Capgemini invent

DIGITAL THERAPEUTICS IN ONCOLOGY

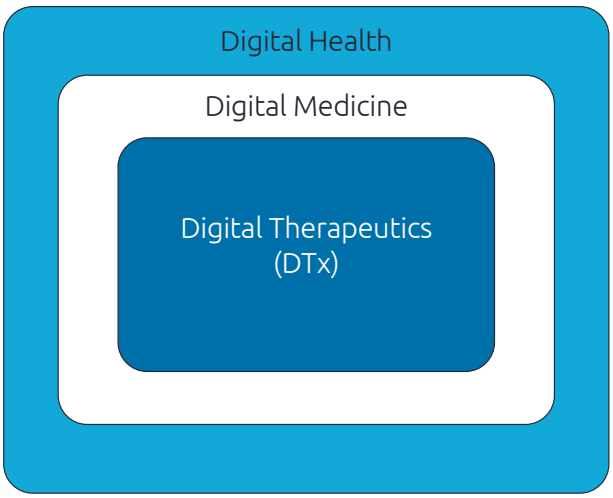
Innovation Models

SETTING THE CONTEXT FROM A COMMERCIAL PERSPECTIVE

Leading pharma and medical devices companies are shaking hands with digital health startups to explore one of the fastest growing segment of health tech – digital therapeutics (DTx).

The growth in the DTx market segment is largely driven by startups and a huge influx in investments. Global venture capitalist funding in DTx has quadrupled since 2017, crossing the $1 billion mark in 2022.[1]

Today, companies are hoping to advance the use of DTx and move faster than traditional medical devices, but we do not have an ideal use case for a DTx in the oncology disease area.



[1] Dealroom.co (2022) Digital Therapeutics – medical intervention beyond the pill

Organizations developing DTx solutions would benefit by critically questioning the trifecta of innovation i.e., desirability, feasibility, and viability.

In PART 1 of our two-part point of view on "Digital Therapeutics in Oncology," we examined the advent of DTx, its applications (both broad and oncological), and how it improves both practitioner and patient experience. In PART 2 of this point of view, we develop an understanding on the evaluation criteria for DTx solutions in oncology. Further, Capgemini experts explore business questions that can stimulate 'Innovation Discovery' for the launch and development of DTx solutions in the oncology disease area.

Through the use of various frameworks, models, and evidence, our point of view critically dissects the trifecta of innovation and summarizes innovation models. The document is supported by a methodology section.

LEAPFROGGING INTO THE FUTURE

FINDING THE INNOVATION SWEET SPOT

Traditional pharma and medical devices companies are determined to find innovative solutions for cancer patients.

Innovative frameworks are being used to build business cases and understand the 'product-market fit' before launching a DTx solution in the market.

DTx solutions have an interesting and promising lean canvas.

In this section, we will understand the business model of a DTx solution and summarize the key building blocks (as described below).

The business model canvas for a DTx should drive Innovation. A successful DTx Innovation is a marathon, not a sprint.

AN ILLUSTRATIVE BUSINESS MODEL CANVAS FOR DTX IN ONCOLOGY

PRODUCT

Top 3 Problems

- Delayed reporting of symptoms and adverse events
- Relapse cancer patients without medical input for weeks between appointments
- Toxicities or adverse events after treatment

Unmet Needs

- Routine follow-up care is a maior challenge for cancer patients
- Physical and emotional challenges including depression, anxiety, stress, and fatigue can go unnoticed in cancer patients

DTX Solution (Intended Use)

- For prevention, management or treatment of disease
- In oncology, it is majorly being used for management of disease

Ket indicators/ measurable Clinical Evidences

- Overall Survival (OS) at 12 months
- Relapse rate (detection of relapse)
- Quality of Life (QoL) gained
- Or reduction in fatigue, reduction in psychological distress
- Patients remaining on chemotherapy for longer
- Significantiy lower Emergency Room admissions
- Imaging cost savings

Value Proposition

- An evidence-based, proprietary digital behavioral intervention for cancer patients powered by smart technology and providing on-demand access to patients and peer-network
- Offering proven clinical (efficacy) operational, technological and cost benefit as (Effectiveness) compared to routine standard care
- DTx and traditional pharma model can co-exist and result in greater benefits than pharma

MARKET

Positioning/ Place in Therapy

- PDT (prescription digital therapeutics) used adjunctively with multidisciplinary oncology care regimen
- DTx for oncology are helping in "management" of the disease (as of now not for prevention or treatment)
- DTx support or enhance current medical care by empowering physicians and patients

Channels/ Accessibility

- Web platform
- Mobile App
- Wearables
- Free downloadable
- Often accessible via smartphones, tablets, virtual reality (VR) headset, or other devices
- HCPs and/or care team provide access code to assist users log in and create profile

Target Customers

- Cancer patients
- Oncologists
- Nurse teams
- Psychiatrists
- Psychotherapists
- Other Care Providers
- Employers
- Third-parties

Key Resources & Activities

- Propietary platform, Patient-level Data, Partnership, Funding, IP, Human Capital, Medical Fraternity
- Due Diligence, R&D, Product/ Platform Design & Develooment, Testing, Launch Operations, User Feedback Assessment & Marketing
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Technology and Reporting

