Will medtech SMEs deliver the promises of P4 medicine?

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P4 Medicine

Predictive
- Identification of individual risks of developing certain diseases based on the person’s genetic profile and other personal information

Preventive
- Methods and treatments to avoid, reduce and monitor the risk of developing certain diseases

Personalised
- Clinical interventions based on the unique genetic, medical and environmental characteristics of each patient-citizen, and genomic profile of his/her diseases

Participatory
- Citizens are fully engaged in personal health management
EC Political priorities

Juncker
- Focus on innovation to stimulate investment
- Encourage more SMEs and businesses to join H2020,
- Maximise synergies between H2020 and EU’s priorities

Moedas
- Open Science
- Open Innovation
- Openness to the World

Gabriel
- Digitization of society
- Digital Single Market
4 major challenges in healthtech

- Need for cross-technology products
- New EU regulatory framework
- Digitization of healthcare
- New business models
Providing integrated, innovative and smart healthcare solutions for European patients by promotion of an innovative European Health Technology Industry
Objectives

- Maintain the competitiveness of healthtech industry in a changing regulatory environment
- Support SMEs from R&D&I to market access
- Deliver value based healthcare solutions with outcome based payment
- Leverage EU vision for healthtech
EU landscape in healthcare

- Integrated, innovative and smart healthcare solutions for European patients
  - ESTHER

- Speed up the development of better and safer medicines for patients
  - IMI

- Promotes entrepreneurship and innovates in healthy living and active ageing
  - EIT Health
ESTHER structure

- European association (AISBL) with members from all the value chain of healthtech
  - SMEs
  - Large companies
  - Trade associations
  - Technology providers
  - Clinicians
  - Regions & clusters
  - Others: payers, patients advocacy groups, HTAs...

- Industry lead (Medtech-Europe)
- From 1st Jan, 2018
ESTHER actions all along the value chain

**R&D&I**
- Roadmaps / convergence Kets/digital in medtechs
- Financial support to cross-KETs projects
- Financial support to innovation in SMEs
- Support technology platforms incl. DIH
- Open labs for prototyping and characterisation

**Clinical validation**
- Support to clinical research and validation infrastructures
- Financial support to SMEs (proof of concept in first patient)
- Public procurement on Healthcare Innovation (on innovative products?)
- Access to networks of KOLs

**Manufacturing**
- Supply chain building in Europe (ex: FCH JU)
- Interregional cooperation and use of ESF
- Pilot lines to facilitate industrialisation
- Living labs to evaluate business models and social acceptance

**HTA**
- Harmonisation of HTA criteria
- Support HTA cross European activities
- Reinforcement of medico economic studies in SMEs

**Market approval**
- Support to transition of SMEs to MDR and IVDR
- Support to export in emerging economies

Support to translation of innovation in SMEs: TAB, HelpDesk
Start-up accelerator: Catapultor
Stakeholders along the value chain

- **Basic research**
- **Technology development**
- **University**
- **RTOs**
- **Manufacturing**
- **Regulatory approval**
- **Clinical validation**
- **CMO, OEM**
- **Medtech companies**
- **HTA agencies, health insurances**
- **EMA, national agencies**
- **Hospitals, CROs**
- **Notified bodies**
- **HTA, reimbursement**
- **Marketing**
- **Buyers**
- **Patients**
- **Patient advocacy groups**
- **Hospitals, patients**

The diagram visualizes the interactions and roles of various stakeholders along the value chain in the context of medical technology development and commercialization.
Networking and mapping

What?
- Companies
- Initiatives, PPPs, ETPs...
- Regions
- RTOs and research infrastructures
- Clinical centers
- R&D priorities established

How?
- Informal structure
- Existing networks (Medtech Europe, ETPN, EARTO, ECRIN, Vanguard..)

2016

2018

ESTHER Platforms and Joint Actions
- Projects proposed to existing programmes
- NOBEL Coordination and Support Actions
- Implementation under existing instruments

Existing funding tools and support measures (regional, national, European)

2020

ESTHER in FP9

Integration of priority actions in a single initiative ESTHER PPP-like

Joint Undertaking in healthtech?

Roadmap towards FP9
Timing (tentative)

- Task Force Mapping Influencing
- Support to clusters and regions Impact assessment Mapping
- Legal association SME instrument Support to R&D Support to clusters
- SME instrument Support to R&D Support to clusters Risk financing ...
- Legal Partnership

Deployment:
- 2016: 0%
- 2017: 100%
- 2018: 0%
- 2019: 100%
- 2020: 100%

Date: 6/30/2017
Take home message

1. ESTHER is a totally **innovative and holistic way** of supporting the healthtech industry to make it happen.

2. ESTHER is actively shaping the European healthtech ecosystem with emphasis on **supporting start ups and SMEs**.

3. ESTHER combines synergistic **actions all along the value chain**.
## ESTHER Task Force

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- **R&I/Ind tech.**

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Thank you for your attention