EXECUTIVE SUMMARY
Second DTx Monitoring Report

The Second DTx Monitoring Report expands the research focus from digital therapeutics (DTx) to **digital health technologies (DHT)**, which currently represent a gray area with limited regulation, known as *connected care*.
This report aims to:

1. Clarify definitions of DHT and DTx.
2. Map the evolution of DTx in Europe.
3. Examine the ecosystem of Digital Health Technologies (DHT) and the current framework of DTx in Italy.
4. Define the budget impact of DTx in Italy.
5. Propose operational recommendations developed by the working group.

1. DEFINITIONS: FROM DIGITAL HEALTH TECHNOLOGIES (DHT) TO DIGITAL THERAPEUTICS (DTx)

The working group aimed to clarify the concept of DTx and classify digital health technologies **(DHT) with clinical purpose**, even if different from therapeutic claim, identified as patient-managed digital medical devices (pDMD). These technologies have been categorized based on their medical purpose into **5 categories: Digital therapeutics, Remote Patient Monitoring** (RPM), **Digital Diagnostics and Digital Prevention**. This classification helps in identifying digital health technologies and supports the development of regulations to facilitate their use in clinical practice and subsequent reimbursement.

2. MAPPING OF DTx IN EUROPE

a. COUNTRY SITUATION

The global market revenue for digital therapeutics is expected to reach **$4.68 billion in 2024**, with a compound annual growth rate (CAGR) of 16.61% from 2024 to 2029, reaching a market volume of **$10.09 billion by 2029**. In Europe, **Germany** leads the digital health technologies sector **with 55 reimbursed DiGAs**, compared to 49 in the same period (Q3) of 2023 (+12%), with 20 on the provisional list and 35 on the permanent list. The **United Kingdom** follows with **35 DHTs** approved by NICE (National Institute for Health and Care Excellence), a 150% increase from the 14 devices approved in Q3 2023. **France** with at least **4 DTx** and **3** remote monitoring devices **(RPM)** included in PECAN. In July 2024, **Spain** developed a methodological framework for evaluating digital health technologies in the post-market authorization phase.

b. ANALYSIS OF DiGAs PRICES

A price analysis of 33 permanently listed DiGAs in Germany shows an average DiGAs price of €222, with an **average permanent list price** ranging from **€220 in 2021 to €235 in 2024**. Among the DiGAs analyzed, 30 of them had a price reduction following negotiations, averaging **-47%**. One DiGAs was reimbursed at the same price as on the provisional list, while **two were reimbursed at a higher price** than on the provisional list (an average increase of 33%), both for the treatment of tinnitus.

3. THE ITALIAN CONTEXT

a. MAPPING OF PATIENT-MANAGED DIGITAL MEDICAL DEVICES (pDMD) IN ITALY**

Based on the medical device registry of the Ministry of Health, the CND (National Classification Codes of Devices) related to software as a medical devices were identified with the aim of mapping pDMD in Italy. Out of 344 devices analyzed, **45** met the definition of **pDMD**. Of these, **46%** (n=21) perform monitoring (Remote Patient Monitoring - **RPM**), **38%** (n=17) **therapy** (DTx), 9% (n=4) **prevention** (Digital Prevention), and 7% (n=3) **diagnosis** (Digital Diagnostics). Of the devices analyzed, 31 are registered as **Class I**, 12 as Class IIa, and 2 as Class IIb, while no devices are assigned Class III.

b. MAPPING OF DTx IN ITALY

The number of **Italian companies** developing digital therapeutics is growing significantly: **23** in 2024 compared to 13 in 2023. Of these, **16 are innovative startups**, 3 are innovative SMEs, 1 is a non-innovative startup, and 3 are established companies. The total number of **potential DTx** in Italy is now **41**, compared to 18 reported in 2023, with **17** already registered as **medical devices** with the Ministry of Health. Currently, 7 technologies are undergoing **clinical trials in Italy**, one more than in 2023. Of these, three are also registered as medical devices.

4. BUDGET IMPACT ANALYSIS OF DIGITAL THERAPEUTICS IN ITALY

A budget impact analysis (BIA) was conducted to evaluate the impact of digital therapeutics in the Italian national context. The model considers **17** DTx from the medical device registry of the Ministry of Health, associated with 8 therapeutic areas, over a three-year period (2025-2028). Various scenarios were considered, using the following variables: a) the treatment rate of the target population (5% - 10% - 20% of the affected population) b) the price of technologies (€100 - €200) estimated based on the value of DiGAs currently reimbursed on the permanent list in Germany. The most plausible scenario considers an adoption rate of 10% and a technology price of €200, estimating a budget of approximately **€18.2 million in year 1, €36.4 million in year 2, and €54 million in year 3**. This model provides an indication of the size of a dedicated DTx fund.

5. OPERATIONAL PROPOSAL

Given the complexity and lack of specific regulations on digital health technologies (DHT), the working group of the Digital Health Policy Lab proposes in the Second DTx Monitoring Report an operational model to support policymakers in developing regulations for innovative health technologies. The proposal includes an **evaluation and reimbursement model** inspired by the accreditation process for new technologies being introduced in Emilia-Romagna, a region known for its high concentration of medical devices. This process involves an eligibility assessment (accreditation evaluation) followed by the accreditation process. The procedure includes the involvement of a dedicated evaluation committee and healthcare facilities that intend to adopt the innovative solution.

*The DTx Monitoring Report is the result of the work of the **Digital Health Policy Lab**, a research project established in 2022 in collaboration between **Indicon Società Benefit** and the **University of Milan**, aimed at promoting the development and access of digital health technologies (DHTs) in the Italian National Health Service.*