

Building Blocks for a National Health Data Strategy

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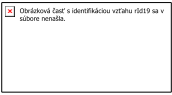
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The Challenge – Lack of insights & data access to evaluate every stage of patient care delivery



Diagnosis



Based on an incomplete picture of disease



Patient care plans



Medical information may be incomplete or out-dated



Access to care



Suboptimal access to care and limited awareness of care options



Patient monitoring



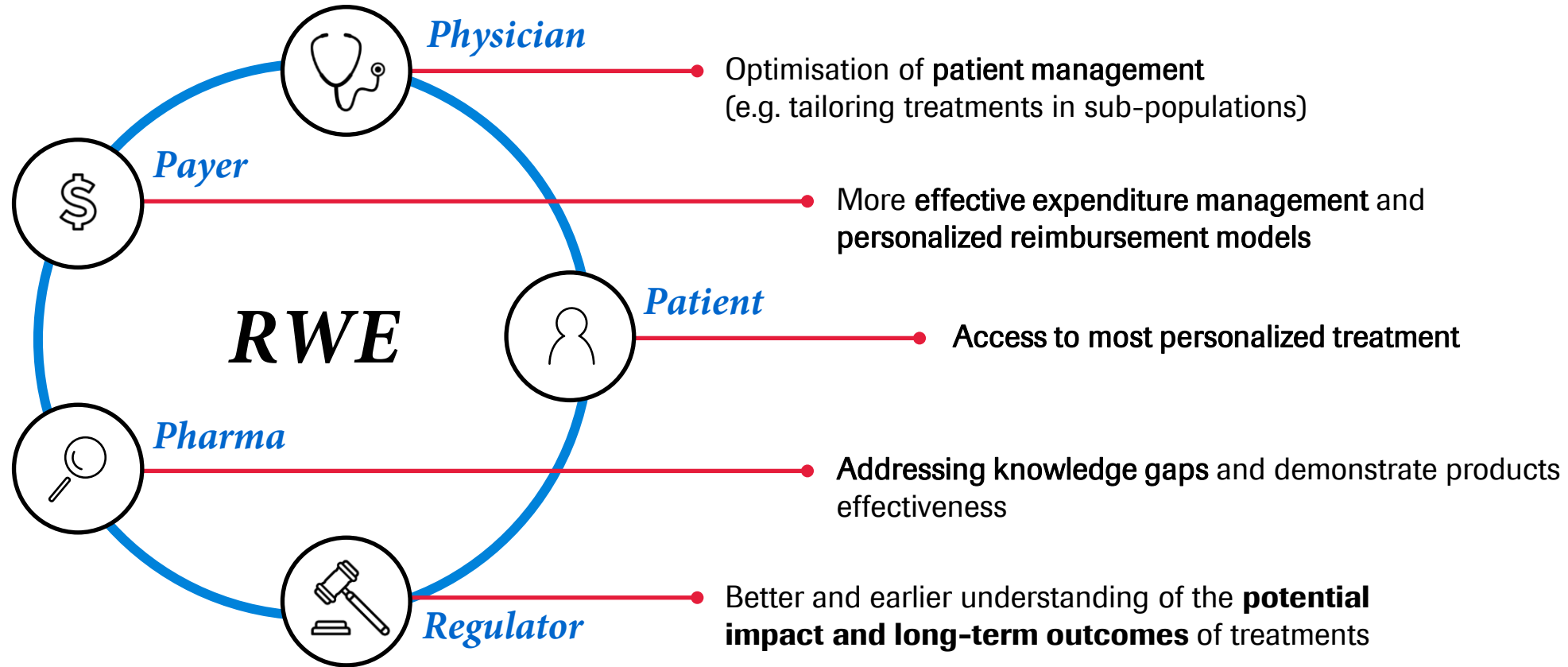
Delayed and incomplete picture of disease progression, treatment response and symptoms between clinic visits

Implications of Healthcare Spending disconnected from Medical Value & Outcomes

- Up to 30% spend waste in Healthcare according to OECD
- Significant variances in healthcare outcomes between and within countries

Transformation of the Healthcare Ecosystem

Shifting from a **Cost-driven** to **Value-Based, Outcome-Driven Healthcare system**, based on a foundation of quality, accessible **real-world evidence** so that **all stakeholders can benefit**.