- Daily, weekly or real-time symptom tracking
- Quantitative or Qualitative questionnaires to access the severity of symptoms or adverse events
- Advanced algorithms or AI/ML for symptoms assessment

Workflow

- Existing DTx have the ability to integrate with clinician workflow but need to clearly demonstrate short- and long-term impact on workflow efficiency and productivity
- Challenges integrating DTx into existing workflow of health system

Business Model

- A service provider business model
- A Companion DTx model ("Around-the-pill strategy") over a Standalone DTx ("Beyond-the-pill strategy")
- D2C model (direct to consumer model) with or without HCPs (but HCPs involvement is preferred)
  - A platform for healthcare system, clinic, or other enterprise setting
  - A platform for clinicians, physicians and support staft
  - A DTx for diagnosing and monitoring patients
  - A DTx that can deliver medical intervention and therapy

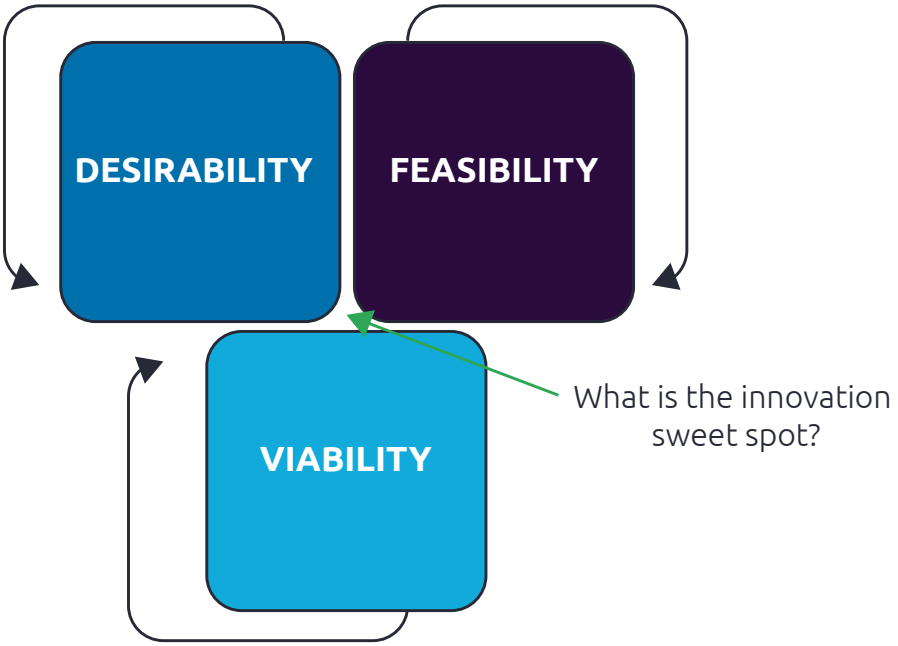
Cost structure

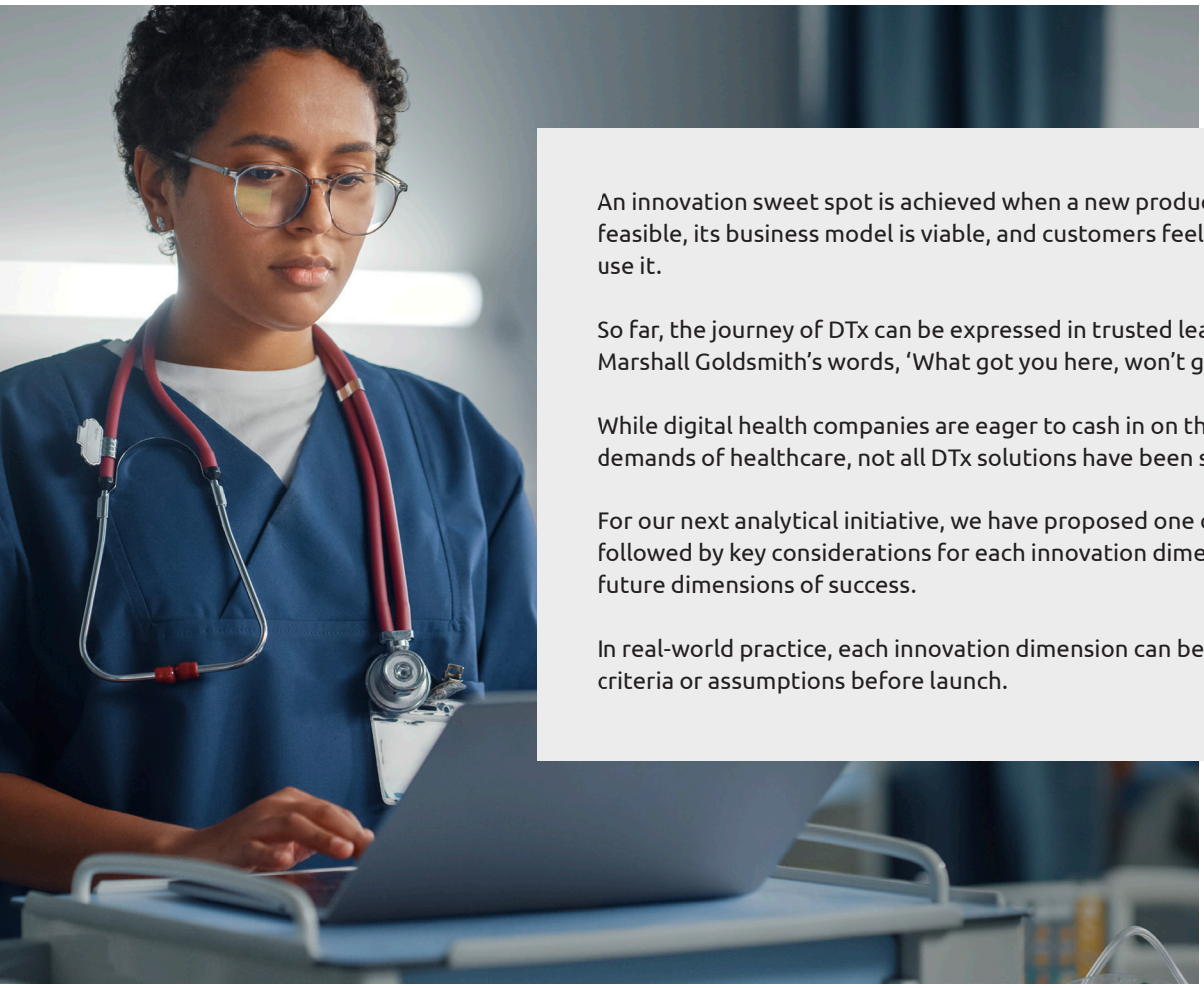
- Research / R&D
- Clinical Testing
- Device/ Platform Development, Operations & Maintenance
- Human Resources
- Marketing

