



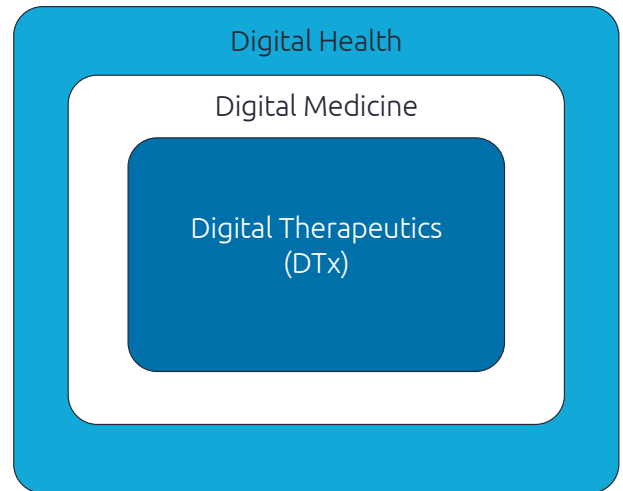
DIGITAL
THERAPEUTICS
IN ONCOLOGY

Advancing outcomes design

SETTING THE CONTEXT FROM A CLINICAL PERSPECTIVE

The digital health market is flooded with direct-to-consumer health and wellness applications. Digital health is a broad category that includes digital therapeutics (DTx). With the advent of technology and innumerable companies entering the digital health space, it is important to understand the significance of proven clinical efficacy of digital health solutions and to differentiate a DTx from other digital health or wellness solutions.

Even though the first DTx was launched a decade ago, this subject demands more attention. DTx so far has been largely driven by mental and chronic diseases, but these solutions are now finding a place in oncology practice. Not all but some digital cancer solutions are DTx.



Four factors are driving the use of DTx in oncology:

1. The **complexity of cancer journeys** with stringent protocols and multiple stakeholders involved in cancer treatment, plus the need for regular follow-ups.
2. A **shift towards remote treatment** (oral chemotherapy or cancer care in outpatient settings).
3. **Offering more personalized cancer care** with increased use of immunotherapies or targeted therapies to mitigate treatment-related issues.
4. **Focus on holistic care** — improving patients' quality of life, including pain and stress management or psychological support.

The DTx landscape is still evolving, which requires a careful assessment of pain points that might prevent these offerings from achieving critical mass.

From establishing the safety and efficacy of a DTx for use in cancer patients and demonstrating superiority over current standards of care, both in a clinical trial setting and in the real-world, companies need to navigate the complex landscape of cancer treatment.

Cancer disease management involves a myriad of diagnostic and treatment protocols. Integrating DTx into mainstream healthcare and creating a steady revenue stream in an evolving regulatory environment is easier said than done. Additionally, the burden of driving awareness and motivating patients and HCPs to see the value in DTx falls on the shoulders of a handful of DTx developers or marketers.

In PART 1 of our “Digital Therapeutics in Oncology” point-of-view, Capgemini experts summarize the importance of building clinical evidence for DTx solutions and lay the foundations for advancing outcome design and bringing successful products to market.

The DTx solutions included in our analysis focus on the monitoring and treatment of cancer patients and not on diagnosis.

In PART 2, we describe the innovation landscape of DTx solutions in oncology, then evaluate its application areas and clinical outcome measures through a trend analysis.



UNDERSTANDING THE MARKET LANDSCAPE

WHAT IS A DTx?

We develop an understanding of the key characteristics of a DTx, its place in therapy, regulatory status, clinical outcome measures and adoption through a real-world example.

Digital therapeutics (DTx) are regulated software products that deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease. Powered by IoT (internet of Things), sensor devices and SaMD (Software-as-a-medical device), the administration of a Tx (therapeutic) has been digitized and hence, called DTx. For example, In recent years, Cognitive Behavioral Therapy for Insomnia (CBT-I) has been adapted into digital formats, often as smartphone applications or web-based programs that enable monitoring.

In a nutshell, DTx should have the following characteristics:

- Clinical evidence and real-world outcomes (and clinically validated, peer-reviewed clinical trial results)
- Products / solutions need to be approved by regulatory bodies
- Products can be prescribed by the HCPs to the patients
- Some products are reimbursed

In oncology, DTx is part of a multimodal cancer treatment involving HCPs and the solutions are complementary to current therapy.





Digital Therapeutic (DTx) was trademarked in 2012 by Click Therapeutics and later defined by Sepah et. Al, in 2015 as:

“Evidence-based behavioral treatments delivered online that can increase accessibility and effectiveness of health care”

Founded in 2017, the DTA (Digital Therapeutics Alliance), a non-profit trade association of industry leaders define DTx as:

“Digital therapeutics that deliver medical interventions directly to patients using evidence-based, clinically evaluated software to treat, manage, and prevent a broad spectrum of diseases and disorders.”

