

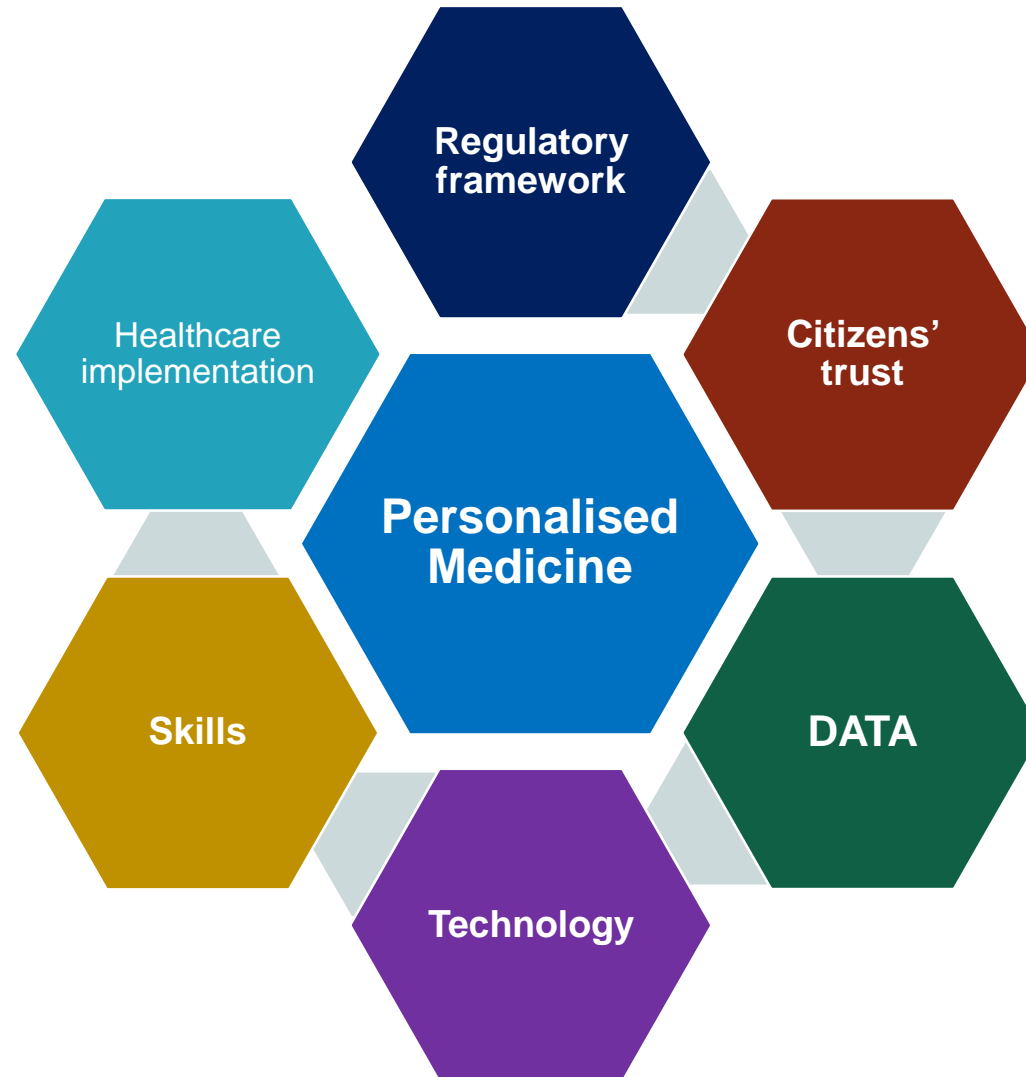


EU policies related to personalised medicine

UIMP Summer School on Personalised Medicine, 2 July 2021

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Ingredients of Personalised Medicine



