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20 Feb 2020

DTxITA
Accesso e Modelli di Business: Scenario Internazionale

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We just saw the highly promising world of DTx

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How do we grant access and sustainability to them ?

Payers readiness

- A recent research of payers shows a clear gap between payers recognizing the value of DTx in certain areas, and their ability to evaluate such solutions.

Applicable Area

Figure 2 Most Applicable Disease States for Digital Health
Number of mentions, n=10 payers

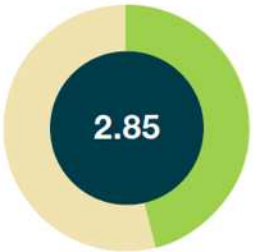
High Perceived Value

Value of digital health solutions across therapeutic areas

On a scale of one to five, with five being "very valuable," the average response was 4.38

Low preparedness

Organisation's preparedness to evaluate digital health solutions



On a scale of one (not prepared) to five (very prepared). Respondents admitted to having little experience with such evaluations.

http://www.iconplc.com/insights/value-based-healthcare/payers-perspectives-on-digital-therapeutics/

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Payers perspectives on clinical evidence

- Payers are interested in clinical evidence from RWE, beyond data from traditional clinical trials.

- Besides clinical outcomes, it is necessary to also demonstrate the benefits for:

✓ Reduced costs on hospital admissions and readmissions

✓ Reduced use of drugs

✓ Better adherence

Relevance of RWE

Likeliness to use real-world outcomes for coverage decisions

On a scale of one (not likely) to five (very likely), the average response was 4.4.

http://www.iconplc.com/insights/value-based-healthcare/payers-perspectives-on-digital-therapeutics/

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The field is fragmented but evolving rapidly and substantially in several countries

Country Case

USA

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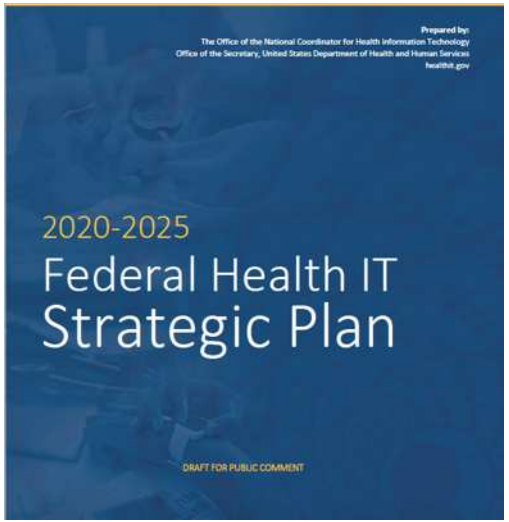
USA: scenario

Very heterogeneous marketplace with many fees paid directly by users, and increasingly also by other players

- **Millions of paying users** by way of monthly subscription fees
- **Private health insurers,** some **hospital providers, e large employers** are beginning to license or develop proprietary DTx solutions for their members and employees.

USA: DTx included in the federal plans for 2020-2025



- Development of plan for use of DTx in prevention and management and treatment of health conditions.
- Necessity for digital solutions to show clinical evidence
- Access needs to be via consumer smartphones, tablets e other personal devices

