RCT
Enrollment	56	273	70	60
Status	Completed	Ongoing	Completed	Recruiting
Output	April 2023	Dec 2023	Jun 2023	Nov 2023

\*In the studies mentioned above, only a digital application was validated. However, our analyses demonstrate that Tele-Coach support contributes to even higher Solution performance. See the chapter about Retention.





### Outcomes Details: Intensive Pilot; Poland, 2023

### **Key Results**

 Statistically and clinically significant reduction of symptoms of depression, anxiety, and distress in women using Living Well, compared to the control group.

### **Study Description**

### Participants:

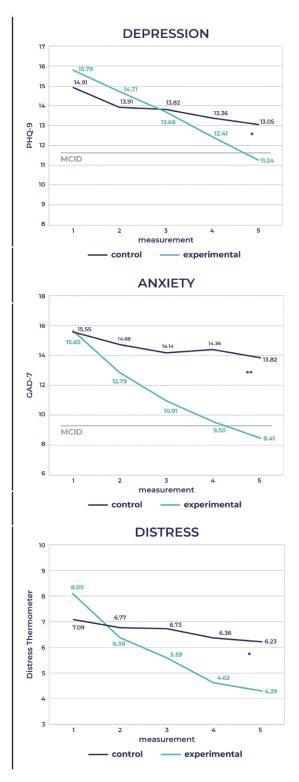
- 56 women with cancer (breast, colon, thyroid or leukemia), under ongoing treatment
- o Aged: 21+
- o Groups:
  - → Experimental (34)
  - → Control (22)
- All Patients experiencing depression (PHQ-9 >=10) and/or anxiety (GAD-7 >=10), and psychological distress (Distress Thermometer >=4)

### Procedure:

- Asked to engage with the App at least three times per week
- Measurements conducted: five in total, every 2nd week (baseline, 2-, 4-, 6- and 8-weeks)
- Evaluated: the severity of experienced
  - → depression (PHQ-9)
  - → anxiety (GAD-7), and
  - → distress (Distress Thermometer)

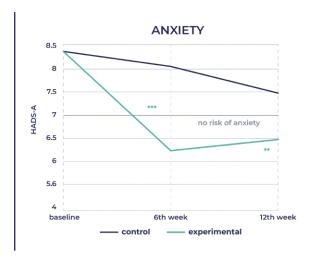
### Annotation:

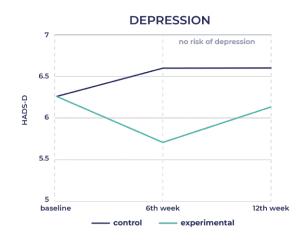
o \*p<.05, \*\*p<.01





### Preliminary Outcomes Details: Randomized Controlled Trial; Poland, 2023





### **Key Results**

- Clinical improvement in anxiety symptoms in 53% of App users after 12 weeks; anxiety
  decreased with statistical significance: no longer considered at risk from the second survey
  onwards in the experimental group, while the control group continued to experience higher
  anxiety levels.
- Clinical **improvement in depressive symptoms in 34% of App users after 12 weeks**; maintained rates of depression not considered at risk (HADS<7), and on average lower than the scores obtained in the control group.

### **Study Description**

 This is an ongoing study. As per the protocol, we had the opportunity to examine the preliminary results upon receiving the first 72 Patients' data after 12 weeks which allowed us to determine the size required for the final sample.

### Participants:

- 72 women with breast cancer under ongoing treatment
- o Groups:
  - →Experimental (47), Control (25)
- Baseline for anxiety and depression symptoms set before the treatment.