EU support for advances in Personalised Medicine

- **political push** – EU Council conclusions of 7 December 2015 ([15054/15](#))
- **funding** – FP7, Horizon 2020, IMI, Horizon Europe, EU4Health, Digital Europe
- **cooperation** – facilitation of Member States' initiatives and exchanges of expertise (e.g. 1+ Million Genomes)
- **legislation** – review or proposals for related legal acts (e.g. orphan medicines, HTA, AI framework, health data space)

Collaborations supported by the EU (examples)

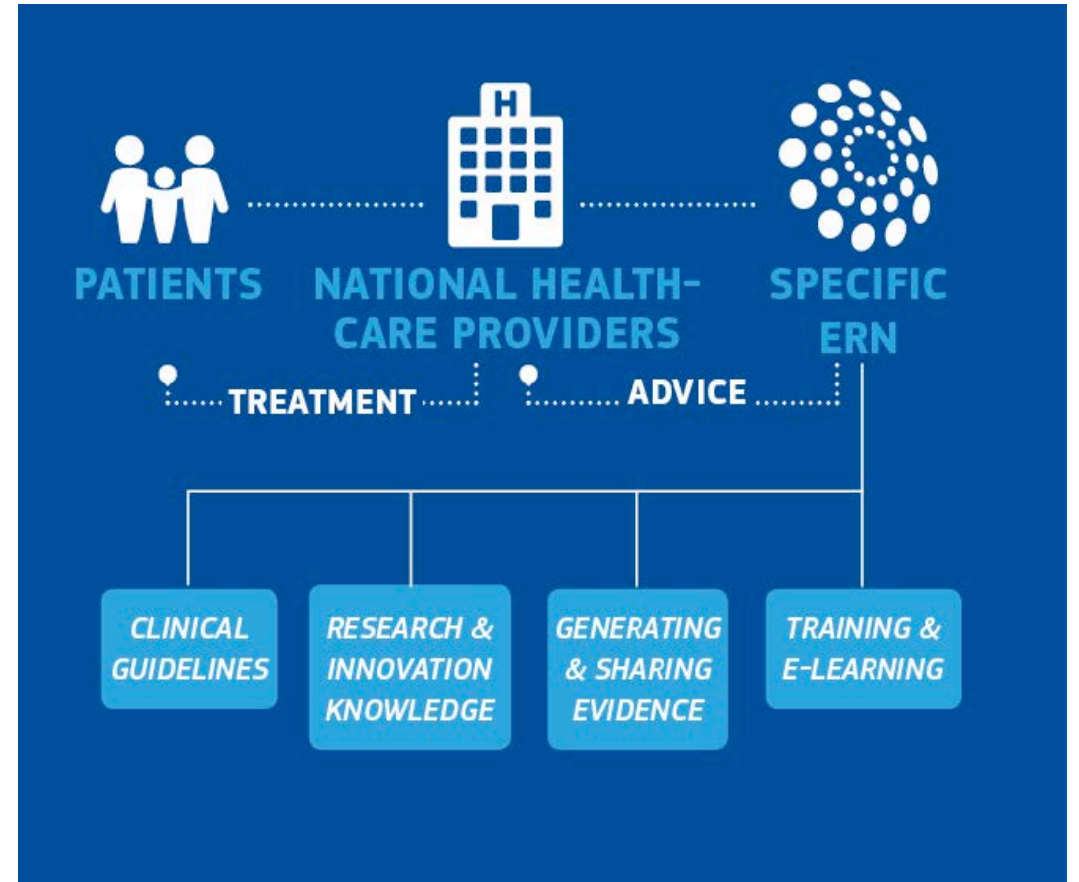
 ERA PerMed

 ICPerMed
INTERNATIONAL CONSORTIUM



ERNs: personalised medicine at small scale

- Virtual remote consultations and clinical data on individual patients' cases
- Advise and exchange of expertise (diagnosis & treatment)
- Established structure with 24 ERNs
- Clear legal basis and institutional setup
- Infrastructure
- Strong political support, example of good European cooperation



Digital transformation of health and care (2018)

European health challenges

- ⊗ Ageing population and chronic diseases putting pressure on health budgets
- ⊗ Unequal quality and access to healthcare services
- ⊗ Shortage of health professionals

Potential of digital applications and data to improve health

- ✂ Efficient and integrated healthcare systems
- ✂ Personalised health research, diagnosis and treatment
- ✂ Prevention and citizen-centred health services

What EU citizens expect...

