



Some EU initiatives relevant to the medtech sector

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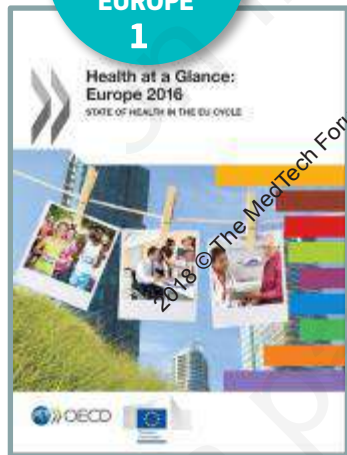


- **State of Health in the EU**
- **Health Systems Performance Assessment**
- **EU cooperation on HTA beyond 2020**
- **Health and Care in the Digital Single Market**

State of health in the EU

European
Commission

HEALTH AT A GLANCE: EUROPE 1



November 2016

COUNTRY HEALTH PROFILES 2



November 2017

COMPANION REPORT 3



November 2017

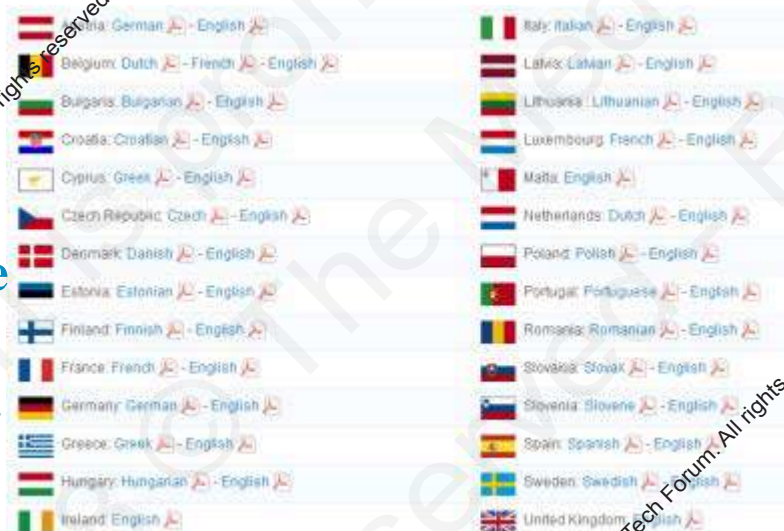
VOLUNTARY EXCHANGES 4



First half of 2018

COUNTRY PROFILES

The profiles form the backbone of the State of Health in the EU cycle.



https://ec.europa.eu/health/state/country_profiles_en





COMPANION REPORT

- **Cross-cutting** conclusions by the Commission, from the twenty-eight Country Health Profiles
- Linked to **shared policy objectives** across the EU countries, revealing potential for EU added value
- Follow the Commission Communication on **effective, accessible and resilient health systems**



Five key conclusions

#1

Health promotion and disease prevention pave the way for a more **effective** and **efficient** health system

#2




A **strong primary care** guides patients through the health system and helps **avoid wasteful spending**





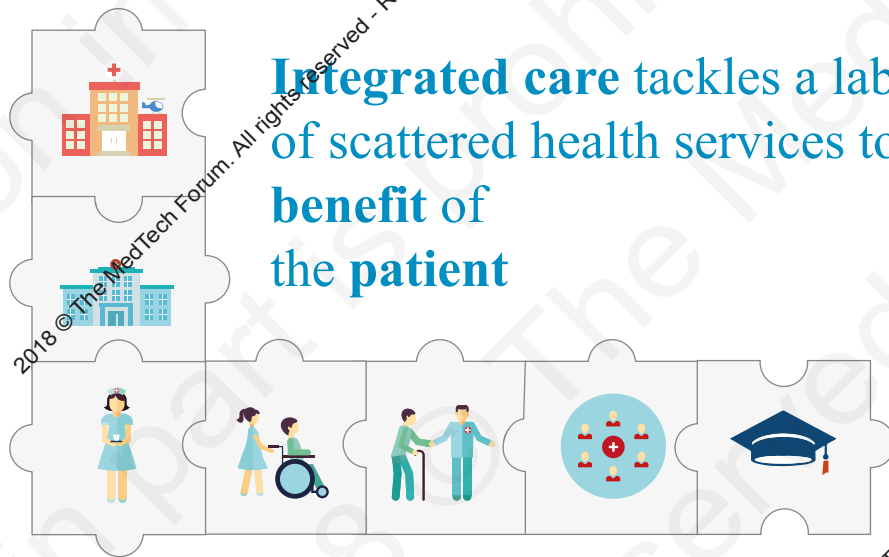
Mandatory primary care referrals indicate strong gatekeeper systems in half of the Member States