Revenue Stream

- Billing through medical claims
- Published RWD/anonymized data
- Pay-for-Performance model

THE THREE INNOVATION DIMENSIONS





An innovation sweet spot is achieved when a new product has proven to be feasible, its business model is viable, and customers feel a desire to get it and use it.

So far, the journey of DTx can be expressed in trusted leadership coach Marshall Goldsmith's words, 'What got you here, won't get you there.'

While digital health companies are eager to cash in on the burgeoning demands of healthcare, not all DTx solutions have been successful in the past.

For our next analytical initiative, we have proposed one criteria for hypothesis followed by key considerations for each innovation dimension to establish future dimensions of success.

In real-world practice, each innovation dimension can be tested on multiple criteria or assumptions before launch.

KEY CONSIDERATIONS FOR INNOVATION DIMENSIONS

At this stage, it is crucial to determine what needs to be retained and maintained, what should be dropped, and what can be improved to leap forward.

DESIRABILITY

Key Hypothesis:
Sufficient clinical evidence varies and depends on the patient condition, population, regulatory requirements, etc. Each institution has its own approval process (according to DTA).

Remarks:
The basic core or inner-shell of a DTx solution is "Clinical Evidence." The stage is being set for robust, long-term evidence-based DTx frameworks.

Futuristic Consideration:
It would involve more awareness and understanding of DTx products place in care, and more RCTs, peer-based reviews and real-world studies.

VIABILITY

Key Hypothesis:
While the opportunities can be unending, developers can draw the line by not boiling the ocean and prioritizing markets and indications (like applying Pareto's 80/20 rule) that are most promising.