### Procedure:

- Asked to engage with the App at least three times per week.
- Measurements conducted: four in total, every 6th week
- Evaluated: the current state of Patients' intensity of depression and anxiety (HADS questionnaire)

### Annotation:

o \*\*\*p<.001, \*\*p<.01, MCID =2





### Outcomes Details: Pilot Trial, Germany, 2023

### **Key Results**

- Statistically significant reduction in symptoms of anxiety and distress in women using Living Well, compared to the control group
- Reduction of depressive symptoms for Patients with a high baseline score (HADS >=11)

### **Study Description**

### • Participants:

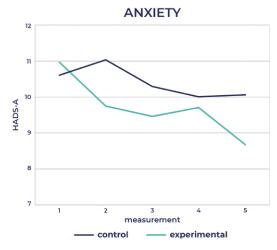
- 70 women with breast cancer, under ongoing or finished treatment
- o Aged: 18-75
- o Groups:
  - →Experimental (32)
  - →Control (38)

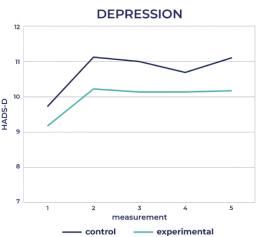
### Procedure:

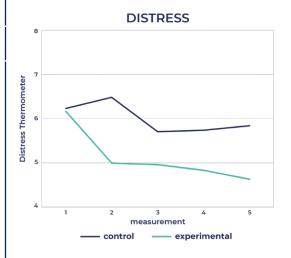
- Asked to engage with the App at least three times per week.
- Measurements conducted: five total (baseline, after 2, 4, 8, and 12 weeks)
- Evaluated: the current state of Patients' intensity of:
  - →depression (HADS questionnaire)
  - →anxiety (HADS questionnaire)
  - →distress (Distress Thermometer)

### Annotation:

- Missing values were imputed using the LOCF
  - (Last-Observation-Carried-Forward)
- o Anxiety:
  - p = 0.01; effect size d = 0.61
- o Distress:
  - p = 0.05; effect size d = 0.46









### **Real-World Data Highlights**

68%

Percentage of active **users** of Living Well with clinical **improvement in anxiety** 

**62%** 

Percentage of active **users** with clinical **improvement** in **depressive** symptoms

40%

Percentage of active **users**initially at risk for
adjustment disorders **no longer exhibit any risk**by the end of the study

The higher the baseline levels of anxiety, depression, and/or distress were, the more impactful

the improvements.

The higher the baseline
levels of anxiety,
depression, and/or distress
were, the bigger the
count of Patients with
improvement.

Statistically significant increase in positive emotions, while statistically significant decrease in negative emotions

### **About Our RWD Validation**

To comprehensively validate and evaluate the Solution, we conduct regular Real-World analyses of App Users' data, in addition to the RCT studies.

### Description

### Participants:

- o 357 cancer Patients from Poland, Germany, and the US
- o Accomplished min. five lessons
- Voluntarily provided at least two measurements from optional psychological assessments (necessary to measure progress)
- Recruited via cancer treatment centers and social media

### Procedure:

- Asked to engage with the App at one's pace for at least 30 days
- Users' activity was tracked in:
  - →time spent using the App, lessons and exercises completed, articles read.
- Regular symptoms tracking and ratings:→obligatory:
  - ♦ daily stress levels

(10-points Distress Thermometer)

- ♦ positive and negative emotions, every 3rd day (40-point Visual Analog Scale)
- →optional:
- ♦ weekly depression (PHQ-9)
- ♦ weekly anxiety (GAD-7)





### Details: RWD Analysis; Poland, 2023

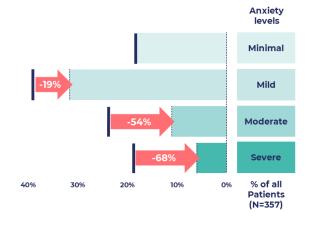
### Key Results

- Depending on baseline levels, Living Well App users **improved in terms of reported anxiety, depression, and distress symptoms** during the course of using the App.
- The result was that **the higher the levels of anxiety, depression**, or **distress** that were experienced at the beginning, **the greater the impact** and improvement that was observed.