-  Primary care physician referral is required
-  Patients have financial incentives to obtain a referral, but direct access is possible
-  No need and no incentive to obtain referral

#3

Integrated care tackles a labyrinth
of scattered health services to the
**benefit of
the patient**





#4

Proactive health workforce planning and forecasting make health systems resilient to future shocks

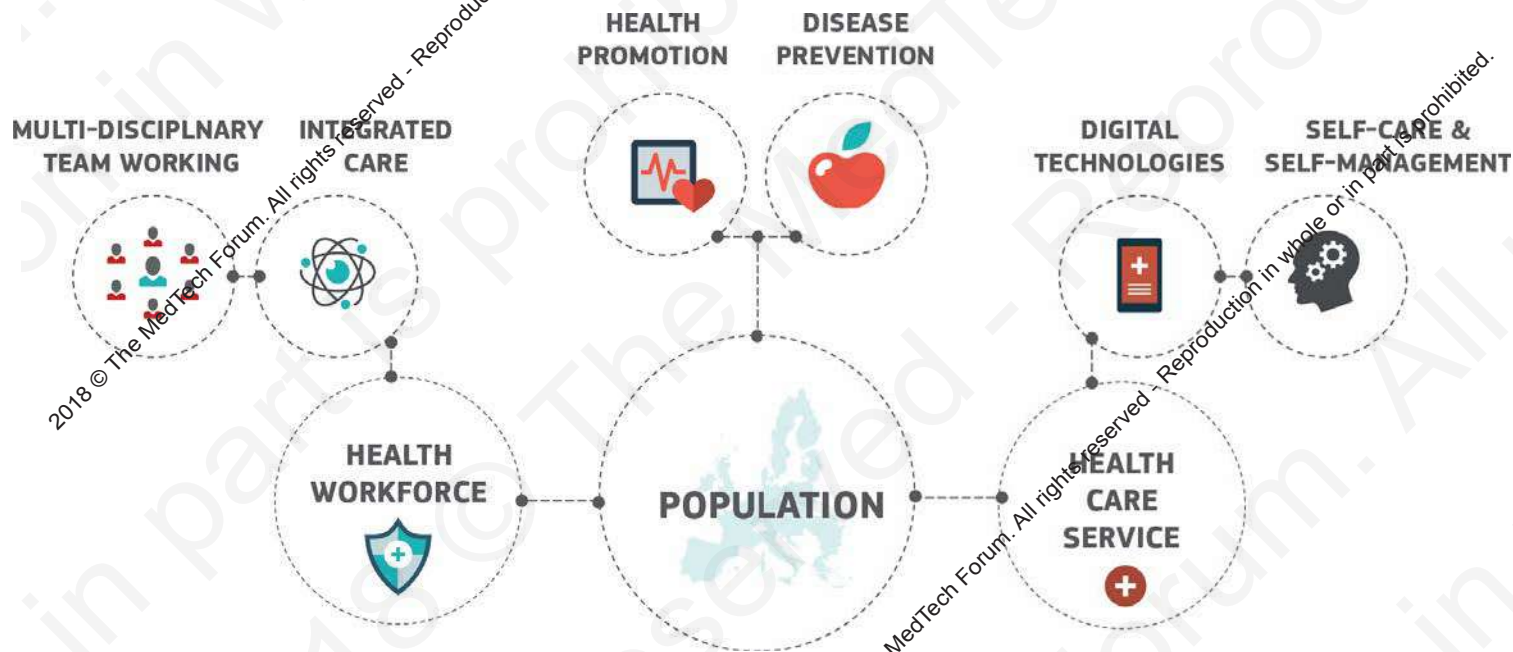


Health and
Food Safety



State of health in the EU

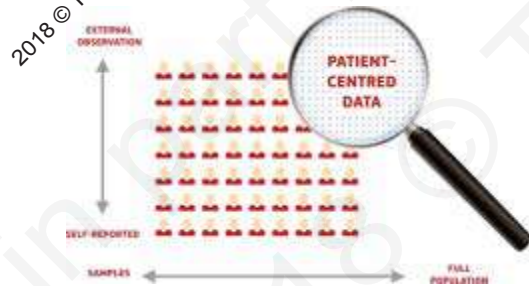
European
Commission



Health and
Food Safety

#5

The patient is at the **centre** of the next generation of better **health data** for policy and practice



Better health data contributes to patient outcomes whilst reducing wasteful spending in health care



Commission Communication on Effective, Accessible and Resilient Health Systems



EU agenda for effective, accessible and resilient health systems

Strengthening effectiveness

Increasing accessibility

Improving resilience

Health systems
performance assessment

Patient safety and quality
of care

Integration of care

A fit-for-purpose health
workforce

Access to innovative
medicines

Optimal implementation of
2011 Directive on cross-