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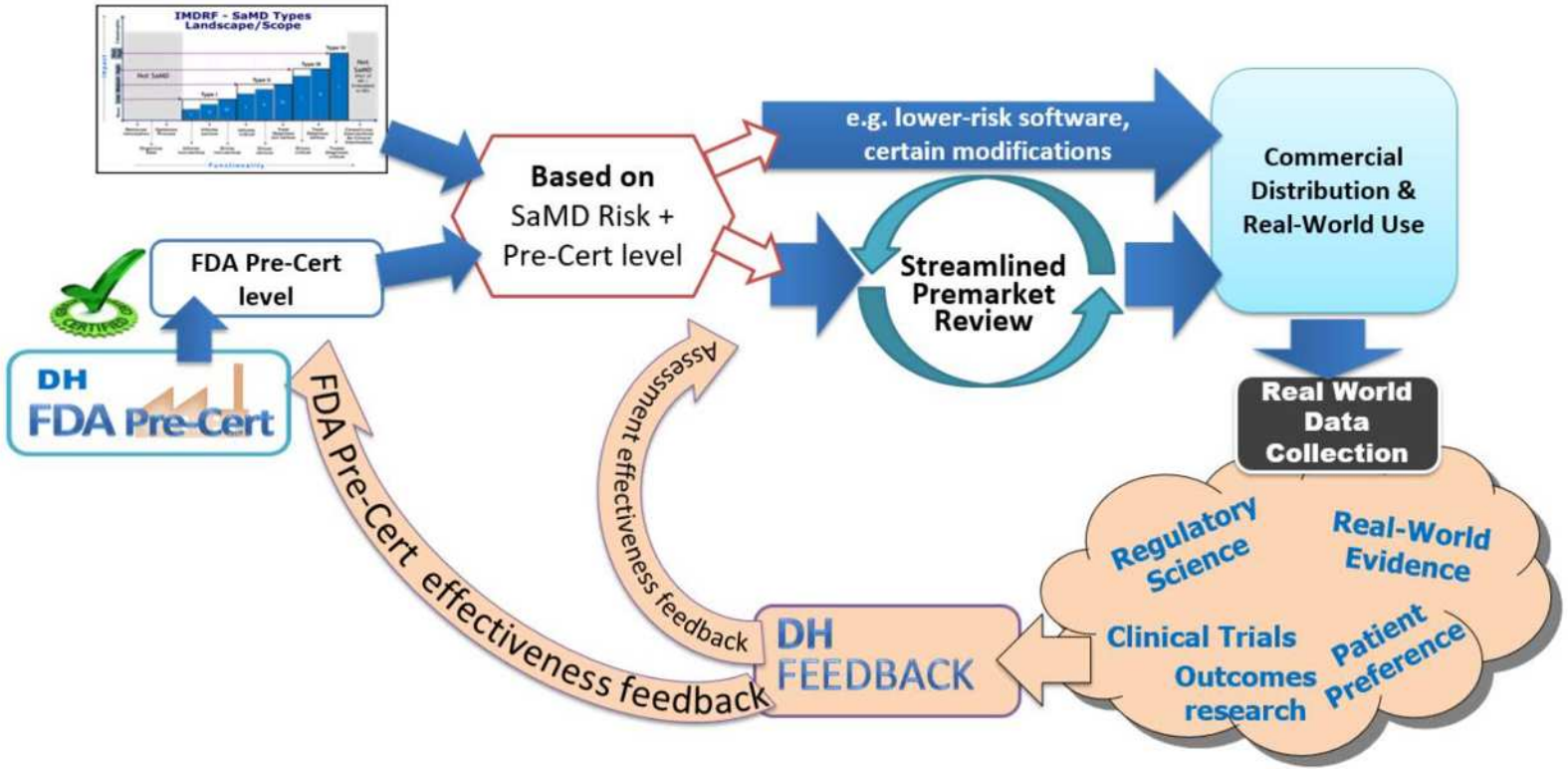
FDA's "Pre-Cert" process



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FDA 510k / 505(b)(2)

- **FDA 510(k) premarket device application** (DTx stand-alone software devices)
  - The device (even software) is at least as safe and effective and substantially equivalent, to a legally-marketed device (Pear's reSET-O device was approved through this pathway)

- **FDA 505(b)(2) application** (reformulations and combo improvements of existing drugs)
  - Can use pre-existing study data (even non-licensed) as part of the submission (with a very significant savings in NDA costs and timelines)
  - Original drug can be combined with a device for improvement (software device as well).
  - Request for non-patent exclusivity is possible for the new developed combo solution