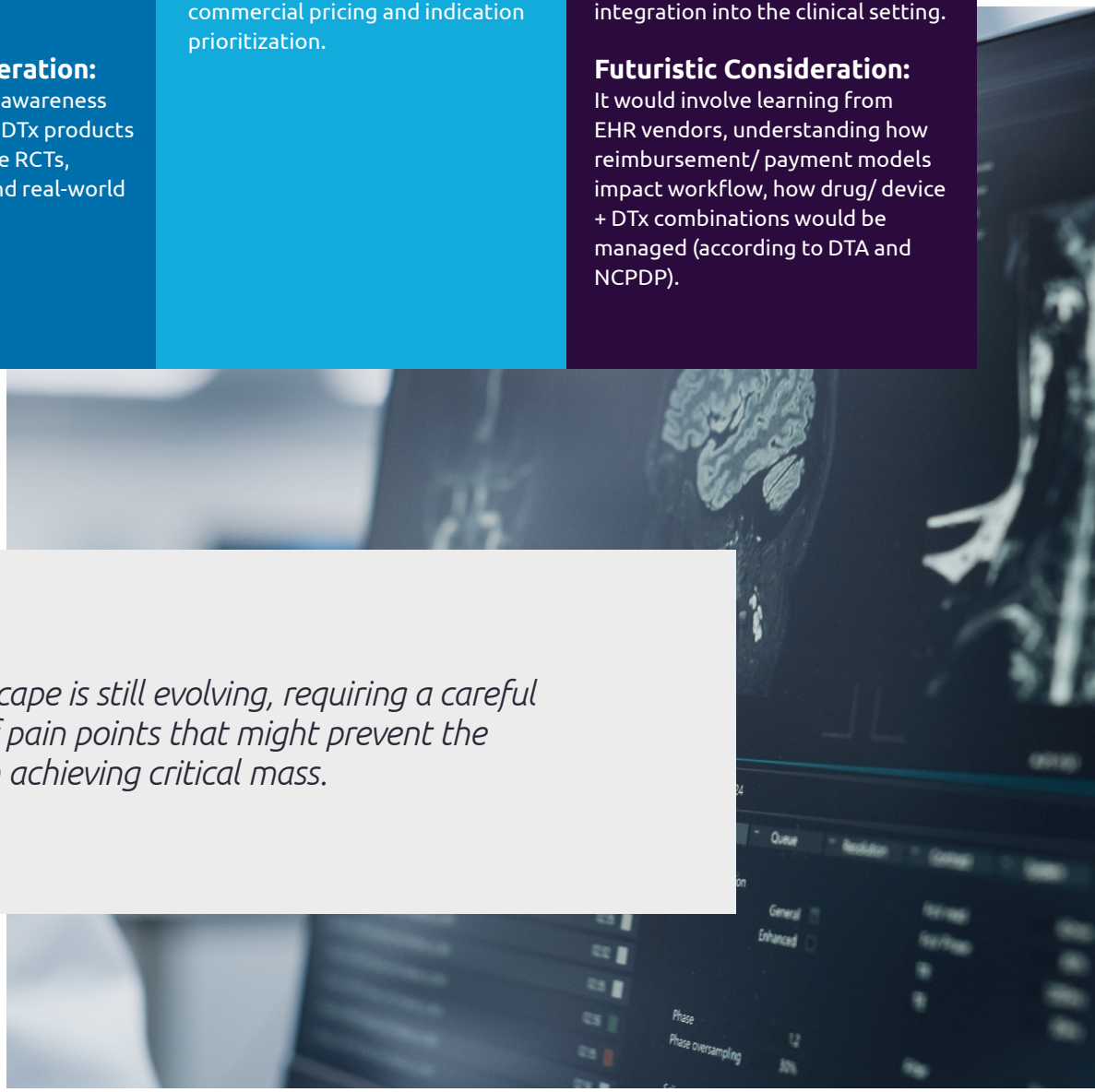
Futuristic Consideration:
It can include market prioritization - European countries are good with clinical validation or approval, and the US is better for commercial pricing and indication prioritization.

FEASIBILITY

Key Hypothesis:
Not all clinicians have access to a full integrated EHR and is integration into EHR necessary for a DTx?

Remarks:
While good clinical validation would make the inner shell stronger, a DTx solution is incomplete without a beautifully designed outer-shell featuring proven user experience and integration into the clinical setting.

Futuristic Consideration:
It would involve learning from EHR vendors, understanding how reimbursement/ payment models impact workflow, how drug/ device + DTx combinations would be managed (according to DTA and NCPDP).



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

WHAT QUESTIONS MUST BE ADDRESSED TO FIND THE INNOVATION SWEET SPOT?

In this section, we have benchmarked ~12 DTx solutions across the trifecta of innovation i.e., desirability, feasibility, and viability.

A scoring criteria was developed for each parameter and one DTx was compared to another. This helped in understanding how various DTx solutions are evaluated.

Based on a subset analysis of 12 marketed DTx solutions in oncology, it can be ascertained that these solutions can have a common, broader criteria for evaluation, but not all digital therapeutics in oncology are the same.

After developing an understanding of the evaluation criteria of various DTx solutions in oncology, Capgemini experts provide an overview of business questions that can be critically analyzed in the 'Innovation Discovery Phase.'

This can enable the successful development, launch, and adoption of DTx solutions over time.

The evaluation criteria and business questions revolving around the three innovation dimensions of desirability, feasibility, and viability are for representation purpose only.

EVALUATION CRITERIA OF DTx

There could be more than one DTx solution approved and available in the market for the same therapy area or cancer indication. While they might be similar, they are not the same. Strength of data or level of evidence vary across parameters for the marketed DTx solutions. While most of the DTx developers are conducting clinical trials and competing with respect to their clinical evidence and technological features, they differ in parameters related to digital reporting of clinical outcomes, real-world evidence generation, and their regulatory and reimbursement guidance.

COMPARATIVE ASSESSMENT OF 12 MARKETED DTX SOLUTIONS USING CAPGEMINI SCORING AND RANKING MODEL

	PARAMETERS FOR ASSESSMENT							
DTx Solutions	No. of Applications	Clinical Evidence	Regulatory	Reimbursement	Technology	Reporting	Real-World Evidence	CONSOLIDATED RANK
DTx 1	1	2	2	2	2	3	2	2
DTx 2	3	3	2	1	3	2	3	1
DTx 3	1	2	3	2	3	3	2	1
DTx 4	3	2	1	2	3	1	1	3
DTx 5	2	3	2	1	1	1	1	6
DTx 6	1	1	2	1	3	2	1	7
DTx 7	2	1	2	1	3	3	1	4
DTx 8	3	1	1	1	1	1	1	8
DTx 9	2	1	3	1	3	1	2	4
DTx 10	2	2	1	1	3	2	1	5
DTx 11	3	1	2	1	3	3	1	3
DTx 12	2	1	1	2	3	2	1	4

Moving forward, we will analyse the three innovation dimensions of desirability, feasibility, and viability separately and then bring them together.