### **ANXIETY DECREASE IN ANXIETY LEVELS** depending on the intensity of the anxiety symptoms at baseline Baseline **End measurement** 14 12 10 11,20 11,65 8,06 18.40 6.87 6,22 Moderate Severe

### **DECREASE IN % OF PATIENTS**

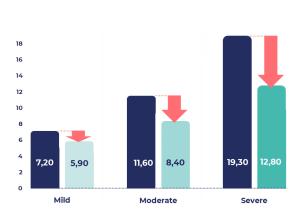
experiencing anxiety depending on their anxiety levels at **baseline** measurements



### **DEPRESSION**

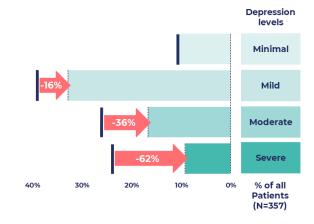
### **DECREASE IN DEPRESSION LEVELS**

depending on the intensity of the depressive symptoms at **baseline** measurement



### **DECREASE IN % OF PATIENTS**

experiencing depression depending on their depression levels at **baseline** measurements







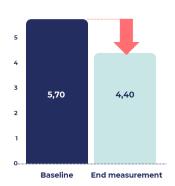
### **Key Results**

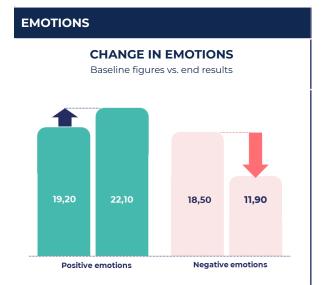
- **68% of users** who experienced severe anxiety levels at baseline had a **clinically significant decrease in anxiety** level (average drop from 18.4 to 11.2). Overall, the whole group also had a statistically significant decrease in anxiety (average from 9.3 to 7.4, p<0.001).
- 62% of users who experienced severe depression at baseline had a clinically significant decrease in depressive symptom levels (average from 19.3 to 12.8). Overall, the whole group also had a statistically significant decrease in anxiety (average from 10.59 to 7.94, p<0.001).
- 40% of users whose baseline ratings of distress indicated a risk for adjustment disorders had a decrease below 4pts. which is a no-risk level in the last measurements (average from 5.7 to 4.4). Overall, the whole group also had a statistically significant decrease in distress levels.
- Statistically significant **increase in positive emotions** (by 2.9 pts. on average) and statistically significant **decrease in negative emotions** (by 6.6 pts. on average).

# DISTRESS DECREASE IN % OF PATIENTS experiencing distress depending on their anxiety levels at baseline measurements Distress levels Low Risk of adjustments disorders 70% 60% 50% 40% 30% 20% 10% 0% % of all Patients ((N=357))

### **DECREASE IN DISTRESS LEVELS**

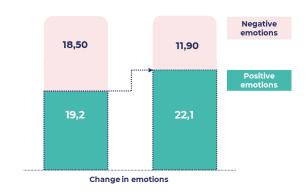
for a subgroup of Patients with risk of adjustment disorders at **baseline** measurement





### PATIENTS' RELATIVE CHANGE IN EMOTIONS

Baseline figures vs. end results







### **About Retention**

In the context of mobile apps, retention measures how many users continue to engage with the App after their initial download/installation over a specific period of time. However, in the case of Digital Health Solutions, this approach does not account for a vital piece of information which is the setting and means within which/where the Solution was introduced/administered to the user, ie. the cancer Patient in our case. In our evaluation, the Living Well Solution was administered in three different settings:

- **Internet**: users participating in UX research studies. They were digitally contacted and asked to engage with the App at one's pace for at least 30 days.
- **Hospital**: users who are regular Patients of German healthcare Providers. The App was recommended to them in person by their Doctors to support medical treatment.
- **Clinical Trial**: users who are taking part in clinical trials and have regular face-to-face contact with researchers who perform a role similar to Living Well's Tele-Coach and who motivate them to use the App.

What can be observed is that the settings described above play a key role in engagement. The more support received from professionals such as Doctors, Tele-Coaches, or psychologists, the higher the rates of engagement observed. In this context, Living Well maintains nearly 100% Patient engagement.

