



**Changing
Health**
by Boehringer Ingelheim

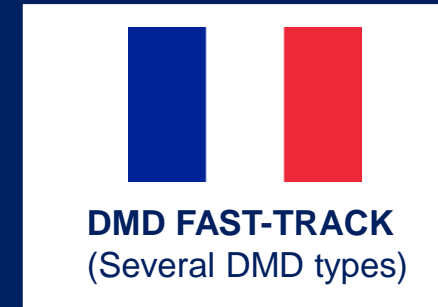
F³T project - framework for fast fast-track of Digital Health Solutions

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Early access to DiGAs/DMDs reimbursement in EU member states

German DiGA: a Digital Health Application is a CE-marked **medical device** class I or II (according to the Medical Device Regulation (MDR), whose medical purpose is mainly achieved by way of its digital function and is used by the patient alone or by patient and healthcare provider together. Its supports the recognition, monitoring, treatment or alleviation of diseases or the recognition, treatment alleviation or compensation of injuries or disabilities.



Digital medical devices (DMDs) are subject to clinical evidence-based requirements and reach a new level of regulatory challenges linked to market access and reimbursement of digital supported patient care. Germany, France, and Belgium do already have national HTA and reimbursement systems for DMDs in place.

Early access to DiGAs/DMDs reimbursement in EU member states



WHAT DO WE, AS EXPERT GROUP RECOMMEND AS PRACTICAL AND VIABLE IDEAS TO:

- ✓ Speed up the process towards a common digital solution's portfolio for the National Health Systems
- ✓ than can be funded (purchased, reimbursed...)
- ✓ To ensure patients and health systems benefits from the best digital apps in a safe way
- ✓ and best ideas and innovators are successful

COLLABORATIVE, INCLUSIVE

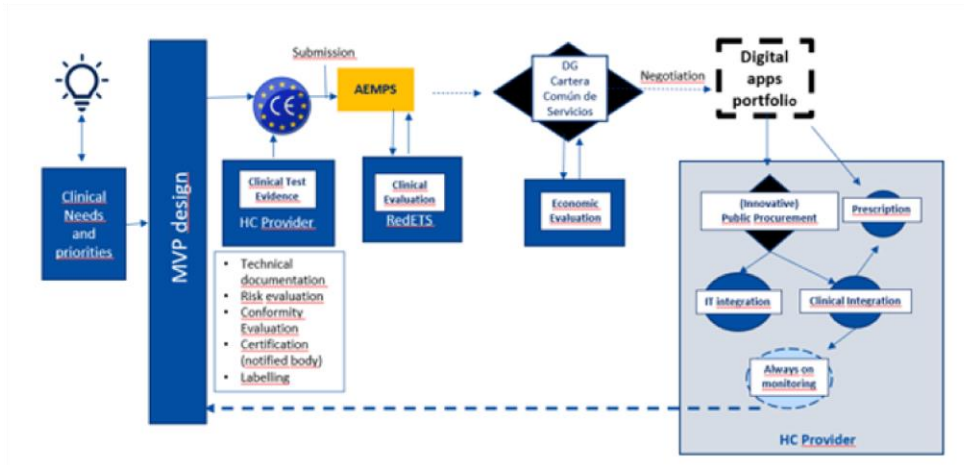
CONNECTED TO EUROPE

TERRITORIAL DIVERSITY

OPENNESS, TRANSPARENCY, NEUTRALITY

COMMITMENT TO SHARE, COMMUNICATE AND IMPACT

Early access to DiGAs/DMDs reimbursement in EU member states



- 1 Draw current **idea to adoption pathways** in Spain and define which one we want to streamline
- 2 Collaborative analysis of **pains and bottlenecks**
- 3 **Co-creation of solutions** and iteration of the “to-be” process
- 4 Design of **pilots and regulatory sandbox** within the regions participating, and use cases as demonstrators for decision markers

CE Pre-certification Pre-registration	Evaluation	Registration (Access) and Funding	Integration and adoption
Support Programme for developers	Decentralized/Harmonized evaluation	DHS Funding Mechanism	Adoption Support Structures (P/P)
Clinical Needs and priorities SNS/CCAA registry	Innovation Funding Mechanism (temporary)	SNS Digital Solutions Portfolio	Adoption success cases repository



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THANK YOU!

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