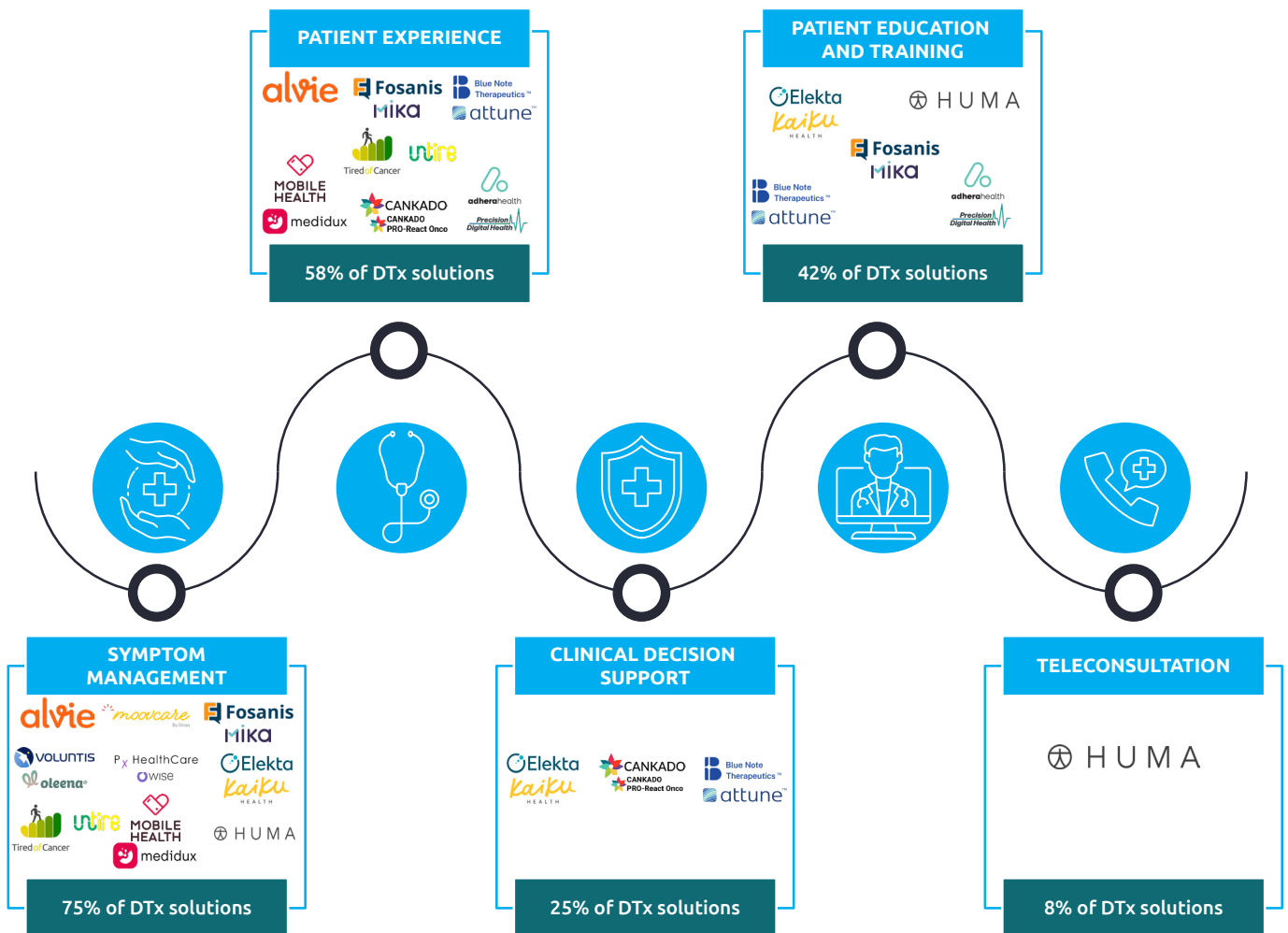
Digital tools can be embedded in cancer patients’ treatment protocols with patient-reported outcomes and direct connection to care providers (physicians, nurses) for decision making, or these can be a diagnostic tool for physicians.

WHAT ARE THE APPLICATION AREAS OF DTx?

A trend analysis of 12 marketed DTx solutions in oncology was conducted to understand its application areas or use cases.

Symptom Management, Patient Experience, Clinical Decision Support, Teleconsultation and Patient Education and Training are observed to be the five key application areas for a subset of 12 marketed DTx solutions.

The analysis would help in identifying areas where DTx solutions are being used most commonly in oncology and areas where they are still emerging.