### **USER ENGAGEMENT IN LIVING WELL BY DAYS; METRICS AND SETTINGS**



### **Settings:**

Internet N = 582 Hospital N = 509 Clinical Trial N = 47

**N:** Number of Patients who completed onboarding in Living Well App

What can also be observed is that regardless of the settings, **Patients voluntarily prolong engagement with the App beyond the recommended Program duration (30 days)**. Thus, Prosoma's goal is to achieve the highest possible engagement rates in non-hospital settings and to provide psychological support to as many Patients as possible. The **Tele-Coach** support available in Living Well is an option here. Tele-Coaches guide Patients through the App, monitor their progress, encourage them, and motivate them to keep using the App.





### Scaling the Value of Living Well



What distinguishes Living Well is delivering support that is scalable. Its capability to engage Patients in its active utilization also benefits providers, allowing them to access unique data, track Patients' mental health progress, and manage care respectively by boosting treatment adherence, modifying plans, or intervening early. Also, by extending its support into post-treatment and recovery phases, it ensures continuity of care, providing additional revenue opportunities all at once. Living Well is, therefore, more than a mere digital Solution. It has the potential to support individual Patients while optimizing healthcare systems' overall effectiveness all at the same time.

Prof. Tit Albreht, MD, WHO Consultant, President-elect of the European Public Health Association; One of the leaders of the European cancer policy, Slovenia

### Supporting Patients, Empowering Providers

Combining world-leading medical expertise in psycho-oncology, extensive industry knowledge, digitalization, and advanced mobile tech, Living Well is capable of bridging the gaps and breaking barriers for accessible care.

Because it addresses Patient needs along every step of the cancer journey, Living Well becomes a part of a connected system. Consequently, while delivering support to Patients, it also scales it to **Healthcare Providers**, addressing their needs, and empowering them with a variety of respective benefits.

### **Reduced Healthcare**

**Demand** as a result of reduced anxiety and depression in Patients, and consequently, enhanced adherence to treatment, tolerance for side effects, and overall outcomes.

Reduction in Use of Care and Costs by promptly addressing Patients' needs through Solution features such as Real-Time Symptoms Tracking or Tele-Coaching, and preventing treatment complications, needless ED cases, and consultations.

Limited Time Spent in Hospital due to the Solution's convenient delivery of care, which can be accessed even at Patients' homes; continuous emotional support means less treatment complications and, thus, reduced need for additional care.

### Care Contracts due to a demonstrated commitment to Patient-centered care and, therefore, enhanced overall Patient satisfaction, leading to their active

Improved Value-Based

leading to their active participation in improving their own well-being and striving for better outcomes.

Optimized Resources, Reduced Costs, Generated Savings, and Higher ROI due to reduced healthcare utilization which frees up resources and personnel, streamlines overall care, and reduces administrative burdens.

Additional Revenue
Stream by delivering
innovative care and, in
turn, market
differentiation and
enhanced reputation.
This attracts Patients and
Partners, which offers
additional billing
opportunities.

Our Solution's potential for widespread impact also benefits the other stakeholders across the system. Insurers, Pharmaceutical Companies, and others are not described in this paper. Yet, our Solution's potential allows them to streamline the care they provide and reduce its costs, contributing to the overall resilience of the healthcare systems.





### Reducing Healthcare Costs. ROI Calculation

Healthcare systems worldwide lack adequate psychological support for cancer Patients, resulting in overwhelming experiences for both Patients and hospitals. This includes managing associated symptoms, such as depression and anxiety.

Living Well ensures that cancer-related anxiety and depression are managed. It improves not only Patients' quality of life and overall outcomes but can also limit the time, cost, and resource utilization of hospital services delivered, such as additional ER visits with symptoms related to stress, anxiety, or poor treatment adherence.

Implementing Living Well can result in financial benefits for Providers through reduced demand and utilization of healthcare services. Our ROI model gathers evidence showing how healthcare costs can be reduced based on already existing studies [REF]. It considers the savings generated by preventing complications and treating Patients, and **it predicts substantial savings in costs for Providers** who choose to implement Living Well.

An example calculation for a group of 1,000 cancer Patients undergoing App intervention indicated a **net savings of nearly \$4M (up to \$4k of savings per Patient)** for a Provider, almost **five times the investment** in the Solution.