Country Case

UK

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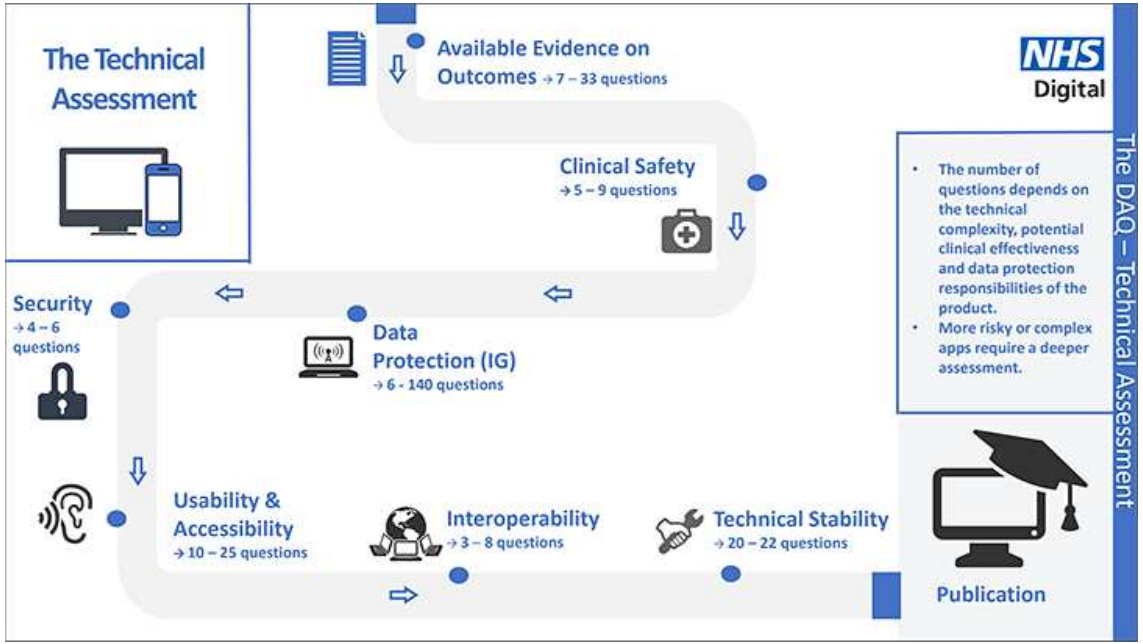
NHS' Digital Health access pathway

- Digital medicines are reimbursed through the standard NHS reimbursement pathway used for drugs.
- Specific standards and access pathways are being developed for digital medicines when seeking an evaluation by NICE as part of the Medical Technologies Evaluation Program.



https://digital.nhs.uk/services/nhs-apps-library/guidance-for-health-app-developers-commissioners-and-assessors/how-we-assess-health-apps-and-digital-tools

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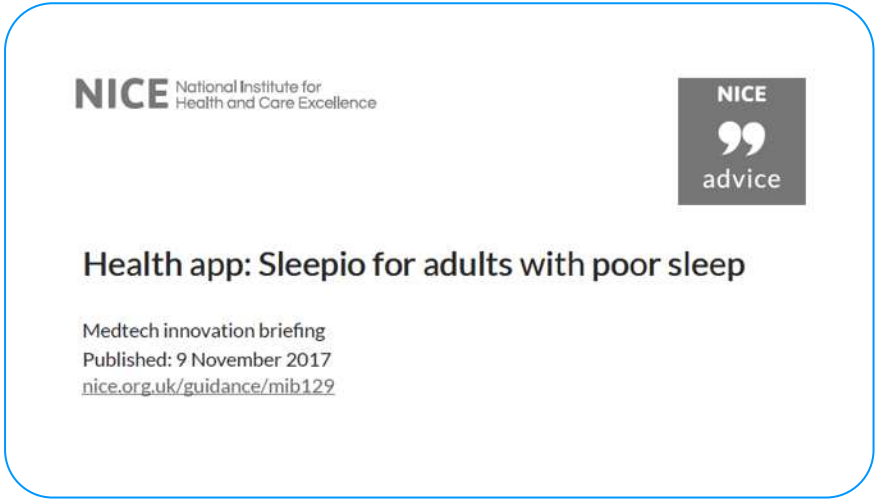
NICE: Assessment of DTx

NICE (National Institute for Health and Care Excellence) has completed the Health Technology Assessment (HTA) for several DTx solutions, including Sleepio e Deprexis, reporting overall positive results with regards to clinical efficacy, impact on costs and resources and benefits to the end users.



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NHS Roadmap for patient digital services

- The NHS has developed, and continues to update an extensive set of digital resources for patients (currently in its 5th version)

Link a Mappa integrale: https://eu-rm.roadmunk.com/publish/0dbd8ebaa98e26573e09b1d1fc74433d486ee5d2/

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Multiple-markets example

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Sleepio: Provisioned & Reimbursed in UK and US

Sleepio

Sleepio is a digital sleep improvement program designed to treat insomnia using Cognitive Behavioral Therapy (CBT).