Source: Capgemini Analysis of 12 Marketed DTx Solutions in Oncology

Moovcare, Kaiku Health (a part of Elekta), Voluntis Oleena, Fosanis Mika, Blue Note Therapeutics Attune, Cankado PRO-React Onco, Tired of Cancer Untire, Mobile Health medidux, Px Healthcare Owise, Huma, Adhera Health, Alvie Health (Previously Onko)

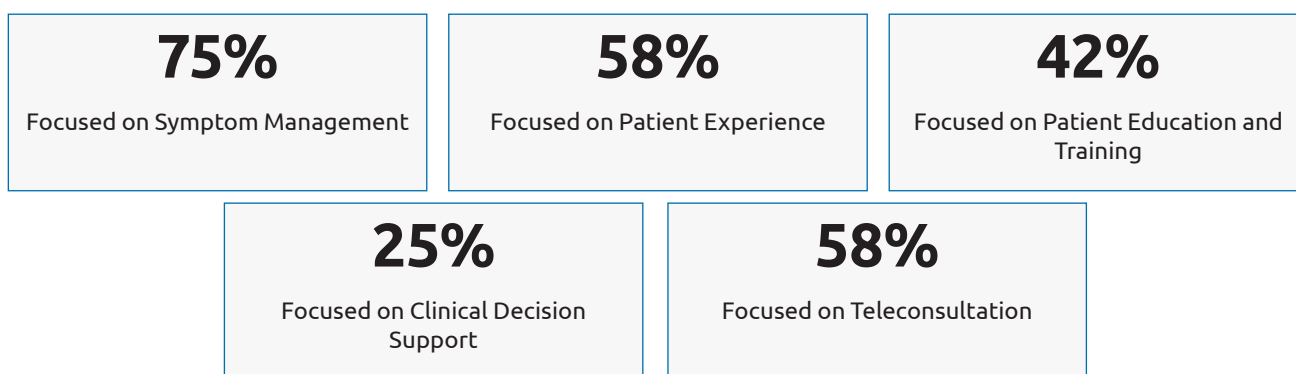
DEEP DIVE ANALYSIS

APPLICATIONS OF DTx IN ONCOLOGY

A deep dive analysis of each application area – **Symptom Management, Patient Experience, Clinical Decision Support, Teleconsultation and Patient Education and Training** has been conducted.

Among the subset of 12 marketed DTx solutions in oncology, most of them focused on Symptom Management followed by Patient Experience and then Clinical Decision Support.

APPLICATION AREAS OF DTx IN ONCOLOGY



It can be implied that currently marketed DTx solutions are more patient-focused – monitoring and reporting symptoms of cancer and improving patient experience.

Except for one DTx solution focusing only on symptom management, most of the DTx solutions offering symptom management also focus on improving patient experience. Additionally, a few extend their offerings to patient education services.

Moving beyond symptom management, several of the DTx solutions or ‘App on prescription’ built on the foundation of patient experience are trying to provide personalized treatment support to cancer patients – primarily behavioral recommendations or drug intake reminders.

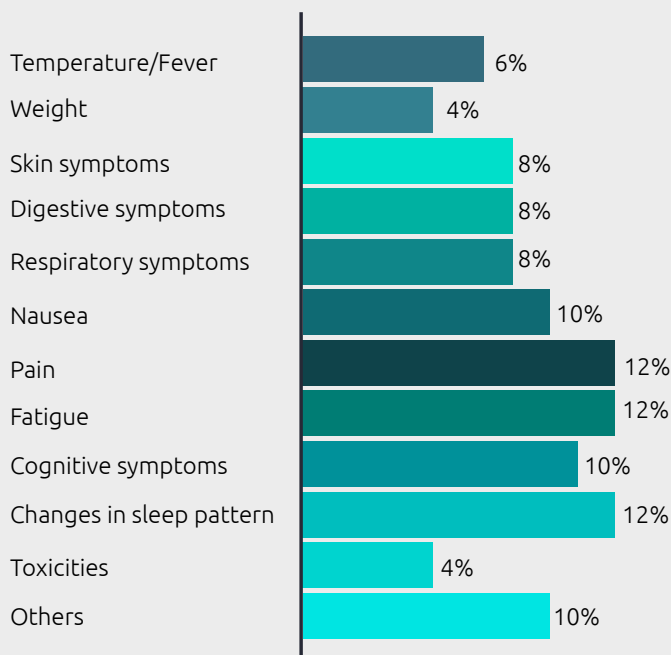
1. SYMPTOM MANAGEMENT:

A subset of 9 /12 marketed solutions were analyzed to understand the role of a DTx in cancer symptom management, the types of symptoms being managed, frequency of tracking of symptoms and the benefit to cancer patients (the remaining three DTx solutions do not meet the criteria of symptom management).