- 90% agree** To access their own health data (requiring interoperable and quality health data)
- 80% agree** To share their health data (if privacy and security are ensured)
- 80% agree** To provide feedback on quality of treatments

Support European Commission:

1 Secure access and exchange of health data



Ambition:

Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

Actions:

- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
- Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
- Recommended exchange format for interoperability of existing electronic health records in Europe.



Updated 24/04/2018

2 Health data pooled for research and personalised medicine



Ambition:

Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

Actions:

- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target).
- Specifications for secure access and exchange of health data.
- Pilot actions on rare diseases, infectious diseases and impact data.

3 Digital tools and data for citizen empowerment and person-centred healthcare



Ambition:

Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Actions:

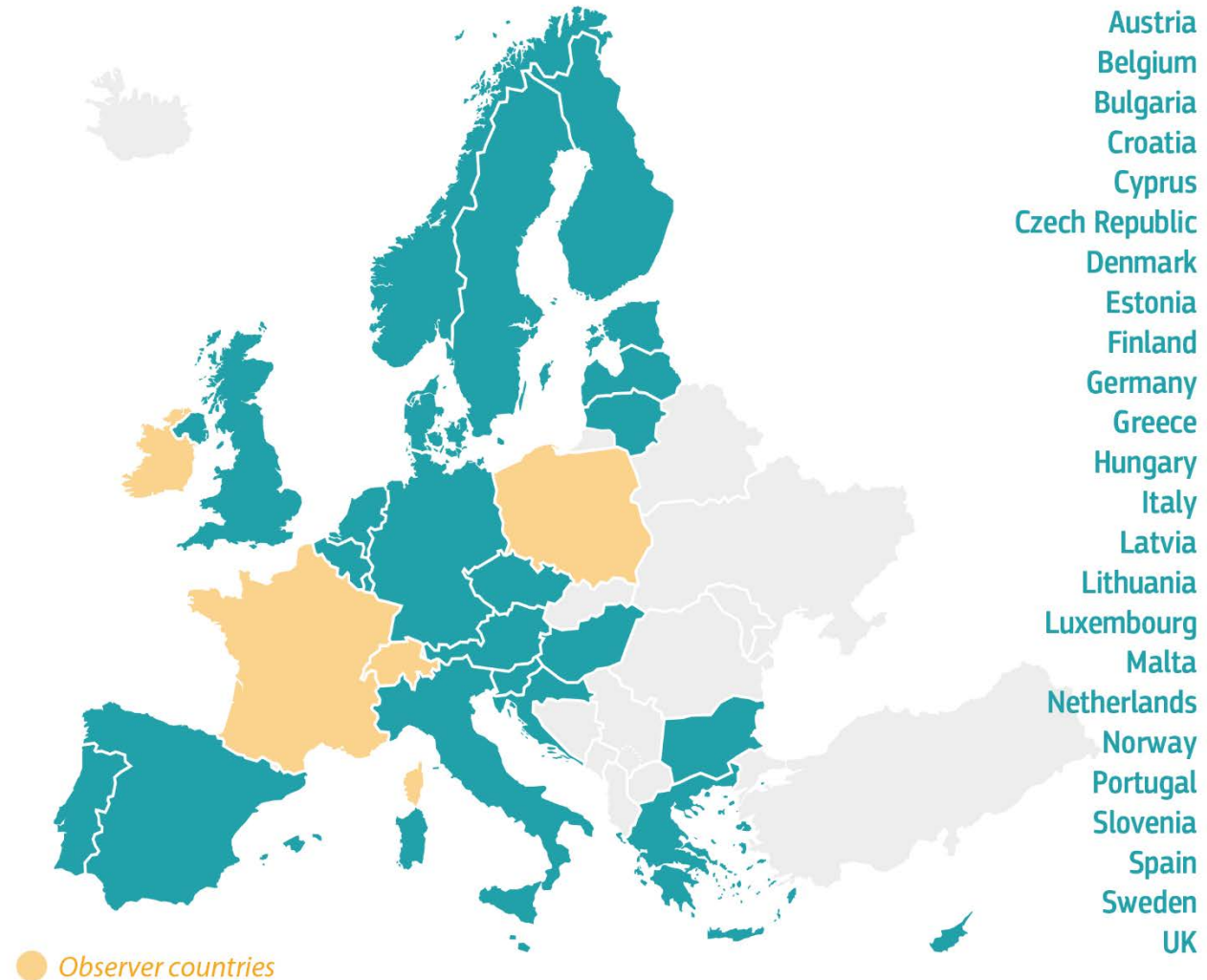
- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
- Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
- Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.