- **UK:** Partnership with the NHS
  - Available for free (by license) to 8M users in London and 2,3M users in the Thames Valley.
- **USA:** Included jn the formulary of CVS Health
  - Administrator for the health and medicines benefit plans of large employers in the US.
  - 12 million employees now have free access to Sleepio via their health benefit plans, alongside traditional medicines.

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Additional cases of reimbursement (DH o DTx)

- There are several other important examples of reimbursed digital solutions at the global level. The links below have additional information on them, and have been included for distribution.

- *Express Scripts' Digital Health Formulary: A Foundation for the Future of Pharmacy* (12 Dicembre 2019)
- *Blue Cross and Blue Shield of Minnesota Launches Omada's Type 2 Diabetes Management Program* (13 Novembre 2019)
- *Big Health's Sleepio product receives coverage by the NHS (20 Maggio 2019)*
- *WellDoc's BlueStar product receives coverage by Business Health Care Group* (14 Maggio 2019)
- *Omada Health's product receives coverage by Priority Health (3 Ottobre 2018)*
- *Palo Alto Health Sciences's Freespira product receives coverage by Highmark Inc.* (24 Settembre 2018)
- *Omada Health's product receives coverage by Cigna* (18 Settembre 2018)
- *Propeller Health's product receives coverage by Anthem Blue Cross and Blue Shield* (16 Agosto 2018)
- *Voluntis' Insulia product receives coverage by WellDyneRx (14 Maggio 2018)*
- *Propeller Health's product receives coverage by Express Scripts* (16 Novembre 2017)

Aggiornamento febbraio 2020; dettagli disponibili su https://dtxalliance.org/dtxcoverage/)

Country Case

France

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France

- La HAS (Haute Autorité de Santé) approved a telehealth law in 2019, allowing medical and other health practitioners to be reimbursed for patient consultations held via approved vdeo conferencing platforms

- Reimbursement for digital health tools prescribed through the telehealth platforms has also been formalized,

- Insulia-Diabeo is the first digital health solution being approved, setting the precedent that other digital health solutions can follow for reimbursement in France.

Country Case

Germany

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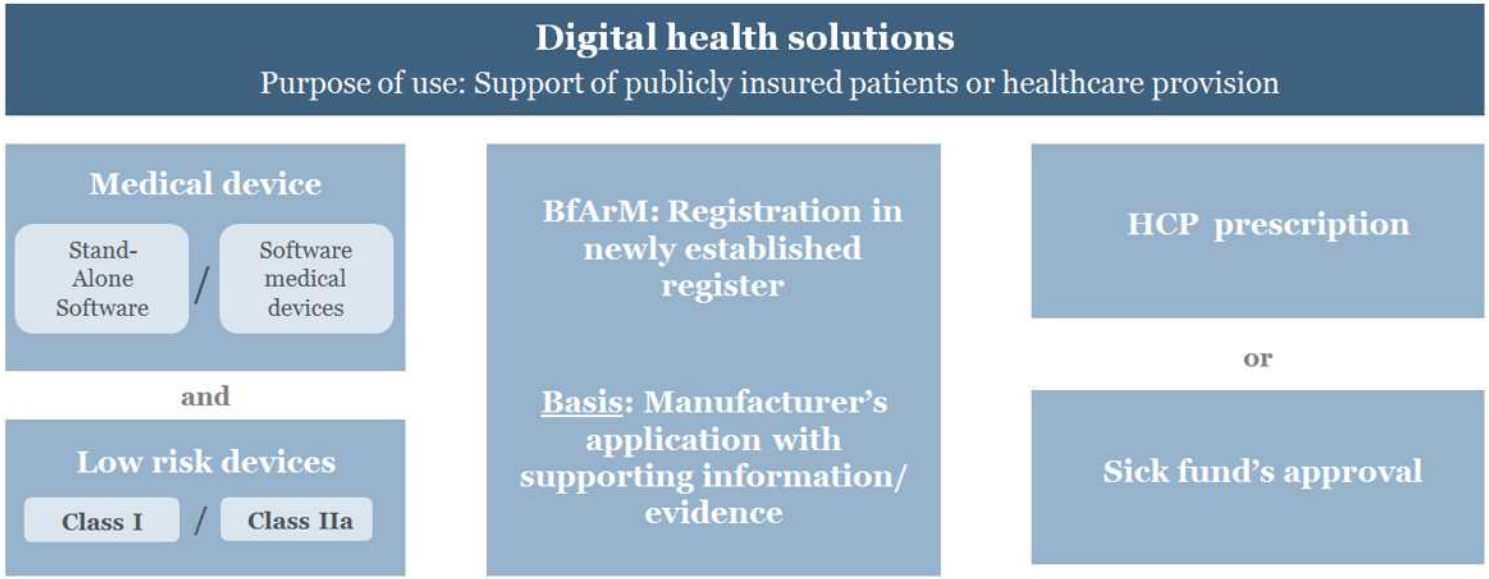
DVG: The new milestone for patients and providers