In general, DTx solutions allow symptom reporting and remote patient monitoring through a web-based platform or a mobile app, and a notification is sent to care providers.

Symptom management through remote patient monitoring is the most sought-after application area for available DTx solutions in oncology (based on a subset of 12 marketed DTx solutions included in our analysis)

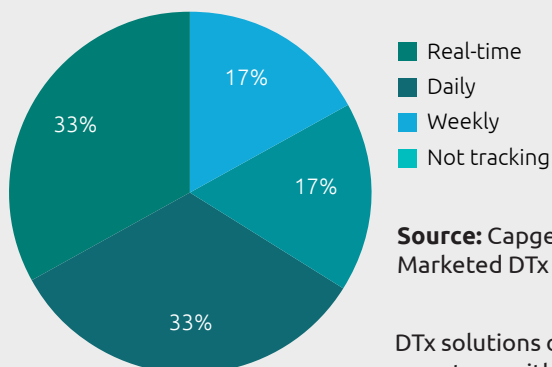
SYMPTOMS OF CANCER TRACKED BY DTx SOLUTIONS



Source: Capgemini Analysis of selected 12 Marketed DTx Solutions

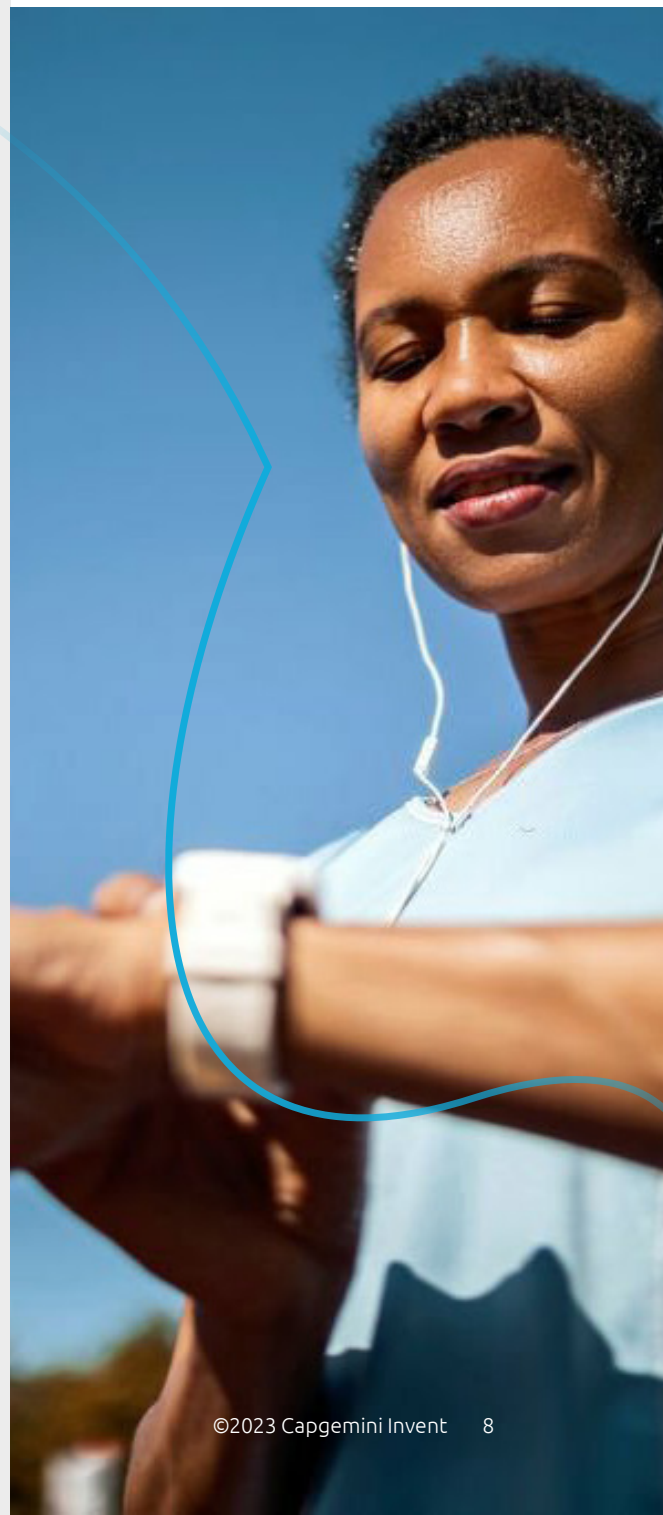
General body aches, fatigue, and changes in sleep pattern after a cancer diagnosis are the most reported and tracked symptoms.

