



Key insights from „Long-term investment plan“ (WP 6)

Andreas Palm
Senior Consultant at Civitta

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<http://ec.europa.eu/digital-single-market/ehealth>

DELIVERABLE | Long-term investment plan for digital health companies engaged in the active and healthy aging (AHA) segment

VALUE PROPOSITION | The report aims to provide actionable guidelines for a **digital health innovator** to better **understand the market, evaluate their investment readiness**, and therefore **position themselves adequately in terms of attracting financing** that in the long term would **increase investments** into the AHA sector.

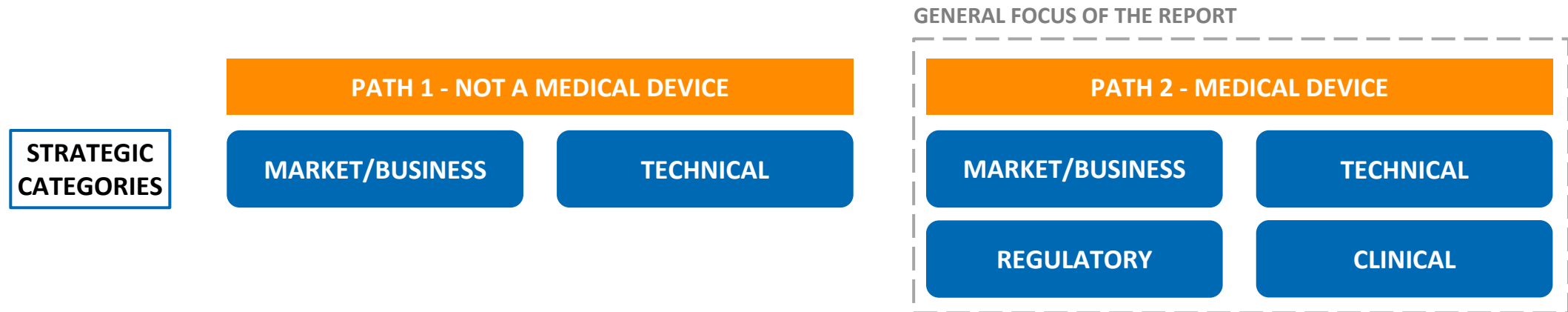


INSIGHTS | After having read the report, an innovator of an elderly-focused or -inclusive digital health solution will:

- **be better prepared** by having a clearer, practical understanding of the digital health market, including its main differences compared to a consumer technology market
- **save time and money** by anticipating the existence (or not) of the regulatory and clinical requirements for their solution
- **be better positioned for investment-readiness** due to:
 - understanding financing implications of different stages in the product development
 - grasping relevant financing sources for their unique situation
 - anticipating the rationale and stakes behind different sources of financing
- **discover actionable insights and tips** from companies developing elderly-focused or elderly-inclusive digital health products

INSIGHT 1 – DIGITAL HEALTH COMPANIES CAN HAVE VERY DIFFERENT PRODUCT-DEPENDANT DEVELOPMENT PATHS AND FINANCING OPTIONS

DIGITAL HEALTH COMPANIES CAN HAVE TWO PATHS FOR DEVELOPMENT, ONE MORE COMPLEX THAN THE OTHER



WHICH PATH TO TAKE IS DETERMINED BY THE CATEGORISATION OF THE PRODUCT

There are two regulations on the EU level that determine categorization of a health solution as a medical device:

- **Medical Device Regulation** (EU MDR; 2017/745) that tackles all medical devices for human use manufactured or sold into the EU.
- **In Vitro Diagnostic Medical Device Regulation** (EU IVDR; 2017/746) that tackles in vitro diagnostic medical devices only.

The definition of a medical device given in MDR is broad. Most importantly to digital health solutions, **the definition also includes software** that is intended by the manufacturer to be used, alone or in combination, for human beings for diagnosis, prevention, monitoring, the prognosis of a disease, or for diagnosis, monitoring, treatment, alleviation of an injury or disability, etc. Therefore, even devices such as **wellness apps** might be argued to fall under the definition.