border healthcare

Health technology
assessment (HTA)

Information for better
governance

eHealth, mHealth



European
Commission

The Expert Group on Health Systems Performance Assessment



OECD



WHO



European Observatory



Health and
Food Safety



**SRSS is involved and ready to provide
follow-up technical assistance.**



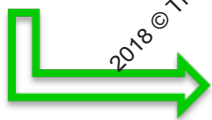
Expert group on HSPA Strands of activity

Annual
work on
priority
areas

Sharing of
national
experiences

Tailored
country-
specific
activities

HSPA
advocacy



2015:
**Quality of
care**

2016:
**Integrated
care**

2017:
Primary care

2018:
Efficiency

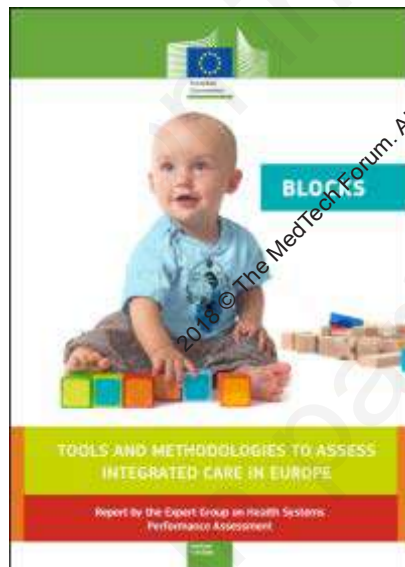
2019:
Resilience



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HSPA Report 2017



Integrated care is not a goal in itself; it is rather a precious tool when it addresses complex care needs.

Measuring integration is different from measuring the performance of integrated care.

Design principles, building blocks and system levers should be included as part of the framework for assessment of integrated care.

Integrated care models can be introduced with different goals in mind

There is no single 'right' approach that would be applicable and valid for every system.