SYMPTOM TRACKING FREQUENCY



Source: Capgemini Analysis of 12 Marketed DTx Solutions

DTx solutions or apps track symptoms either in real-time or daily (once in a day)



Clinical trial studies of DTx solutions are demonstrating an improvement in patient symptoms. **We provide an understanding on the primary and secondary outcome measurements in cancer patients using DTx in comparison to a standard of care.**

Primary Outcome Measurement (POM) of a clinical trial is the outcome that an investigator considers to be the most important among the many outcomes that are to be examined in the study. It is used to study the effect of the intervention (DTx). **Secondary outcomes measurement (SOM)** are additional outcomes monitored to help interpret the results of the primary outcome.

9 /12 DTx solutions in oncology (based on our subset for analysis) qualify for symptom management. Clinical outcome measurements were analyzed for seven out of nine DTx solutions as two DTx developers have not publicly reported the clinical trials.

CLINICAL OUTCOME MEASURES OF SYMPTOM MANAGEMENT

71%

of solutions included one or more of the following Primary Outcome Measures

Primary Outcome Measures (POM)

- Overall Survival
- Median Overall Survival
- Fatigue
- Psychological distress
- Patient adherence

Overall Survival (OS) is the most important primary outcome measure for symptom management in oncology.

The primary outcome Overall Survival (OS) at 12 months was measured in lung cancer patients.

>75%

of lung cancer patients using DTx reported an improved OS compared to routine surveillance.

Median OS for cancer patients using DTx was on an average 6.1 months higher compared to patients on standard care.

85%

of solutions included at least two Secondary Outcome Measures. Three out of seven have four or more measures

Secondary Outcome Measures (SOM)

- Serious Adverse Events (SAE)
- Quality of Life
- Relapse detection
- Patient compliance
- Health literacy
- Health care costs
- Adverse events (AE)
- Emergency Room (ER) visits
- Hospitalization
- Fatigue
- Psychological distress
- Patient adherence

The most important secondary outcome measure is Quality of Life (QoL).

Three companies published results on secondary outcome measures, showing a significant improvement in QoL in patients using compared to patients not using DTx.

Clinical outcome measures such as fatigue, psychological distress and patient adherence could be a primary outcome measure for one DTx and a secondary outcome measure for another DTx.

2. PATIENT EXPERIENCE

Our deep dive analysis of patient experience as an application area involves a **subset analysis of 7/12 marketed solutions**, as the remaining DTx solutions do not impact patient experience.

Improving patient experience through a DTx solution focuses on the behavioral effects, anxiety and stress management, emotional response or well-being of the patient.

Patient experience can be improved with mobile apps that work on a CBSM concept. These apps educate patients on relaxation and coping techniques, supporting emotional responses and addressing patients' psychological needs. DTx solutions can also increase patient adherence towards a medication.

More than half of the marketed DTx solutions in oncology are focusing on patient experience and patient adherence (out of the subset of 12 DTx solutions included in our analysis).

We provide an understanding on the primary and secondary outcome measurements in cancer patients using DTx for improving patient experience in comparison to a standard of care.

6/7 DTx solutions in oncology qualifying for patient experience application area have been studied for clinical outcome measurements (Based on our subset for analysis. One DTx has not publicly reported its clinical trial).

CLINICAL OUTCOME MEASURES FOR PATIENT EXPERIENCE

71%

of solutions included one or more of the following Primary Outcome Measures

Primary Outcome Measures (POM)

- Overall Survival
- Median Overall Survival
- Fatigue
- Psychological distress
- Patient adherence

Quality of life (QoL), managing psychological distress or fatigue, and reducing Serious Adverse Events (SAE) are some of the primary outcome measures for improving patient experience.

The most common secondary outcome measure is patient adherence. Some of the other secondary outcome measures include stress management and improving health literacy.

Clinical outcome measures such as psychological distress, QoL, and fatigue could be a primary outcome measure for one DTx and a secondary outcome measure for another DTx.

Clinical endpoints for majority of the trials and studies are not yet published. However, pilot trial results of one company mentioned that patients had a 23% reduction in fatigue and a 42% reduction in psychological distress after 12 weeks of using the DTx.

85%

of solutions included at least two Secondary Outcome Measures. Three out of seven have four or more measures

Secondary Outcome Measures (SOM)

- Serious Adverse Events (SAE)
- Quality of Life
- Relapse detection
- Patient compliance
- Health literacy
- Health care costs
- Adverse events (AE)
- Emergency Room (ER) visits
- Hospitalization
- Fatigue
- Psychological distress
- Patient adherence

3. CLINICAL DECISION SUPPORT

The next application area we studied was clinical decision support. 3/12 of the marketing solutions were relevant to the analysis.

Clinical decision support (CDS) is an emerging application area in which DTx solutions support the entire care pathway, from remote patient management to improving a patient's treatment outcome. As a major tool in diagnoses, CDS provides both patients and medical practitioners with a wide variety of notifications.