Benefits of a Health Data Strategy

Optimizing the patient journey, reduce unnecessary costs, sustainability



Early & accurate diagnosis

Deeper insights
in a patient's disease

Timely **diagnosis**

Better **defined**
populations

Better monitoring of
disease or remission risk

Continuous and
remote patient
management



Tailored
care plan

More **effective,**
efficient decision-making

Patient **empowerment**

Better outcomes
for patients

Reduction of
unnecessary costs

Sustainability
of the health system



Full access to optimal
care intervention

Faster, better **decisions**
on safety, efficacy & value

Integrated & personalised
treatment options

A pan-European and cross-sector strategy for data that aims to position the EU to:
*'become a leading role model for a society empowered by data to make better decisions
– in business and the public sector'*

THE VISION:

The EU will become an attractive, secure and dynamic **data economy** by:

- setting clear and **fair rules on access and re-use of data**,
- investing in next generation **standards**, tools and **infrastructures** to store and process data,
- joining forces in European cloud capacity,
- pooling European data in key sectors,
- creating **EU-wide common and interoperable data spaces**
- giving users rights, tools and skills to stay in full control of their data.

European Health Data Space

The creation of a European Data Space is one of the priorities of the Commission 2019-2025, including the health sector.

A common European Health Data Space will **promote better exchange and access to different types of health data** (electronic health records, genomics data, data from patient registries etc.), not only to support healthcare delivery (so-called primary use of data) but also for health research and health policy making purposes (so-called secondary use of data).

Strategic BluePrint for a National Health Data Strategy



Health Data Strategy

Use Real-world Evidence to optimize patient outcomes, achieve greater cost efficiency by evolving laws, systems, care pathways, and reimbursement

ACCESS TO AND USE OF DATA

Advance legislation and projects that enable access to and use of meaningful data at scale

ACCEPTANCE OF SOLUTIONS

Accelerate regulation, approval, and access to personalised healthcare innovations

Data Policy		Regulatory Policy	Access Policy
<i>Legal & regulatory frameworks for data collection & sharing</i>		<i>Regulatory & clinical guidelines / policies</i>	<i>Innovative / adaptive reimbursement models & resource allocation</i>
<i>Investment in interoperable data technologies (systems, methods & infrastructure)</i>			
A. Legal basis , standards and codes of conduct	A. Infrastructure for data collection, housing and sharing	A. Acceptance of RWE* in regulatory approval	A. Acceptance innovative & adaptive reimbursement frameworks based on RWE
B. Data ethics - Privacy & Security - Artificial intelligence	B. Data quality standards and attributes	B. Digital Dynamic Labeling/ Dynamic Regulatory Assessments/ Cloud submissions*	B. Health system funding , accessibility & adoption
	C. Interoperability – Map existing data sources and establish database interfaces	C. Advanced diagnostics*	C. Advanced diagnostics *
	D. Global Data Flows – increase collaboration and exchange of data across borders	D. Digital Health Intervention* - Software as medical device (SaMD) - Digital/novel endpoints - Digital therapeutics - Clinical decision support (CDS)	D. Digital Health Intervention * - Software as medical device (SaMD) - Digital/novel endpoints - Digital therapeutics - Clinical decision support (CDS)

* Artificial intelligence/machine learning is being explored as a way to support the above priorities

Broad external collaboration & Multilateral Consortia between Government, Health Insurance Companies, Medical & Scientific Community, Patients/Patient Organisations, Industry associations, and IT industry

Data quality & interoperability

FAIR Principles should be used when evaluating data

*F*indable:

All data must be catalogued and annotated with descriptions that enable easy search to identify what data is available and where the data is located.

*A*ccessibility:

Data access should aspire to be seamless with appropriate restrictions by user, retention and legal compliance requirements.