1+ Million Genomes EU initiative (1+MG)

- 2018 Member States' Declaration signed by 24 countries by now
- Strategic overview: 1+MG Group („special group”)
- Expert work: 11 working groups
- Coordination support via the B1MG project
- National implementation: National Mirror Groups
- The Genome of Europe - complementary multi-country project

Countries that have signed the 1+MG Declaration since 2018



1+MG objectives

Declaration for delivering cross-border access to **genomic databases**



1 million **genomes accessible** in the EU by 2022



Linking access to existing and future genomic databases across the EU



Providing **proper scale** for research with clinical impact

Why collaborate on genomics?

Data and expertise

- data dispersed across Europe – sequenced genomes
- link, connect, protect, collaborate
- secure access
- scale effect

Research

- better understanding of diseases
- causes, risk factors, probabilities, cure



Healthcare

- quicker diagnosis and treatment
- personalised medicine
- improved prevention programmes
- more efficient healthcare systems



EU data strategy (2020) - 4 pillars



A cross-sectoral governance framework for data access and use

including a legislative framework for the governance of European data spaces and other cross- sectoral measures for data access and use



Enablers

Total investments of € 4-6 billion in a High Impact Project on European data spaces and federated cloud infrastructures



Competences

Empowering individuals, investing in digital skills & data literacy and in dedicated capacity building for SMEs.