### **Return on Investment in Living Well**

Ovei

\$4.7M

in **total cost savings and cost avoidance** for every **lk Patients** engaged with the Solution.

In to

\$4M

in **net savings** for every **1k Patients** engaged with the Solution

Up to

\$4k

in **cost-savings**per Patient engaged with the Solution

4.9

**Return On Investment** 





### **About the Model**

Our model aims to quantify the impact of our Living Well App based on CBT for anxiety and depression in cancer Patients, estimating **potential savings and Return on Investment in the Living Well App for Providers**.

- Psychiatric condition costs were obtained from Mausbach et al., with depression, anxiety, and both prevalence rates of 7.49%, 7.77%, and 7.84%, respectively.
- Our model's direct savings inputs were based on a US retrospective cohort study<sup>36</sup> that examined healthcare resource utilization in cancer Patients with depression and/or anxiety. The study found that Patients with depression, anxiety, or both incurred higher healthcare costs of \$28,476, \$57,673, and \$121,426, respectively, compared to those with no depression or anxiety. These incremental charges were used in our cost-saving calculations.
- The clinical efficacy data of Living Well came from Prosoma's internal clinical studies presented above. The improvements in the experimental group, as per the above-mentioned symptoms, were considered to be the cases improved, while the worsening of symptoms by users in the control group was assumed to be the cases left out of the model. These rates were used to calculate the total cost savings.



Living Well is a valuable tool in the realm of psycho-oncological care. Its digital approach to accessible, evidence-based support for Patients has the potential to make a lasting positive impact on the lives of countless individuals facing the challenges of cancer while also enriching the broader healthcare ecosystem. I believe that Living Well's contribution will continue to help bridge the psycho-oncological care gap, paralleling the rising global cancer incidence and its impact on Patients' mental health. The Solution can significantly alleviate this burden.

<sup>&</sup>lt;sup>36</sup> https://pubmed.ncbi.nlm.nih.gov/32485033/

### **Scaling the Value for Partners**

Living Well has been implemented by stakeholders in healthcare systems around the world. While various cooperation models were tested, each model brought a number of benefits to all parties involved.

### CASE STUDY NO. 1: HEALTHCARE PROVIDER

Living Well at Todd Cancer Institute, Memorial Care in Long Beach, California, US



Living Well was introduced to Patients by nurse practitioners and social workers upon diagnosis with a recommendation to use the app at least three times a week at their convenience. Clinicians at the Todd Cancer Institute saw Living Well as a valuable complementary tool that provides continuous support to Patients, helping them navigate their treatment and adopt a more health-centered approach.

### **The Results**

- ▶ Patients express new **motivation** and **gratitude** for the App, especially during treatment. They are keen to access such solutions during their diagnosis.
- ▶ Patients using the app after diagnosis view the program as a **comforting space** for self-care during their cancer journey.
- ► Several Patients reported reduced reliance on anti-anxiety medication due to mindfulness and **relaxation** exercises in the App.
- ▶ TCI staff reported higher job **satisfaction** and better work management.



As it is very hard for Patients to schedule additional counseling sessions when they have just been diagnosed, it really is a huge relief for us clinicians to know that they are not left alone in that situation, but they have this app in their pockets and may reach for it anytime, and that this initial shock can be significantly reduced with the skills taught in the app.

Mariusz Wirga, Medical Director, Psychosocial Oncology, MemorialCare Todd Cancer Institute, US.

Living Well's other partner clinics around the world. More partnerships are to come.

















### CASE STUDY NO. 2: HEALTHCARE INSURER

### Living Well and Techniker Krankenkasse, Germany

TK integrated Living Well into their mental health services as a way of demonstrating the insurer's commitment to digital health for improved Patient outcomes. It has aided over 800 TK Patients, leading to its inclusion in the Disease Management Program, offering Patients reliable information on therapies, mental health, and other support. Living Well received solid recommendations here.



### The Results

► TK's Patients were provided innovative, psycho-oncological **support** that was tailored to their needs.