*I*nteroperability:

Data sharing infrastructure should be, to the extent possible and permissible, interoperable and based on industry standards to allow for diverse stakeholders with different organisational data/IT systems to contribute to and benefit from the data ecosystem with a reasonable level of investment/effort.

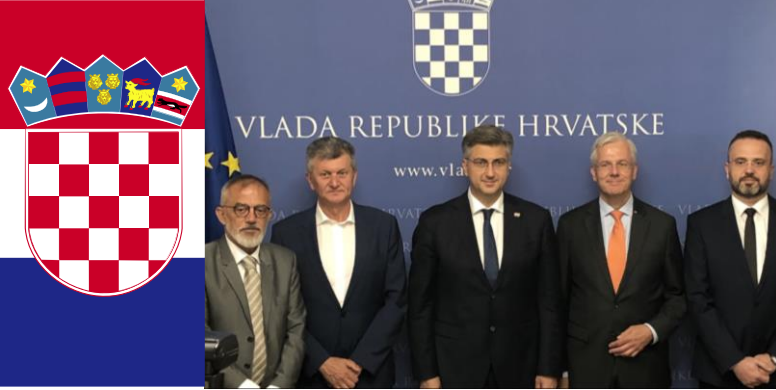
*R*eusability:

Data should be collected in a manner that supports lawful and sustainable sharing or reuse.

Government/Pharma Collaboration – Healthcare companies can offer value & expertise into National Health Strategies and Programs



PRESS RELEASE



Total Croatia News | Zagreb, July 18, 2019

Government Gives Go-Ahead for Personalised Medicine in Oncology

Personalised Medicine in Oncology project: establish a national laboratory for personal medicine diagnostics, a national Molecular Tumour Board (MTB) and the Croatian Oncology Database to systematically capture clinic-genomic data

CO-CREATE

Joint effort
between Roche
& Government of
Croatia

CO-INVEST

Croatian Health Insurance Fund
establishing national-level funding
for CGP & MGTOs for metastatic
cancer patients

Roche investing in genomic
profiling lab & Croatian Oncology
Database

CO-BENEFIT

For patients
Rapid access to CGP and personalised treatments

For Croatian healthcare system
Investment in additional expertise and resources needed to make PHC a reality

For industry
Generation of high quality clinico-genomic data, with the potential to inform the impact of PHC through publications, guideline updates and policy changes

Romania – Example of incorporating Personalized Healthcare & Data Strategy into National Health Strategy



- Romanian government has **only basic health-related plan** in place
- Romania formed a multi-stakeholder working group to developing their **National Health Strategy**
- Industry experts, including Roche, contributed to the National Health Strategy
- As a result, Roche was given the opportunity to develop the Personalized Healthcare Chapter of the newly developed National Health Strategy

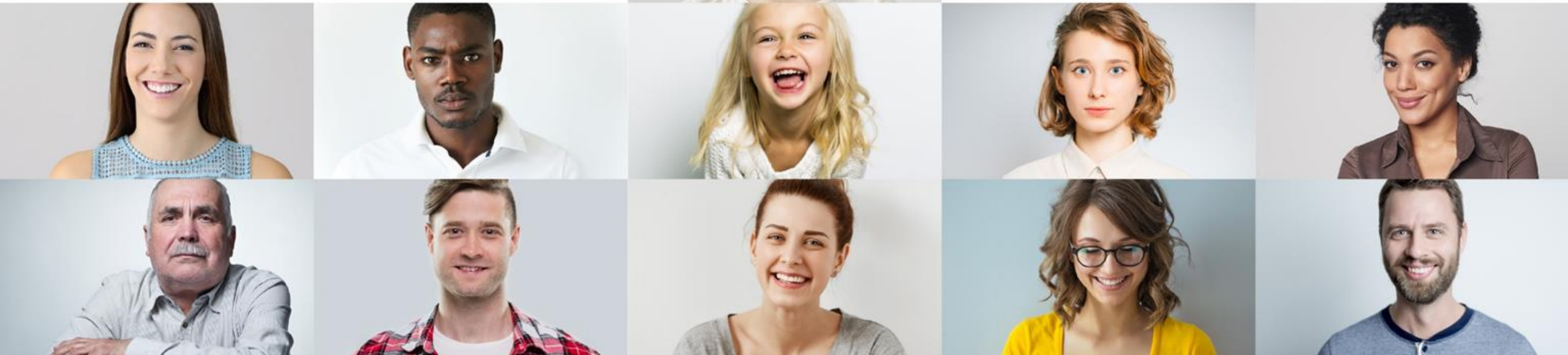
Putting the Building Blocks of a Healthcare Data Strategy Together

What if... we could accelerate Healthcare Transformation through the benefit of more collaboration and partnership between Government and key public/private stakeholders & experts?