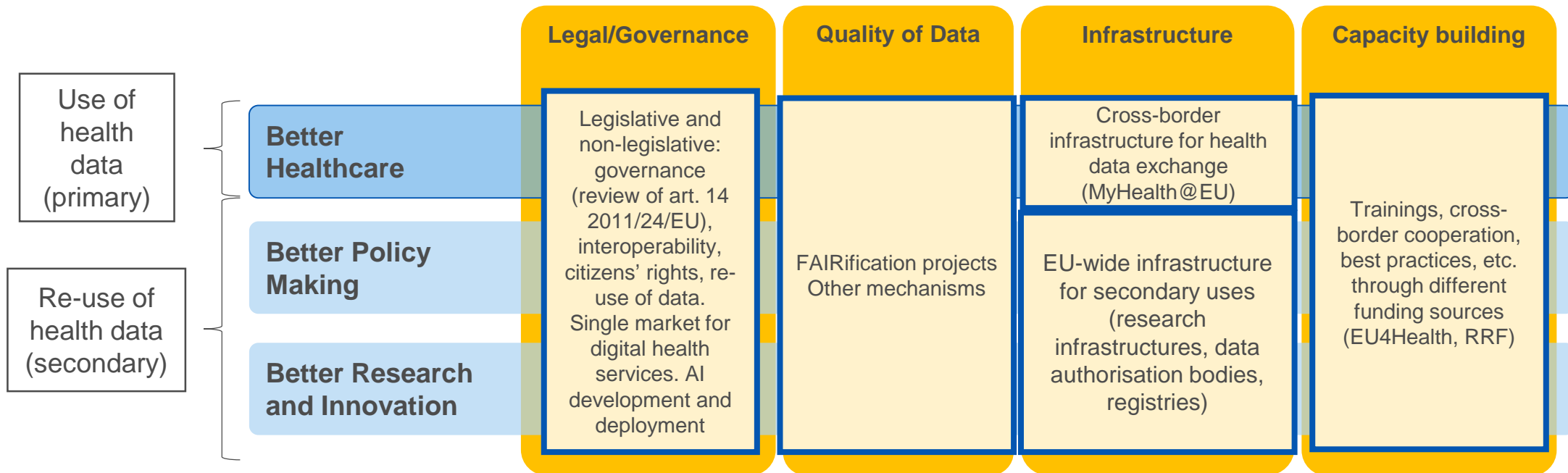
Rollout of common European data spaces

in crucial economic sectors and domains of public interest, looking at data governance and practical arrangements.

International Aspects

European Health Data Space

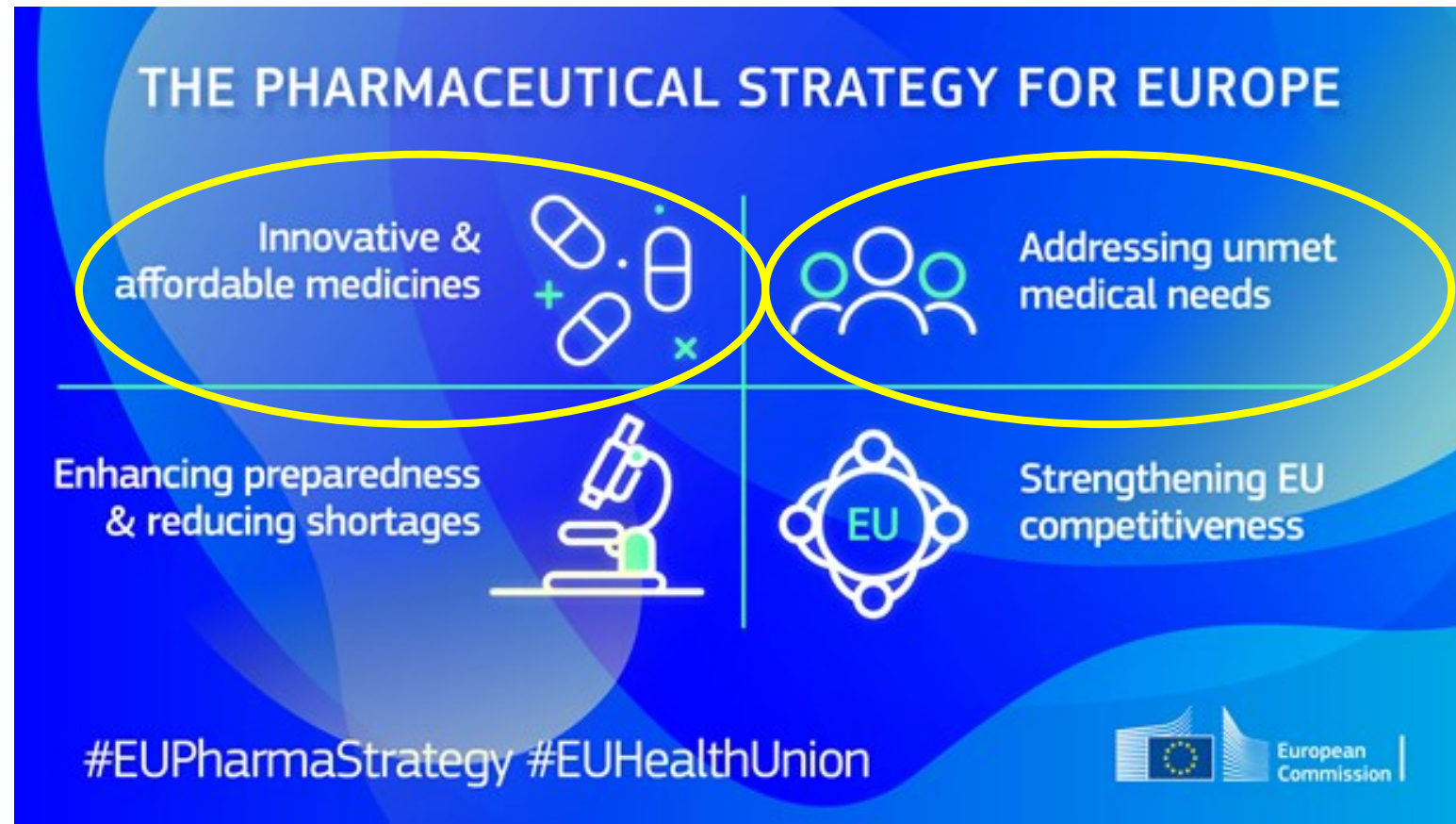
- Timely and simplified *exchange of* and *access to* health data for different use cases:
 - Healthcare provision, access and control of patient over their data, (cross-border) exchange of health data
 - Digital health services (including telehealth and m-health)
 - Research (e.g. on cancer, rare diseases, COVID-19, etc.), pharmacovigilance, public health, policy making