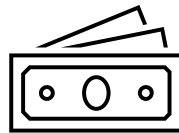
INSIGHT 2 – THERE ARE MANY STAKEHOLDERS INVOLVED, ALL OF THEM SHOULD BE ACCOUNTED FOR AND ENGAGED FOR SUCCESS

A SUCCESSFUL MEDICAL DEVICE DIGITAL HEALTH COMPANY MUST ARRIVE AT A VALUE PROPOSITION SUITABLE FOR ALL THE STAKEHOLDERS



HEALTHCARE PROVIDER

Wants solutions to be useful for patients



PAYOR/INSURER

Wants solutions to be cost-efficient



REGULATOR

Wants solutions to be safe for society



INVESTOR

Wants solutions to be scalable and revenue-generating



END-USER (PATIENT)

Wants solutions to improve wellbeing and be maximally convenient

„You can have a product **patients** really need, **healthcare providers** want to prescribe but if the **insurer** does not finance it, you don't have a monetisation channel and **investors** are not interested.“

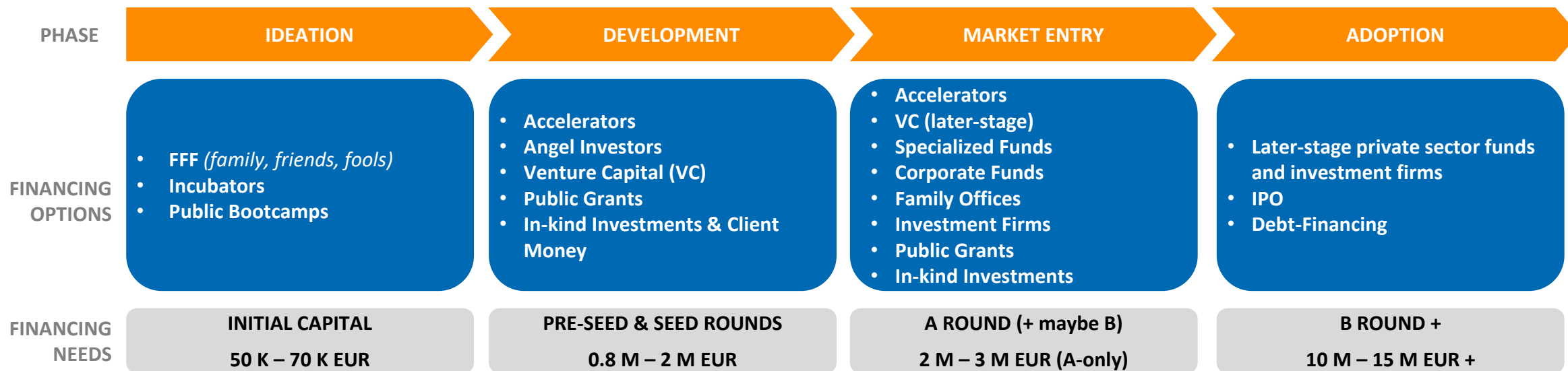
Quote from an expert interview

End-user testing is crucial for adjusting the value proposition to the user needs, especially if the **founders do not belong in the target segment**.

- For example, a case study company **TempID** developing temperature patches and an accompanying application discovered during living lab tests that the **aging population segment** had no problems using the app but struggled with attaching the patch due to **limited flexibility**.

INSIGHT 3 – MANY DIFFERENT CHANNELS OF FINANCING EXIST FOR DIGITAL HEALTH COMPANIES

INDICATIVE FINANCING OPTIONS AND NEEDS FOR MEDICAL DEVICE DIGITAL HEALTH COMPANIES



FIVE GENERAL ATTRIBUTES FOR DIGITAL HEALTH COMPANIES TO BE SUCCESSFUL IN ATTRACTING FINANCING

1. Solving a problem that is severe enough.
2. Committed to development.
3. Relentless in their pursuit of feedback from various stakeholders, including the elderly customer segment.
4. Strategic in their monetisation channels and intended product use.
5. Attentive to the regulatory and clinical needs of their development.

Consortium partners