Imagine a world where...

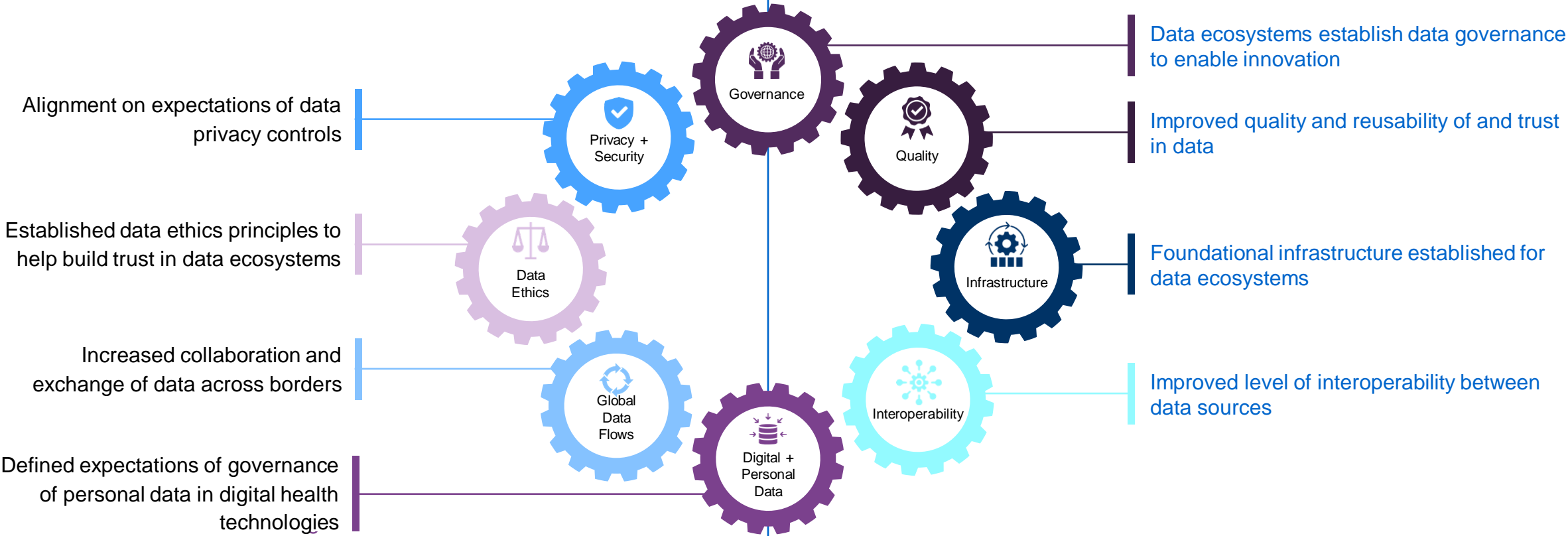
EVERY patient has the best possible support