All three DTx solutions qualifying for clinical decision support have been studied for clinical outcome measurements.

Improving patient adherence, reducing disease progression and managing psychological distress are some of the primary outcome measures for DTx solutions used in clinical decision making.

Secondary outcome measures include stress management skills, improving QoL, etc.

Patient adherence could be a primary outcome measure for one DTx and a secondary outcome measure for another DTx.

The majority of the clinical studies are ongoing. However, one company has published results indicating that 53% of DTx users reported an improved QoL compared to 38% of patients on standard care after just six months.



4. PATIENT EDUCATION AND TRAINING

DTx solutions can extend their offerings to educational services, providing articles, videos and training modules to encourage self-care in cancer patients. These resources are scientifically and clinically validated to improve patients' ability to manage any adverse events or severe symptoms.

For example, Kaiku Health, Mika, Attune and Huma have a robust collection of educational material that is available to the users weekly or daily to learn, practice and incorporate symptom self-management in their lifestyles.

It is not necessary that all DTx solutions will provide patient education related services.

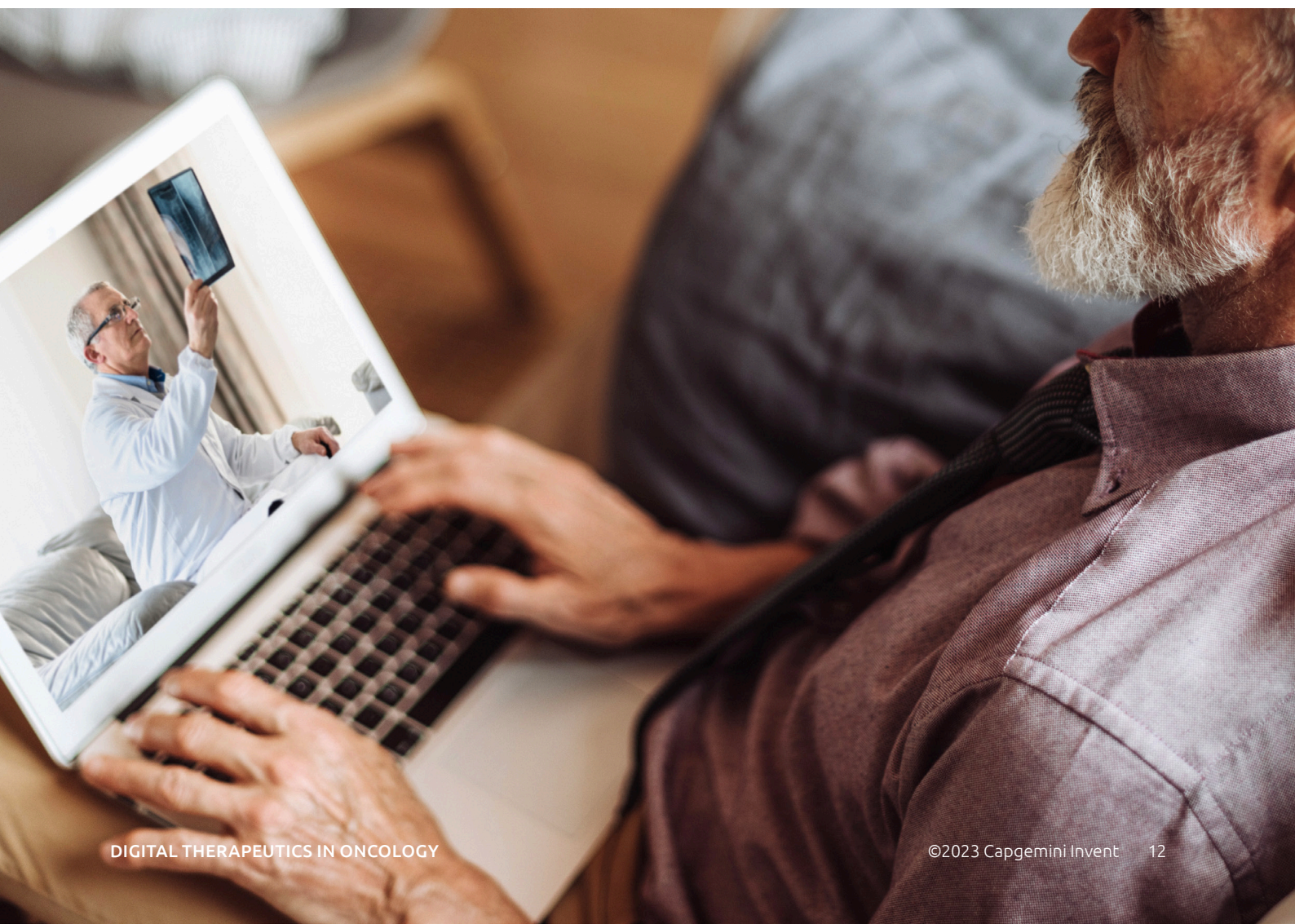
Less than half of DTx solutions included in our analysis (subset of 12 DTx solutions) extended their offerings to, 'anytime, anywhere access,' 'self-care' or 'self-educational services.'