Approval of the new rules to support digital innovation in health (**Digitale-Versorgung-Gesetz, DVG**) November 2019 –

- **Prescrivability** of DH / DTx solutions on the part of doctors, and pathway to their reimbursement from the national health system
- Availavility of a **fast-track** approval procedure to facilitate DTx accessing the marketplace
- **Access to 72 million German citizens** covered by the national health system.

Which solutions are included in the DVG?

- DH / DTx (main functionality digital) solutions that qualify as class I or IIa medical devices
- Diagnosis, monitoring, treatment of pathologies or improvement of the health services related to them
  - However, the reimbursement rule does not initially apply to digital apps that help to make medical diagnoses (this may be amended in the future).



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The Fast Track Process

1 MEDICAL PRODUCT CERTIFICATION

- Health App needs to be certified as a medical product class I or IIa
- Regulatory basis: European Medical Device Regulation (MDR)

2 APPLICATION FOR LISTING

- To be submitted to BFARM (Federal Agency for Drugs and Medical Products)
- Agency decides within 3 months
- Basic requirements: security, quality, functionality
- Additional requirement: positive effect on quality of care

3 OFFICIAL LISTING

- In case of missing proof of effects on quality of care: provisional listing for 12 months
- Missing evidence must be generated within 12 months
- All listed Apps are reimbursable and can be prescribed by doctors

4 PRICE NEGOTIATIONS

- Negotiations take place directly between app publishers and the roof organization of the public health insurers (GKV)

5 REIMBURSEMENT

- During the first 12 months: based on app publishers' price
- Afterwards: agreed price between GKV and publishers applicable for all public insurers

CHALLENGES FOR APP PUBLISHERS

- *High documentation needs to obtain MDR Class I or IIa*
- *Neccessity to create evidence data on quality, as well as data on security and safety*
- *Small number of official notified bodies to do MDR certification*

CHALLENGES FOR ESTABLISHED PLAYERS

- *Very few Apps listed in the beginning*
- *High competition for listed Apps*

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CONCLUSIONS

Going Forward

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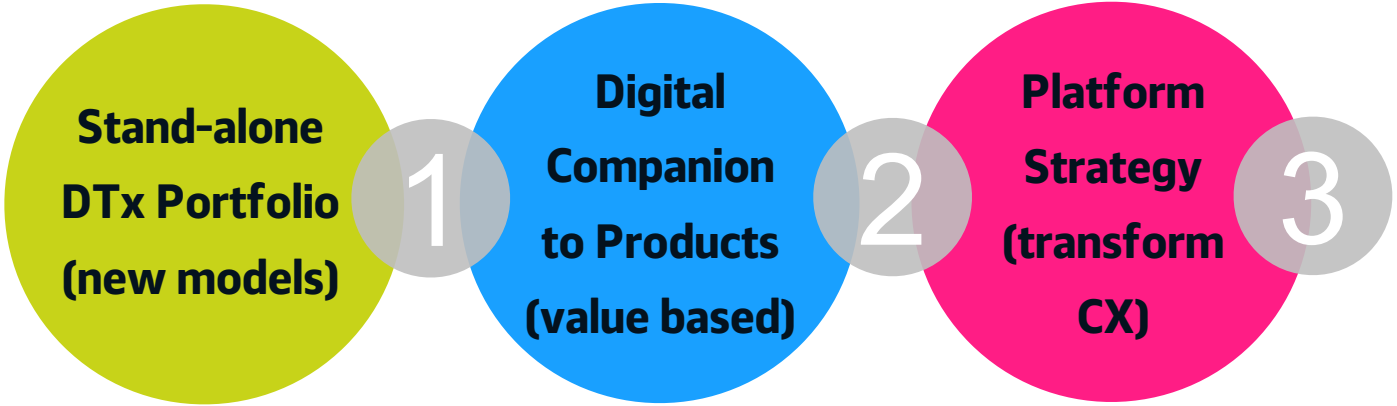
Strategic Opportunities for the Industry