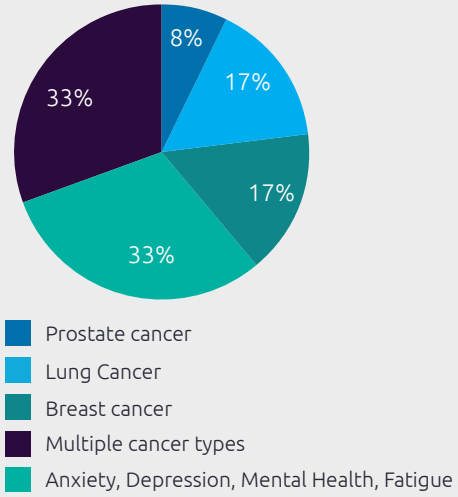
DESIRABILITY

The adoption of any innovative solution is guided by the benefits perceived by the medical community and patients, their beliefs, and expectations. DTx developers are assessing the 'desirability' for a proposed solution and building a hypothesis for 'user adoption' before taking the giant leap. While companies are making considerable efforts to educate HCPs, oncologists, and cancer patients on the use of digital therapeutics, these solutions are yet to disrupt the current workflow and garner high volume of prescriptions. Focusing on long-term clinical evidence as compared to current standard of care, ensuring seamless onboarding, and improving digital therapeutic experience is essential.

Criteria for Evaluation:

Intended Use:
Important to ascertain that the DTx solution or product prevents, manages, or treats a disease. Of the 12 evaluated DTx solutions, majority are helping with "management" of cancer. A DTx can target only one application area and one cancer indication, or it could be used for at least three application areas and more than one cancer indication. A DTx could monitor symptoms of one cancer indication like breast cancer or lung cancer or prostate cancer patients or it could be used for multiple cancer indications. For example, Kaiku Health is currently in clinical routine use for over 25 different cancer types.

Target Cancer Indications



Clinical Evidence:

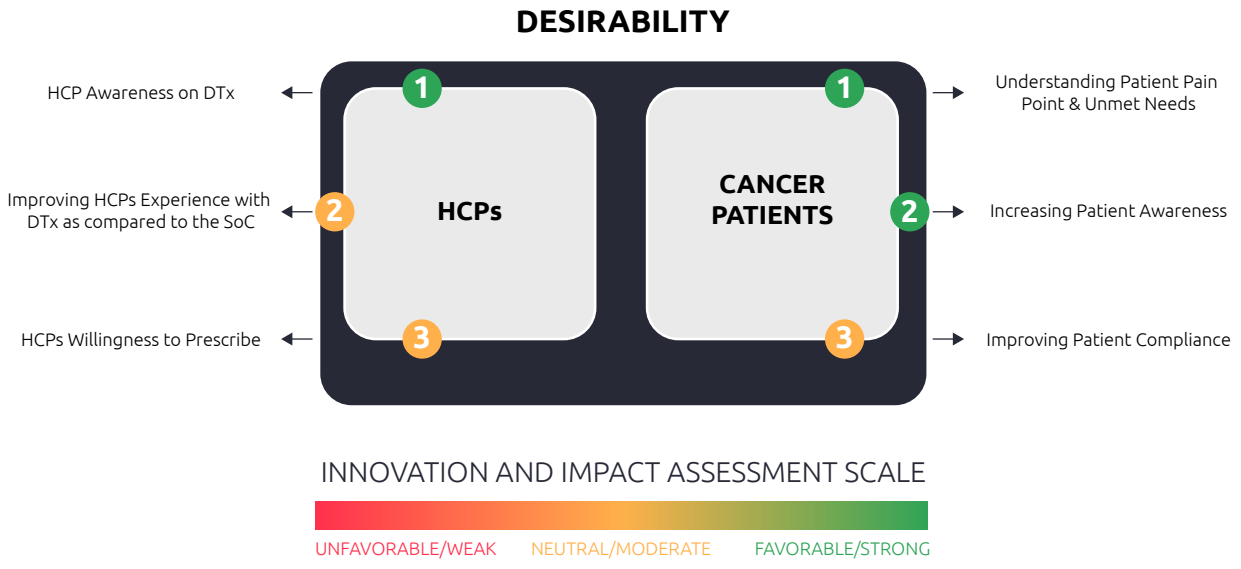
~50% of DTx have at least one completed RCT (randomized clinical trial). For the remaining, clinical trials are ongoing. For example, in a multicentre phase III RCT, a DTx (web-based symptom monitoring) was compared with a conventional symptom monitoring (routine surveillance following lung cancer treatment/standard schedule imaging to detect recurrence) in ~98 lung cancer patients. Pilot studies to confirm clinical efficacy, effectiveness, and safety are making way to large, phase III pivotal trials with primary outcome measures, including Overall Survival (OS) data or reduction in symptoms related to cancer (change in psychological distress). Clinical evidence is being published in credible scientific journals. For example, a DTx has been validated by clinical studies in France with published evidence in leading oncology journals such as JAMA, JNCI, JCO. Abstract presentations in oncology conferences such as the ASCO (American Society of Clinical Oncology).