5. TELECONSULTATION

A structured and detailed video or audio consultation between healthcare teams and patients from the comfort of their own homes is possible with teleconsultation platforms. For example, one DTx (Huma) is proving this feature to cancer patients and is enabling HCPs to remotely monitor and consult cancer patients.

Telehealth can enable prescription of DTx, patient acquisition and patient support within a DTx platform.

Integrating direct-to-patient telehealth for DTx can accelerate speed to therapy, but would this be a viable commercial model for the oncology disease area – an industry-first?



CAPGEMINI POSITION

Advancing the development of DTx solutions in oncology would require more collaboration. It would involve a network of partners – DTx developers, HCPs, clinicians, patients, regulators, payors, health system administrators, and non-profit organizations who would be the torchbearers of innovation, education, and decision-making.

Initiating early discussions with regulators and end-users, and making agile refinements in early stages of product development, can result in significant cost savings.

The industry is rapidly evolving like never before and early-on considerations for development of DTx tools in oncology would drive success.

Commercial strategy and pharma R&D teams are prioritizing opportunities for development of DTx solutions in order to cater to individual needs. Patients who are suffering from hard-to-treat chronic diseases and healthcare practitioners who are treating difficult diseases expect personalization of the HCP-patient journey.

Published clinical evidence indicates that symptom-monitoring tools improve Quality of Life for cancer patients, while also increasing adherence to cancer medications and giving insights into patient experience.

As the oncology portfolio becomes more complex, involving novel mechanisms and combination treatments, it is imperative for companies to develop strategies for the inclusion of sophisticated tools in their oncology portfolio.