The pharmaceutical strategy for Europe (2020)

Personalised medicine is an integrated package of healthcare solutions comprising elements of medicines and medical devices that are structured to meet an individual patient's needs. In the future, patients may still be prescribed a tablet but that tablet may be combined with a new technology to determine the right usage, the right schedule and the right dosage according to their personal situation. This can also support treatments in multi-disciplinary settings like long-term care. Digital therapeutics can use app-based platforms to help patients manage chronic diseases such as diabetes, depression and heart conditions, and reduce medication.

[\(COM\(2020\) 761 final\)](#)



Europe's Beating Cancer Plan (2021)

Europe's Beating Cancer Plan proposes actions for all stages of the disease

PREVENTION

- ◆ 4 out of every 10 cases of cancer are preventable. The Plan will draw attention to:
- ◆ taxation's role for tobacco and alcohol
- ◆ reducing exposure to carcinogens in the work place and in the environment
- ◆ Farm to Fork Strategy to promote healthy diets

DIAGNOSIS

- Address gaps in knowledge
- Digitalisation reduces detection time
- Technical support to Member States
- Regulatory support reduces inequalities

TREATMENT

- ▶ Improved treatment times
- ▶ Incentivising innovation
- ▶ Pharmaceutical strategy for affordable therapies
- ▶ European Health Data Space promotes exchanges and research

QUALITY OF LIFE OF PATIENTS & SURVIVORS

- + improving quality of life for patients and survivors
- + Avoiding discrimination
- + Psychological support
- + Back-to-work support