DESIRABILITY: QUESTIONS TO BE ADDRESSED BY DTx DEVELOPERS

Based on secondary analysis of currently available DTx solutions, DTx developers score favourably/strongly on 50% (3/6) of the desirability factors while the remaining 50% (3/6) of factors fall under a moderate score.

HCPs' Perspective	Cancer Patients' Perspective	Competition
1. Are the HCPs aware of the benefits/ characteristics of DTx solution over standard practice?	1. What is the pain point? Is the DTx solution solving for the problem?	1. Are there other DTx solutions in oncology? How are the other solutions positioned in clinical practice with respect to the target indication, primary and secondary outcome or clinical benefits, place in patient journey, etc.?
2. Are the HCPs comfortable with the use of digital remote solutions?	2. What percentage of patients would comply with HCP recommendation for a DTx solution?	2. Are the companies doing enough for patient related engagements?
3. Do the HCPs believe that this solution will improve their experience? Would this likely ensure a prescription for DTx?	3. Do the patients believe that this solution will improve their experience? Does it support their underlying motivator?	3. What are the reasons for the successes or failures of DTx solutions?

When it comes to desirability, companies are trying to increase HCP and patient awareness. However, HCPs need more evidence and experience with newer solutions like DTx. Building evidence is the key to gaining acceptance.



FEASIBILITY

Feasibility involves evaluating factors that limit the adoption of innovative digital modalities/ DTx solutions and understanding the product-market fit. Factors related to technology, regulations, reimbursement, and workflow integration, among other factors, can impact feasibility. Additionally, feasibility is affected by the understanding of whether there is a widely adopted solution available in the market. If not, how is the problem circumvented? Feasibility also entails an understanding of which metrics underpin developers' decision to build/continue or not launch/ discontinue a DTx solution.

Criteria for Evaluation:

Technology:
Technological aspects are critical since the benefits of DTx should effectively reach the end-users. The majority of DTx solutions competing on such parameters as ease-of-use, accessibility, language, end-user guidance and support, and interoperability, etc. The DTx may or may not be AI/ML driven.

Digital Reporting:
ePRO and an active reporting system is followed in the majority of the DTx solutions. Typically, DTx solutions have a patient reported outcome and not physician reported outcome. Digitally reported outcomes include cancer related symptoms, muscle strength, anxiety, depression, mental health or fatigue related concerns, medication compliance, or quality of life. Active reporting is done either through an e-form or an e-patient diary. Not all DTx solutions have automatic reporting in case of emergencies and anomalies. Personalised follow up and recommendations enabled by care teams are provided in a few cases.

Regulatory Validation:
Regulatory clearance or approval can vary for a DTx, from country to country. Very few DTx solutions have an approval in both the US and a European country (for example, one DTx has a CE class IIa medical device in Europe and a Class II medium risk device in the US). In the US, the FDA allowed for enforcement discretion or exempted the SaMD from market authorization requirements. During the COVID-19 pandemic, emergency use authorization was granted by the US FDA. In Germany, the Digital Healthcare Act of 2019 paved the way for reimbursement and a fast-track regulatory pathway for DiGA. One of the fast-tracked solutions has been recently removed from the DiGA directory, with the developer expected to submit clinical trial results. In Europe, under the new EU Medical Device Regulation (MDR 2017/745) of May 2021, DTx solutions require CE mark for safety, effectiveness, and performance, except for class I, which can still self-certify with a notified body.

FEASIBILITY: QUESTIONS TO BE ADDRESSED BY DTx DEVELOPERS

Based on secondary analysis of currently available DTx solutions, DTx developers score favourably/strongly on 20% (1/5) of the feasibility related factors while 80% (4/5) of factors fall under a moderate score.

Technology

1. What are the digitally reported outcomes that will be most credible/relatable to HCPs?
2. Are HCPs and patients comfortable with web or app-based access? Are DTx solutions easy to use?
3. What type of patient reporting format – active vs. passive – would integrate with clinician workflow?
4. What would be the most feasible mode of reporting? What is the breaking point where patients would stop using a DTx solution?