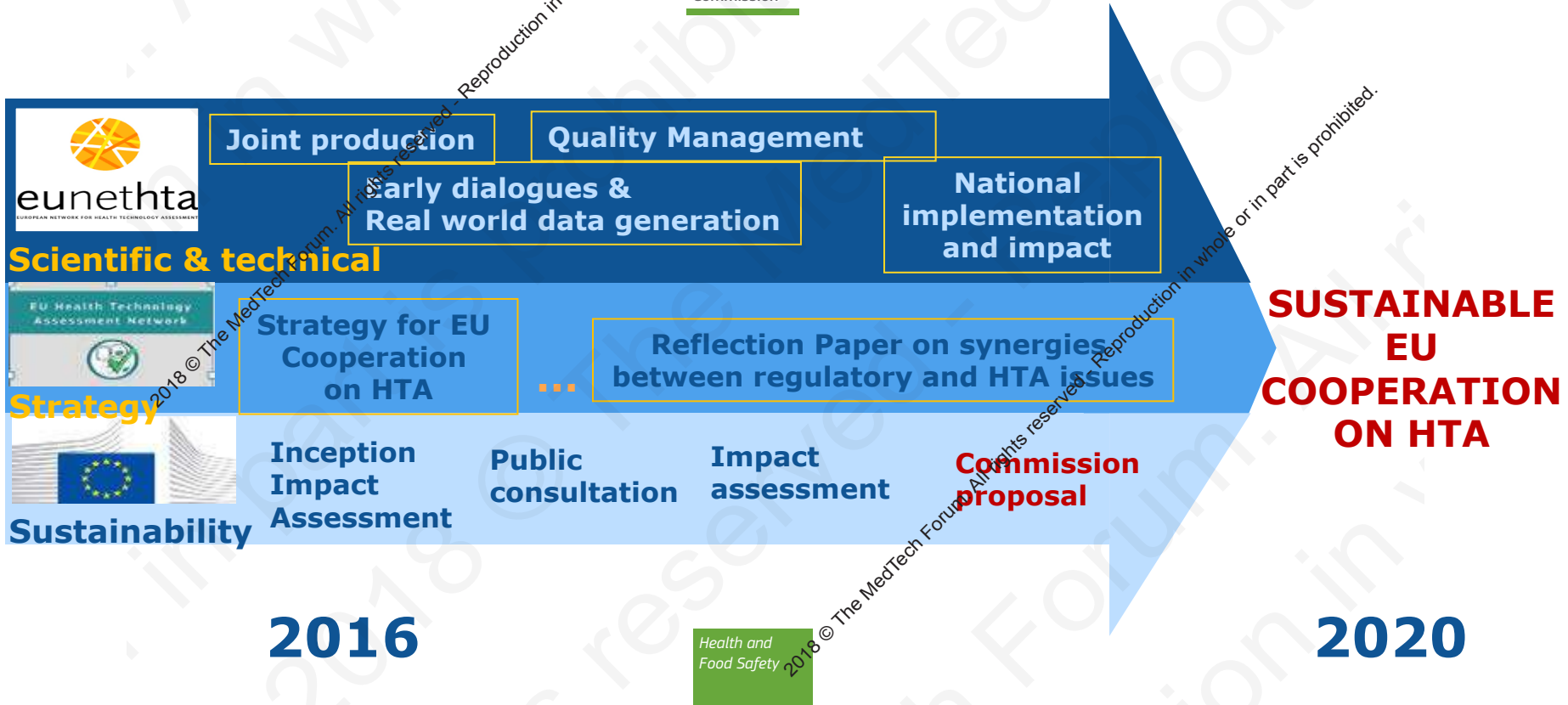


Expert Panel on Investing in Health

- Provides independent non-binding advice on effective ways of investing in health
- Established by Commission Decision 2012/C 198/06 following the Council conclusions of June 2011 'Towards modern, responsive and sustainable health systems'; renewed in 2017
- Currently working on **benchmarking access to health care, performance assessment of primary care, and innovative payment models for high-cost innovative medicines.**



EU cooperation on HTA





EUnetHTA JAs (2010-2020)



+

- **Trust** between HTA bodies and **capacity building**
- Development of **joint tools** (e.g. EUnetHTA Core Model, POP EVIDENT databases)
- Piloting **joint work** (e.g. early dialogues, joint assessments)
- JA3 – **upscaling of joint work**

-
- **Low uptake of joint work** ⇒ duplication of work
 - **Differences** in the procedural framework and administrative capacities of Member States
 - **Differences** in national methodologies
 - **No sustainability** of current cooperation model

EU cooperation on HTA

EU funded projects



EUnetHTA JAs (2010-2020)



Research projects

- **Joint work on medtech:**

- **Methodologies, guidelines**

- E.g. "Therapeutic medical devices" guideline (2015)

- **Joint early dialogues:** 3 – SEED/EunetHTA 2 (total 11)