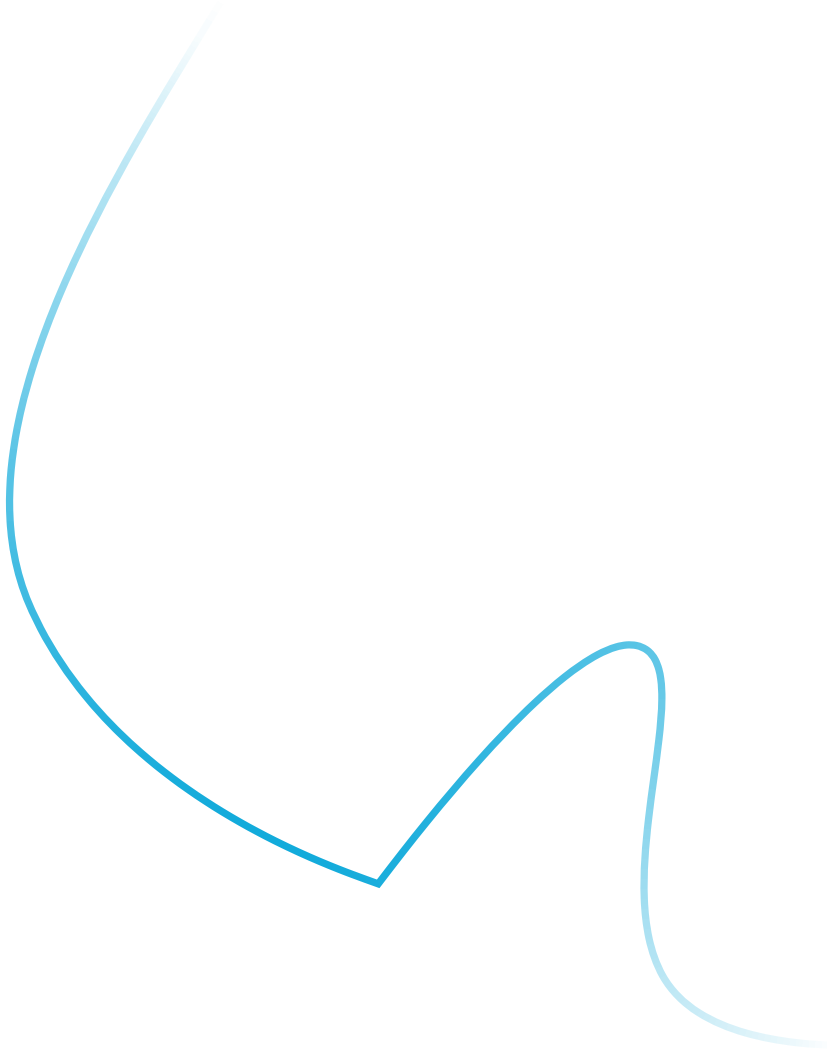


SOURCES

1. <https://www.nature.com/articles/s41746-023-00777-z/tables/1>
2. [https://edps.europa.eu/press-publications/publications/techsonar/digital-therapeutics-dtx_en#:~:text=Digital%20Therapeutics%20\(DTx\)%20are%20evidence,have%20a%20proven%20clinical%20benefit](https://edps.europa.eu/press-publications/publications/techsonar/digital-therapeutics-dtx_en#:~:text=Digital%20Therapeutics%20(DTx)%20are%20evidence,have%20a%20proven%20clinical%20benefit)
3. <https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd>
4. <https://link.springer.com/article/10.1007/s00432-018-02835-6>
5. Digital Therapeutics Alliance. 2021. Understanding DTx - Digital Therapeutics Alliance. [online] <<https://dtxalliance.org/understanding-dtx/>>
6. <https://orthogonal.io/insights/digital-therapeutics/introduction-to-digital-therapeutics-dtx/>
7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10006069/#:~:text=Definition%20of%20digital%20therapeutics,healthcare%20accessibility%20and%20effectiveness5.>
8. Moovcare: <https://www.moovcare.com/>
9. Kaiku Health: <https://kaikuhealth.com/>
10. <https://www.elekta.com/products/life-sciences/elekta-kaiku/>
11. Voluntas (Oleena): <https://oleena.com/>
12. Fosanis (Mika): <https://mikahealth.co.uk/>
13. Blue Note Therapeutics (Attune): <https://attunerx.com/>
14. Cankado (PRO-React Onco): <https://partners.cankado.com/>
15. Tired of Cancer (Untire): <https://untire.me/en/>
16. Mobile Health (medidux): <https://mobilehealth.ch/en/>
17. Px Healthcare (Owise): <https://owise.us/about-us/>
18. Huma: <https://www.huma.com/>
19. Adhera Health: <https://www.adherahealth.com/>
20. Alvie Health (Previously Onko): <https://www.alviehealth.com/>
21. <https://clinicaltrials.gov/>
22. Moovcare: <https://jamanetwork.com/journals/jama/article-abstract/2721170>
23. Kaiku health: <https://link.springer.com/article/10.1007/s00432-018-02835-6>
24. <https://www.jmir.org/2020/12/e18655/>
25. <https://formative.jmir.org/2020/10/e17898/>
26. <https://link.springer.com/article/10.1007/s00432-023-04622-4>
27. <https://jamanetwork.com/journals/jama/fullarticle/2630810>
28. Voluntas (Oleena): https://journals.lww.com/amjclinicaloncology/Abstract/2017/10000/Improving_Survival_in_Patients_Treated_for_a_Lung.5.aspx
29. Fosanis (Mika): https://www.annals-research-oncology.com/wp-content/uploads/2022/02/Gussoni_ARO-2.pdf
30. Cankado (PRO-React Onco): https://event.eortc.org/ebcc13/wp-content/uploads/sites/22/2022/11/EJC-175S1-EBCC_13.pdf
31. Tired of Cancer (Untire): <https://onlinelibrary.wiley.com/doi/full/10.1002/pon.5886>
32. Px Healthcare (Owise): <https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3971-6>

ABBREVIATIONS

1. DTx: Digital Therapeutic
2. DTA: Digital Therapeutics Alliance
3. NCPDP: National Council for Prescription Drug Programs (American non-profit standards development)
4. CNEDIMTS: National Committee for the evaluation of medical devices and health technologies
5. HAS : Haute Autorité de Santé
6. ePRO: Electronic patient reported outcome
7. ICI: immune checkpoint inhibitors
8. DiGA: Digitale Gesundheitsanwendungen, digital health application in Germany
9. MDD: Medical Device Directive
10. NHS: National Health Service
11. AI/ML: Artificial Intelligence and Machine Learning
12. JAMA: The Journal of the American Medical Association
13. JCO: Journal of Clinical Oncology
14. JCRCO: Journal of Cancer Research and Clinical Oncology
15. JMIR: The Journal of Medical Internet Research (JMIR)
16. CBSM: Cognitive Behavioural Stress Management
17. NCCN: National Comprehensive Cancer Network
18. ICI: Immune Checkpoint Inhibitor
19. FINCCHTA: Finnish Coordinating Centre for Health Technology Assessment;
20. OS: Overall Survival
21. mOS: Median Overall Survival
22. QoL: Quality of Life
23. IoT: internet of Things
24. SaMD: Software-as-a-medical device
25. POM: Primary Outcome Measurement
26. SOM: Secondary outcomes measurement
27. SAE: Serious Adverse Events



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