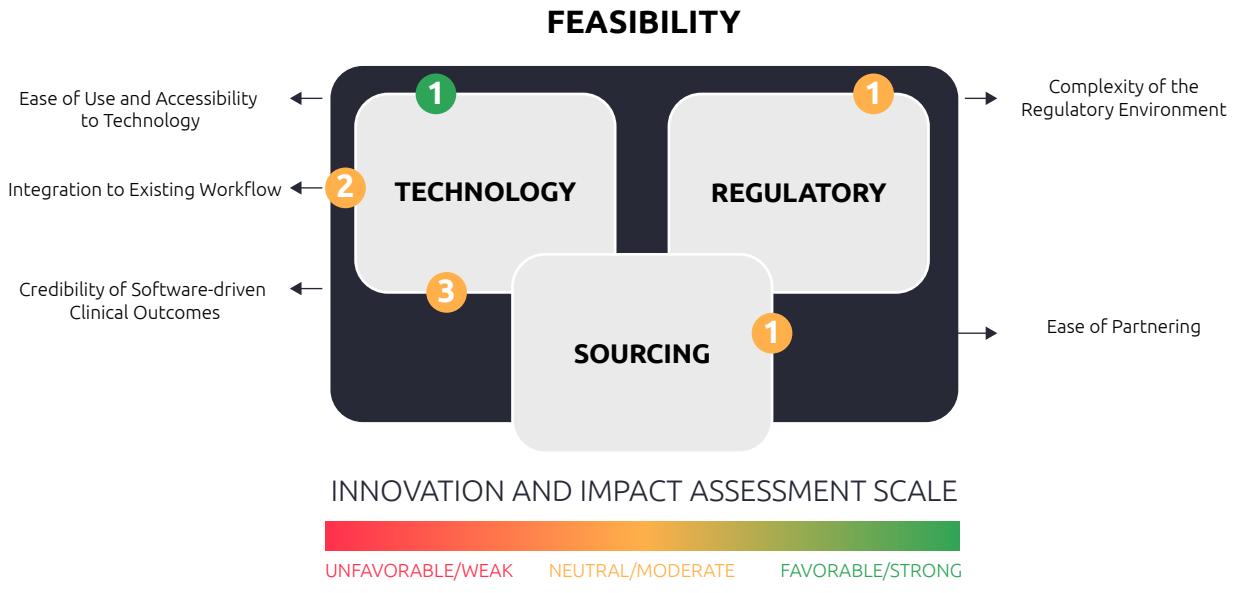
Regulatory

1. What would it take to get the DTx approved?
2. Are there any barriers for market entry? Do the HCPs, regulators have liability concerns around the use of a DTx?

Partnerships / Sourcing

1. Who would be the essential partners? Is it realistic to find partners with both clinical and commercial experience to market DTx solutions?
2. What would be the most appropriate channels to market?
3. Does the mechanism of action and engagement of the DTx solution fit with current practices or would it require guideline modifications?

Technological capability is the backbone of DTx solutions, but gaining acceptance from multiple stakeholders - HCPs, regulators and payors for digitally driven clinical outcomes is an arduous task.



VIABILITY

Whether a business model is viable in the long run is often difficult to predict. Nevertheless, answering some of the basic questions – What is the potential market size, what to expect, how to win, what is the go-to-market approach, etc. – can help develop a business roadmap. Furthermore, estimating the viability of a DTx business model is extremely difficult. Public disclosures of financials of DTx developers are limited. Many DTx developers are privately-owned startups aspiring to partner with big pharma organization, who are less versatile when it comes to marketing software-driven devices for medical purposes. At the outset, the entire disease population can be an "opportunity," but narrowing down on the "right segment" and assessing the viability of the business model is important. Opportunity assessment, indication, and market prioritization to identify a market-entry and market-growth strategy can be crucial for success.

Criteria for Evaluation:

Reimbursement:
DTx solutions are increasingly seeking and gaining reimbursement by various stakeholders. The reimbursement status of DTx can vary from country-to-country. European countries like Germany and France have taken a lead in approving DTx, compared to, say, the US. In the US, the private payer adoption for DTx has been better than the public system. However, in 2022, the US passed the "Access to Prescription Digital Therapeutics Act" to provide Medicare coverage and reimbursement for DTx, which can improve access related issues. Despite a regulatory validation, not all marketed DTx are being reimbursed currently. A DTx developer is compelled to negotiate with every payer for reimbursement as there is no common EU approach to reimbursement.

Real-World Evidence:
Finally, evidence of use of DTx in the real world is becoming increasingly important. One DTx developer conducted a retrospective real-world study. The study established that real-world symptom data collected through the ePRO application on cancer patients receiving ICI therapy aligns with the data from clinical trials. While companies are trying to provide insights into the practical use of DTx through physician and patient feedback, the real-world evidence through retrospective or prospective observational real-world studies is yet to be established.

VIABILITY: QUESTIONS TO BE ADDRESSED BY DTx DEVELOPERS

Based on secondary analysis of currently available DTx solutions, 50% of viability factors are strong/favorable while 50% fall under a weak score.