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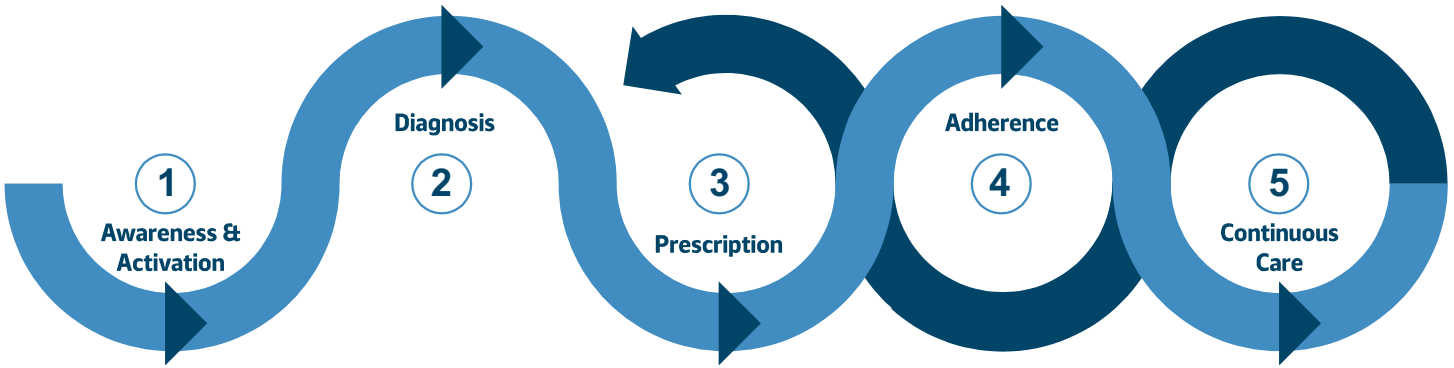
Important to focus on the patient journey



Accelerate access to the right pathway or treatment	Diagnose sooner or predictively and continuously monitor	Timely treat with optimal workflow	Empower patients through adherence and behavior change.	Seamless engagement between patients and physicians

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Potential DH/DTx progression strategy

(**Digital Health**)
Test, validate, and sell in-market – Reimbursement negotiations after 12 months

RWD + User Reported wellness outcomes + value to payer validation + reimbursement

(**Digital Health**)
Listing in NHS certified store
Negotiate NHS licensing

Listing in NHS digital formulary, launch of initial clinical study and collection of data for NICE clinical validation

(**Digital Health**)
CVS Health + Private Insurers
FDA 501k **DTx** or 505(b)(2) **Combo** (pill + software device) . Non-patent exclusivity

Launch of formal clinical study towards FDA 501k or 505(b)(2) approval/label

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Execute through a Build/Buy/Partner/Invest Process

Identify Opportunities and Business Cases

Digital Health Factory
Design & pilot, develop digital health products

Investment & Partnerships
Identify suitable digital health solutions for partnership and/or investment

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Take-aways

Payers interested in DTx

They understand the potential but need clear guidance, based on RWD validation, to respond in a correct and timely fashion

International Scenario

Is beginning to provide examples of access, acceleration of the go-to-market and reimbursement models for various DTx

Pharma & MD companies

Are beginning to staff up with internal capabilities to be able to develop DTx solutions; some with ambitious therapeutic area targets as their objective.

Opportunity

To scale solutions aided by capital, partnerships, HCP desire to embrace digital health, TA vertical expertise, increased access.
Very viable for Italy.

Thank you.

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