Health and Food Safety

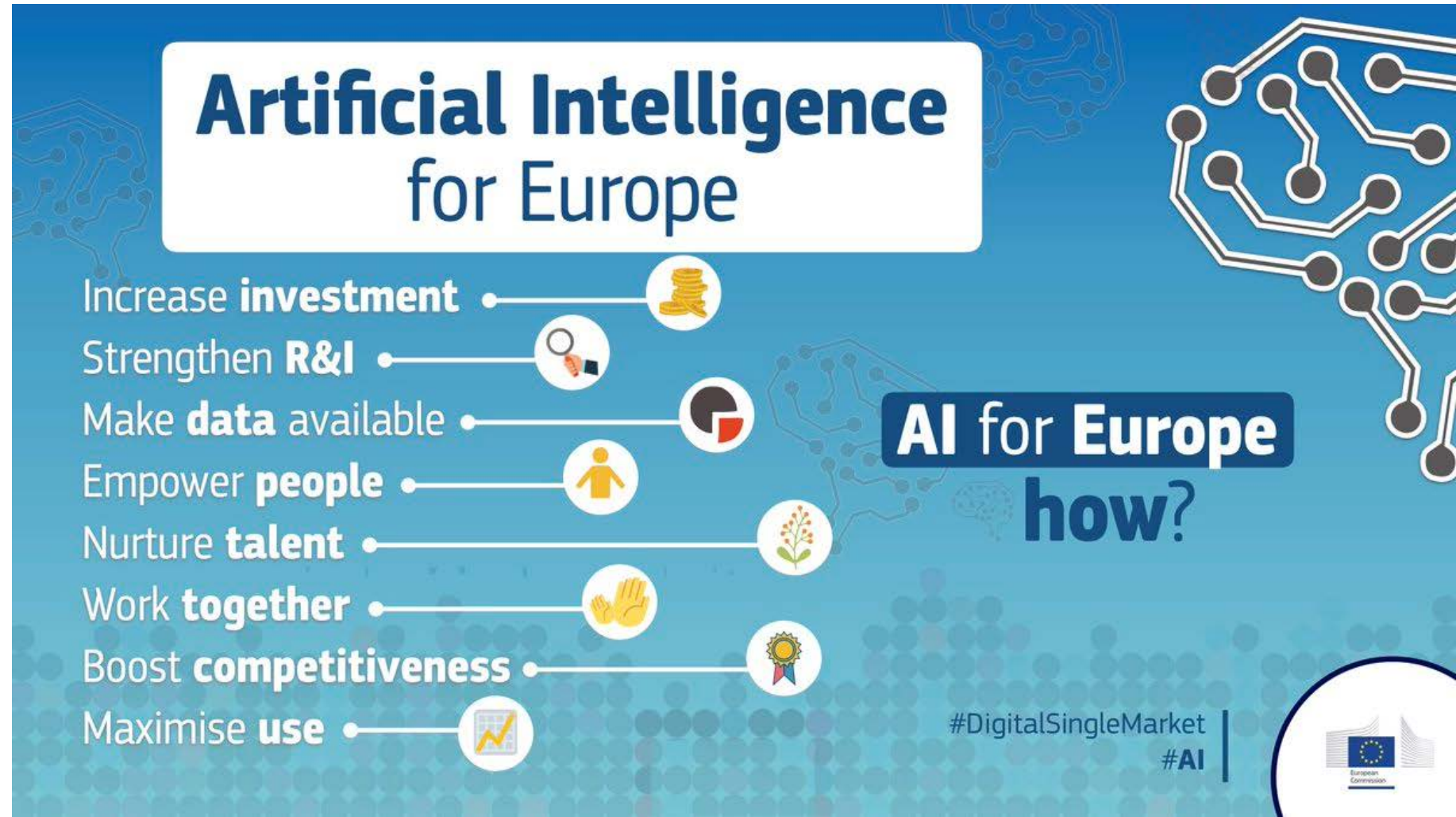
Towards a new EU framework on AI

promises vs. challenges

Around **€2.6 billion**
over the duration of Horizon 2020
on AI-related areas
(robotics, big data, health, transport,
future and emerging technologies).

EC legislative [proposal](#):

- trust / fundamental rights
- excellence
- risk-based approach
- links with sectorial laws
- foster innovation
- liability and safety issues



Have your say!

European Health Data Space:

- [Public consultation](#) on digital health data and services (the European health data space) – **by 26 July 2021**
- [Public consultation](#) on cross-border healthcare – **by 27 July 2021**

Pharma strategy and legislation:

- [Public consultation](#) on the revision of the legislation on medicines for children and rare diseases (medicines for special populations) – **by 30 July 2021**
- [Public consultation](#) on the revision of the EU general pharmaceutical legislation – upcoming (Q4/2021)

Thank you very much for your attention!

More info: [eHealth | Shaping Europe's digital future \(europa.eu\)](https://ehealth.europa.eu)

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