More to come.

► TK gained access to valuable patient data. This allowed for further tailoring of the Solution

demonstrated patient-centricity and innovative care enhanced TK's to perfectly align with its reputation. target audience's needs.

► TK saw an **increase** in the number of enrollees due to the solution.

Digital health services are becoming ever more significant. We recognize the value of mental health apps such as Prosoma's Living Well.

▶ The

Thomas Heilmann, Head of the Care Insurance, Techniker Krankenkasse (TK), Germany

### CASE STUDY NO. 3: PHARMACEUTICAL COMPANY



Daiichi Sankyo partnered with Prosoma to pursue innovative, patient-centric cancer care. Together, they promoted Living Well to oncology communities, including Continuing Medical Education training that was focused on raising awareness of the significance of mind-body treatments for cancer Patients. Over 400 doctors participated. Living Well's value was highlighted, emphasizing its 360-degree patient care.

### The Results

► Enhanced value of a portfolio

**► Strengthened** the market image of a Patient-centric and innovative company

► Increased doctors' and **Providers' base**; strengthened relationships

► Increased number of Living Well's users; access to valuable **Patient data** 



More to come.



Doing more for Patients by expanding our partnerships with Providers of support services that can help make a difference in Patients' lives is of the utmost importance to us. We believe that Prosoma is the right partner to help reduce the mental burden for Patients.

Martina Witzel, Head of Oncology, Daiichi Sankyo, Germany

### **Closing Remarks**

In the face of escalating cancer cases and their associated costs, it is critical to address the often-overlooked aspect of cancer care – the mental well-being of Patients. Yet, cancer's impact on Patients' mental health is profound and extends beyond the emotional realm, affecting their quality of life and overall outcomes. This white paper underscores the urgency of integrating mental health support into the care landscape while presenting a Solution that addresses the challenge.

Living Well represents pivotal а advancement in cancer-related mental health care. Its unique combination of a Digital Program and Personal Support empowers Patients to address their mental health needs in a convenient, accessible, and cost-effective manner. By leveraging the power of digitalization, Living Well delivers evidence-based psychotherapeutic CBT interventions, mindfulness techniques, and Personal Support to alleviate their distress, anxiety, and depression.

However, this solution's power lies not only in its ability to directly benefit Patients but also in its **scalability**. In other words, its potential for widespread impact and a capacity to support stakeholders across the system, including healthcare

Providers, Insurers, Pharmaceutical Companies, and others. This potential positions Living Well as an invaluable tool for not only enhancing cancer Patients' well-being but also reducing healthcare costs, thus contributing to the overall resilience of healthcare systems.

Moreover, the value of Living Well is reinforced by clinical and real-world data validation. showcasing proof delivering reliable mental health support Patients while fostering impressive engagement The integration of Living Well via various means, including clinical trials, hospitals, and internet-based access, demonstrates its adaptability and potential to cater to a diverse Patient population and therefore highlights its transformative potential.

As we navigate the increasing challenges posed by cancer, both on the individual and societal levels, innovative Solutions like Living Well pave the way for more comprehensive and effective care. The future of cancer-related mental health care is digital, scalable, and Patient-centered. Living Well is

a testament to the transformative potential of technology and innovation in reshaping the landscape of cancer care for the better.



I still use it today. At those quiet moments when I am stressed or when I have a lot on my mind. Sometimes you lose yourself because of the fear. So if you use this app, it will help you regain confidence. And you can really feel you are alive again, you know? You did a good thing.

Patrina, cancer Patient taking part in a Living Well's clinical trial at MemorialCare Cancer Institute, Long Beach Medical Center, US

### **Meet Prosoma**

We are a global, interdisciplinary team of world-class scientists, psychologists, engineers, as well as experienced and passionate new-tech entrepreneurs brought together to deliver digital healthcare Solutions, striving at the forefront of innovation for oncology. In constant searching for new concepts, our mission is to improve existing care in the field, address emerging challenges and needs of the stakeholders across the system, and bridge the respective gaps.

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