- 1 planned EunetHTA 3 (total

- **Joint assessments:** 3 – EunetHTA 2 (total 15)

- **Collaborative assessments:** 7

(carried out by a group of interested MS):

<http://www.eunethta.eu/joint-assessments>

- **AdhophTA**

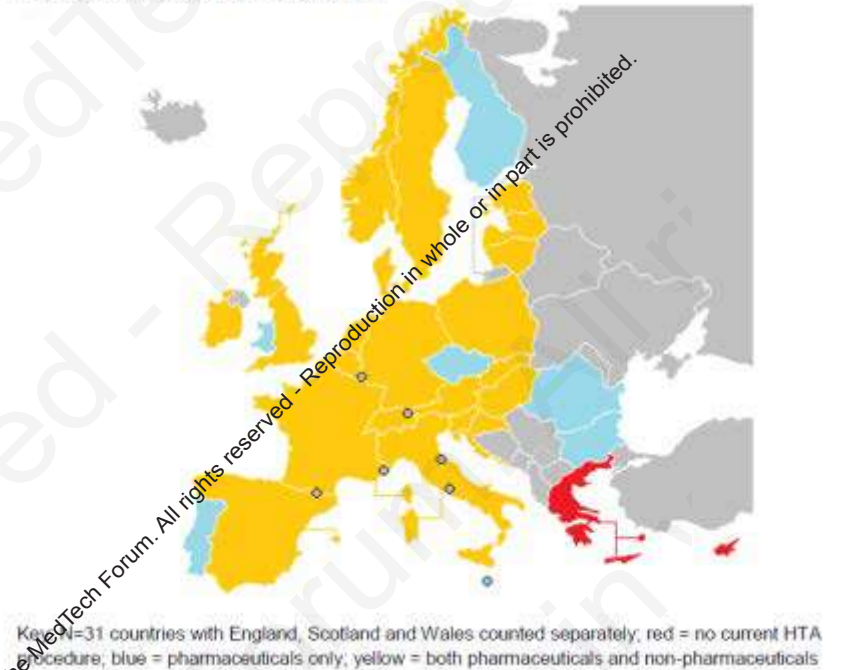
- **MedtechTA**

- **INTEGRATE-HTA**

- **ADVANCE-HTA**

Most of the Member States indicated that HTA procedures are in place at national level to inform pricing and reimbursement decisions about **pharmaceuticals and medical devices**.

Figure 2: Overview of HTA activity





EU initiative for strengthening EU cooperation on HTA

- Addresses the shortcomings of the current cooperation model
- Objectives :
 - Promote convergence in HTA tools, procedures and methodologies
 - Reduce duplication of efforts for HTA bodies and industry
 - Ensure the uptake of joint outputs in Member States
 - Ensure the long-term sustainability of EU HTA cooperation



Adoption January 2018



Key elements (1)

- **Member State driven**
 - *MS → scientific work and decisions*
 - *EU → support function*
- **Focus on clinical assessment**
 - *no common appraisal*
 - *no common economic assessment*
- **High quality and timely output**
 - *Joint REA: at the time of MA (Pharma)/ later (Medtech)*
- **Mandatory uptake → no duplication at national level**
- **Transparency → stakeholders' involvement**
- **Fit for purpose → pharma vs medtech**



Key elements (2)

