

Ipsos Playbook for Development & Commercialization of Digital Therapeutics (DTx)



GAME CHANGERS



What is DTx?

Digital therapeutics (DTx) are defined as health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.



Source: ISO/TR 11147: Health informatics—Personalized digital health— Digital therapeutics health software systems (2023)

Why present this playbook?

DTx, a novel medical category, holds remarkable potential to address unmet medical needs innovatively. However, their commercial launch can encounter hurdles due to agile development processes, unique market access pathways, and challenges integrating into standard clinical practices.

Market planning and commercial launch of DTx necessitate a blend of existing drug and device frameworks, complemented with unique launch and market access strategies.

At Ipsos, our passion for healthcare innovation fuels our commitment to assist DTx companies in developing and commercializing their solutions. We created this playbook to share our perspective on the ideal framework for product development and approaches for how we can help you expedite success.

What are we presenting?

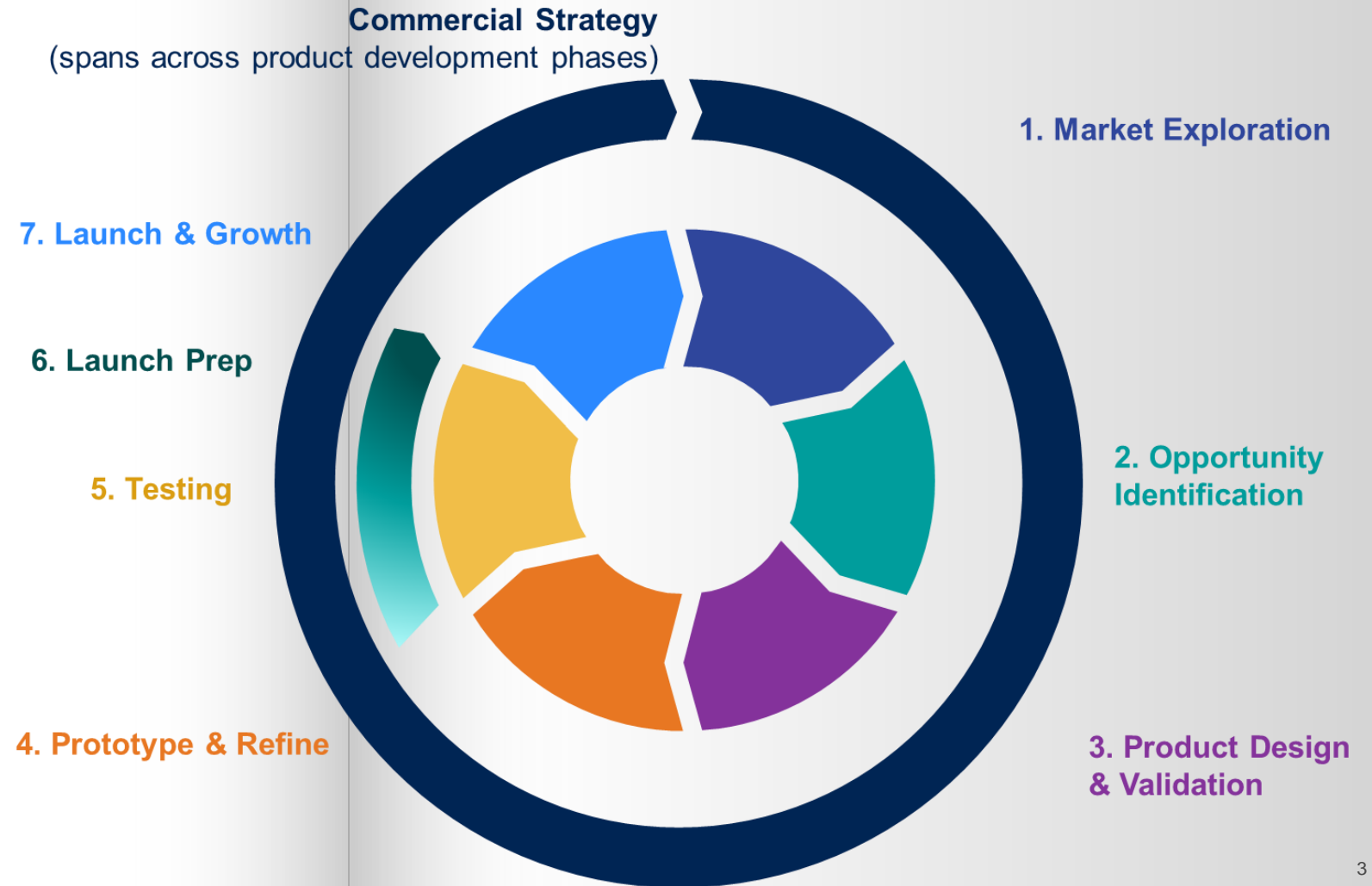
This playbook is a step-by-step guide to navigating DTx product development and commercialization. We've organized it into clear phases, each with its own specific goals and key questions to help guide your progress. Additionally, the playbook incorporates our suggested approaches for generating insights to these key questions and achieving phase goals.

Phases in Digital Therapeutic Product Development

DTx product development is a cyclical journey that starts with pinpointing a market need through in-depth analysis of trends and patient demands. This initial phase informs the entire process, leading to development, testing, and iterative refinement.