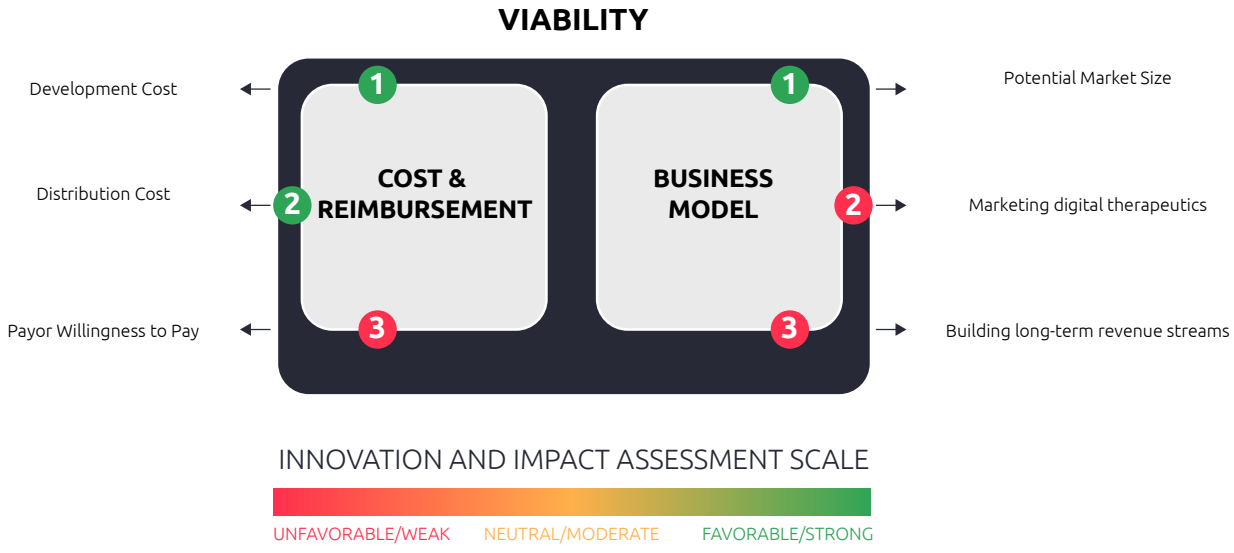
Cost & Reimbursement

1. What are the costs associated with development of a DTx solution?
2. What are the costs associated with the distribution of a DTx solution?
3. Are the costs less than the existing standards of care?
4. How can payors reimburse the DTx?
5. Is the DTx perceived as a cost-effective solution?

Business Model

1. What is the potential market size for such a solution?
2. What is the scope for a stand-alone solution compared to a combination therapy?
3. How long will it take to launch? When will it be too late (not reaching breaking point) to launch this DTx solution?
4. Is there a potential to generate significant enough revenues from this DTx solution?

With lower development and distribution costs compared to traditional pharma, and growing opportunities to synergize with pharma, the sky is the limit for DTx. But digital therapies still need to get over the hump. Reimbursement of DTx solutions is a major challenge. Moreover, stakeholders need to be convinced that a DTx solution can deliver on its promises.



FINDING THE INNOVATION SWEET SPOT CAN BE AN EXPENSIVE AND CONTINUOUS PROCESS

With new initiatives in the pipeline (e.g., new legislation in the US is in favor of the coding and reimbursement of DTx by Medicare), companies must continue to create an opportunity roadmap and allow DTx solutions time to grow on users (both HCPs and patients alike). At the same time, it would be critical for companies to quickly and reliably assess the implications of the evolving regulatory and reimbursement needs of each country and align them to their business model.

The recipe to long-term success would involve a few key ingredients: sufficient clinical evidence, including real-world outcomes, easy integration into existing technological workflows for cancer patients, and improved accessibility.

Improving accessibility will require DTx solutions to be built for multiple cancer indications, including rarer forms, and not just for a handful of targets. Allowing DTx to collect patient data and generate novel digital biomarkers would help in early management of cancer.

The DTx innovation sweet spot sits at the center of desirability, feasibility, and viability. The question is: have DTX oncology companies found the innovation sweet spot?

Right now, there is no perfect solution. But developments are rapid, and the future is still to be written.

The winners will be those that combine the highest level of desirability, feasibility, and viability. It is important to build evidence around therapeutic efficacy that can drive adoption of DTx solutions in oncology. It is also important to build an interesting UI/UX that can stand the test of time. Short-term wins need to lead to long-term successes and make more scientific/therapeutic and economic sense in the real world.

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ABBREVIATIONS

1. DTx: Digital Therapeutic
2. DTA: Digital Therapeutics Alliance
3. RCT: Randomised Clinical Trial
4. EHR: Electronic Health Record
5. UX: User Experience
6. UI: User Interface
7. NCPDP: National Council for Prescription Drug Programs (American non-profit standards development)
8. HCP: Health Care Professional
9. JAMA: The Journal of the American Medical Association
10. JCO: Journal of Clinical Oncology
11. ASCO: American Society of Clinical Oncology
12. JNCI: Journal of the National Cancer Institute
13. ePRO: Electronic patient reported outcome
14. AI/ML: Artificial Intelligence and Machine Learning
15. SaMD: Software-as-a-medical device
16. ICI: Immune Checkpoint Inhibitor
17. OS: Overall Survival
18. MDR: Medical Device Regulation
19. CE: Conformité Européene
20. FDA: Food and Drug Administration
21. DiGA: Digitale Gesundheitsanwendungen, digital health application in Germany

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About Capgemini Invent

As the digital innovation, design and transformation brand of the Capgemini Group, Capgemini Invent enables CxOs to envision and shape the future of their businesses. Located in over 30 studios and more than 60 offices around the world, it comprises a 12,500+ strong team of strategists, data scientists, product and experience designers, brand experts and technologists who develop new digital services, products, experiences and business models for sustainable growth.

Capgemini Invent is an integral part of Capgemini, a global leader in partnering with companies to transform and manage their business by harnessing the power of technology. The Group is guided everyday by its purpose of unleashing human energy through technology for an inclusive and sustainable future. It is a responsible and diverse organization of nearly 350,000 team members in more than 50 countries. With its strong 55-year heritage and deep industry expertise, Capgemini is trusted by its clients to address the entire breadth of their business needs, from strategy and design to operations, fueled by the fast evolving and innovative world of cloud, data, AI, connectivity, software, digital engineering and platforms. The Group reported in 2022 global revenues of €22 billion.

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