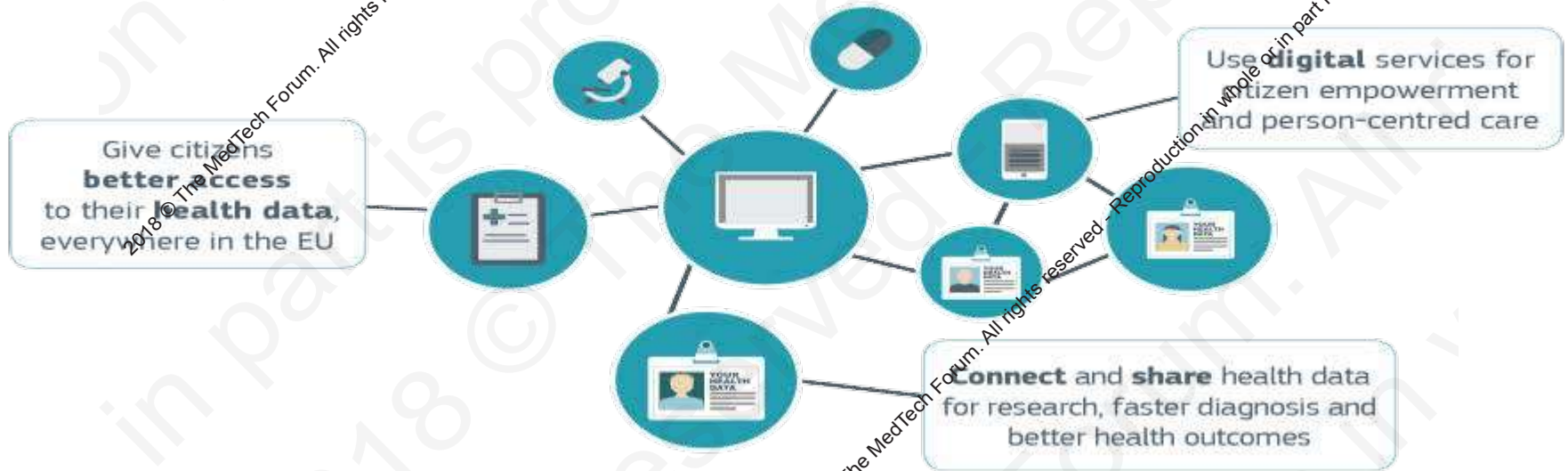
- Possible areas of joint work
 - *Common tools and methodologies*
 - *Horizon scanning/topic selection*
 - *Joint early dialogues*
 - Multi-HTA
 - Parallel with regulators (e.g. parallel consultation with EMA)
 - *Joint REA → limited scope*
 - medical devices → relevant to MS, EU-added value
- **Pragmatic approach → phase-in approach**



Digital Single Market (DSM) Strategy (May 2015)

- The European Commission has **placed digital at the core of its strategy**, by setting the Digital Single Market as **one of its 10 priorities**
- The aim is to **open up digital opportunities** for people and business and to make the EU's single market **fit for the digital age**

3 Priority areas on Health and Care in the DSM





Pillar I: Give citizens better access to their health data

The eHealth Digital Service Infrastructure (eHDSI)

1. Enabling the exchange of patient data across borders

- **Patient Summary:** provides access to health professionals to verified key health data of a patient during an unplanned care encounter while abroad
- **ePrescription:** enables patients to receive equivalent medication while abroad to what they would receive in their home country

2. To be expanded to full Electronic Health Records

eHealth DSI Deploying Countries

	PS	EP
Austria	♥	♥
Croatia	♥	♥
Cyprus	♥	♥
Czech Republic	♥	
Estonia	♥	♥
Finland		♥
France	♥	
Germany	♥	
Greece	♥	♥
Hungary	♥	♥
Ireland	♥	♥
Italy	♥	♥
Luxembourg	♥	
Malta	♥	
Portugal	♥	♥
Sweden		♥
Switzerland	♥	♥



Pillar II: Connect and share health data for research, faster diagnosis and better health outcome

- **Connect** different health data sets, scientific expertise and computing capacity federated across borders – **through a decentralised European digital health infrastructure**
- Advancement of **high-performance computing, big data analytics** and **cloud computing** for health research and personalized medicine
- **Use cases** (e.g. for rare diseases (European Reference Networks); for anticipating epidemics and accelerating EU-wide identification of infectious threats)



Pillar III: Use of digital services for citizen empowerment and patient-centred care

- Working with Member States and regions to **deploy solutions**:
 - that support **user feedback** and **interaction** between patients and healthcare providers,
 - that **engage citizens** in the prevention and management of chronic diseases
- **Mobilize relevant EU funding** (from EFSI, ESIF, Health Programme and H2020) and **implement patient-centred integrated care**



Thank you!

<http://ec.europa.eu/health/>