Even after launch, the cycle continues. By actively monitoring market shifts and gathering feedback from users and other key stakeholders, DTx products can be continuously optimized for sustained performance and market relevance.

DTx Product Development & Commercial Strategy



Phase 1 – Market Exploration



Goal

Explore market dynamics and develop a thorough understanding of the market, current and future trends, and unmet needs.

Key Business Questions

- What is the current standard of care?
- What are the current and future trends?
- Who are the competitors? What are they offering and what do they have in development?
- What are the current access and reimbursement pathways? How is this evolving?
- Who are the important stakeholders?
- What are the unmet needs of patients and other key stakeholders?
- Are there any relevant patient advocacy groups? If so, what are they?
- What is the size of the market?

Approaches

Market Landscape Assessment, Competitive Assessment, Stakeholder Mapping



Phase 2 – Opportunity Identification

Goal

Decide which opportunity(s) you are going to act on, loosely define target user and customer archetypes, and establish a clear value proposition.

Note: Customers refer to the primary decision-makers in purchasing the DTx. The customer can vary based on the market but can include health plans, physicians, parents, etc.

Key Questions

- For each unmet need: How important is it? What is the level of need? How are competitors addressing it?
- Which unmet need(s) present the greatest opportunity? Which should we act on?
- What are the appropriate business models for commercialization?
- What is the commercial opportunity for the different market segments? Which segment(s) of the market should we focus on for product design and commercialization?
- What are the demographics, attitudes, and behaviors of the target market segments?

Approaches

Needs Prioritization, Early Commercial Assessment, Market Sizing, Early User Experience, Product Strategy



Phase 3 – Product Design & Validation

Goal

Build a product concept and test your idea with feedback from target users and key stakeholders to gauge demand and commercial potential.

Key Questions

- What features are most impactful for my product?
- Which design elements should be incorporated?
- What external factors need to be considered in the product design to ensure usability?
- How interested are users in adopting this future product? How interested are other key stakeholders?
- What will compel user to adopt? What strategies are needed to ensure engagement and adherence?
- What do customers need to see to be compelled to pay for (or reimburse) the product?
- Does the product have viable commercial potential? What is its commercial opportunity?

Approaches

Product Ideation & Design, Concept Testing & Iteration, Commercial & Market Access Assessment



Phase 4 – Prototype & Refine

Goal

Design a user-centered MVP prototype that addresses core user needs and refine based on user input.

Key Questions

- Is the product usable and easy to navigate?
- Does the product seamlessly integrate into the user's regular workflow or daily life?
- Are there any confusing elements in the design?
- Does the user flow make sense and guide users through the desired actions?
- Does the product address the needs and solve the problems of the target users?
- Are there any missing functionalities that users express a need for?
- Does the product evoke the desired emotions and feelings in users?

Approaches

Human Factors / Usability Design, Usability Testing, Human Factors Validation Testing

Phase 5 – Testing



Goal

Test your product, generate compelling data, and secure appropriate regulatory approval.

Key Questions

- What level of testing is required for my product before market launch?
- Where should I test my product?
- Who are the right partners for testing my product?
- What key metrics should I be collecting during trial to ensure I generate compelling data to maximize access and uptake at launch?
- Does the final product design meet all regulatory requirements for market release?
- Is the product documentation complete and clear for both users and regulatory bodies?

Approaches

Access & Partnership Strategy, Usability Testing, Human Factors Validation Testing



Phase 6 – Launch Prep

Goal

Prepare for commercialization by refining your business model, establishing your product positioning, and developing your marketing strategy.

Key Questions

- What business model(s) should be used to maximize patient access and revenue generation?
- How should the product be priced?
- Should we establish a soft launch strategy before a broader market launch? Who is the appropriate target population for a soft launch?
- How will we uniquely position our product?
- Which market segments will we target for launch?
- What are the unique value stories we will communicate to key stakeholders to compel them to trial/purchase?
- What actions should we take to create a cohesive marketing and sales campaign across all channels?

Approaches

Launch Planning, Market Access & Pricing Strategy, Positioning & Messaging Strategy, Omnichannel Strategy



Phase 7 – Launch & Growth

Goal

Launch your product in the market, execute marketing and sales tactics, and monitor your performance in the market. Refine your product based on market feedback.

Key Questions

- How are we doing on KPIs such as awareness, trial, usage, engagement, and adherence? How does this compare to competition?
- How satisfied are users with the experience, design, and functionality of our product?
- Is our brand message effectively reaching and resonating with our target audience? What message variations perform best?
- How do users and key stakeholders perceive our brand compared to competitors?
- Which marketing channels are driving the most impact?

Approaches

KPI Tracking, Brand Equity, Omnichannel Marketing & Campaign Analytics, Message Testing, Marketing & Sales Assessment

Commercial Strategy



Goal

Evaluate your product in the broader market; consider strategic partnerships and acquisition opportunities.

Key Questions

- What is the current forecast for our product's market share and revenue? What strategies can we employ to expand the market opportunity for our product?
- What type of partnerships would be most beneficial for our company's growth (co-marketing, co-development, distribution)?
- Who are the right strategic partners for us, considering factors like market reach, complementary strengths, and cultural fit?
- Should we consider selling as an exit strategy? If so, how should we value our product?

Approaches

Market Opportunity Assessment, Business Development Strategy, Forecast Modeling

Thanks for reading.

Questions? Comments? Please email:



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