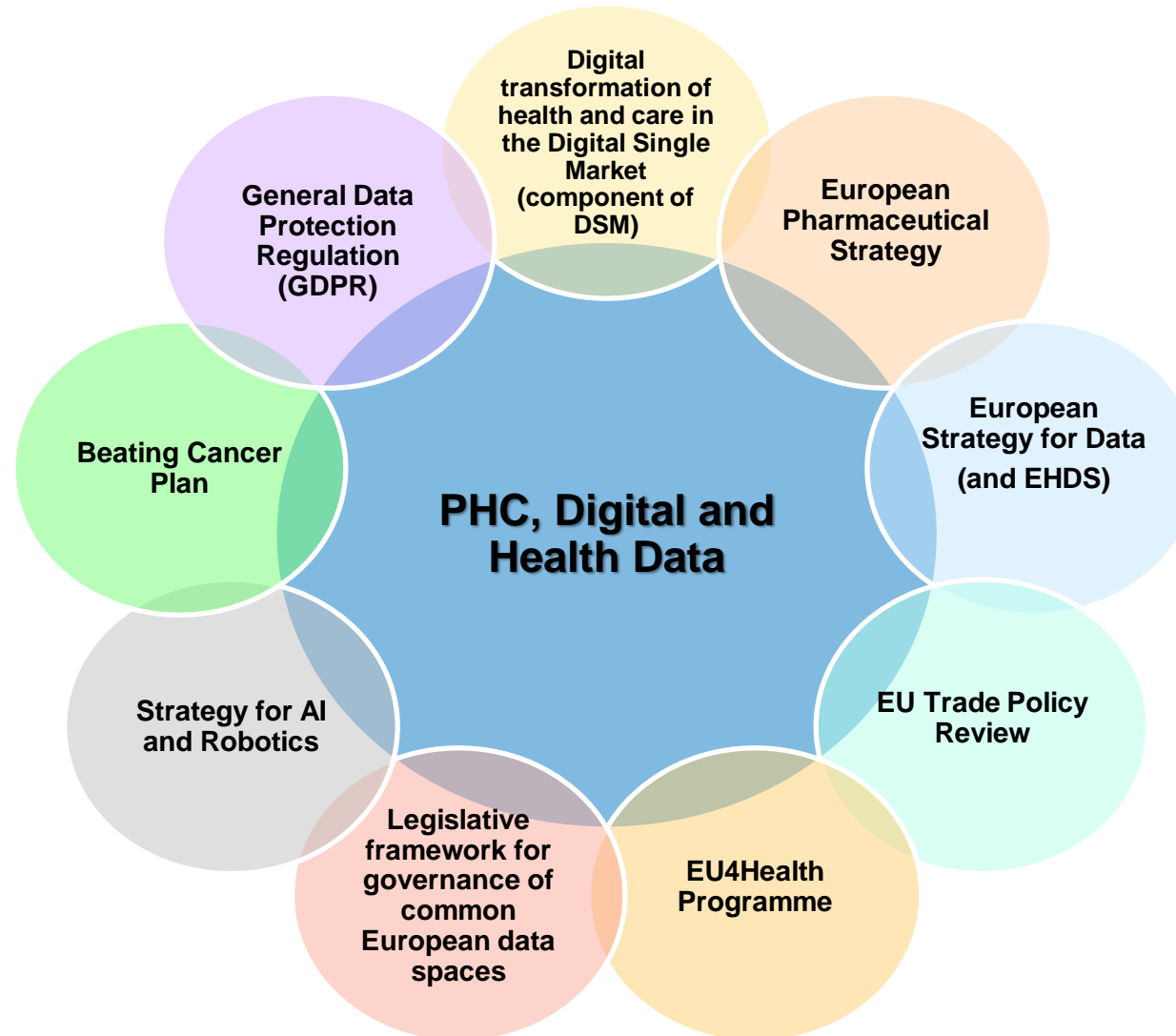
Key Components of a Health Data Strategy

Legal + Regulatory frameworks for data collection + sharing

Investment in interoperable data technologies (systems, methods + infrastructure)



Personalized Healthcare, Digital and Data are a Key Component of Many Commission Initiatives and Programs



EU Environment: Healthcare Policy Outlook 2020-2021



German
Presidency



Portuguese
Presidency



Slovenian
Presidency



French
Presidency



Czech
Presidency



EU Pharma
Strategy
adopted (Q4
2020)

EU Pharmaceutical Strategy implementation

Revision of OMP and Pediatric Regulation (exact timing TBC)

HTA Regulation finalised (exact timing TBC)

EU Strategy
for Data
Released Feb
2020

European Strategy for Data and European Health Data space design and implementation

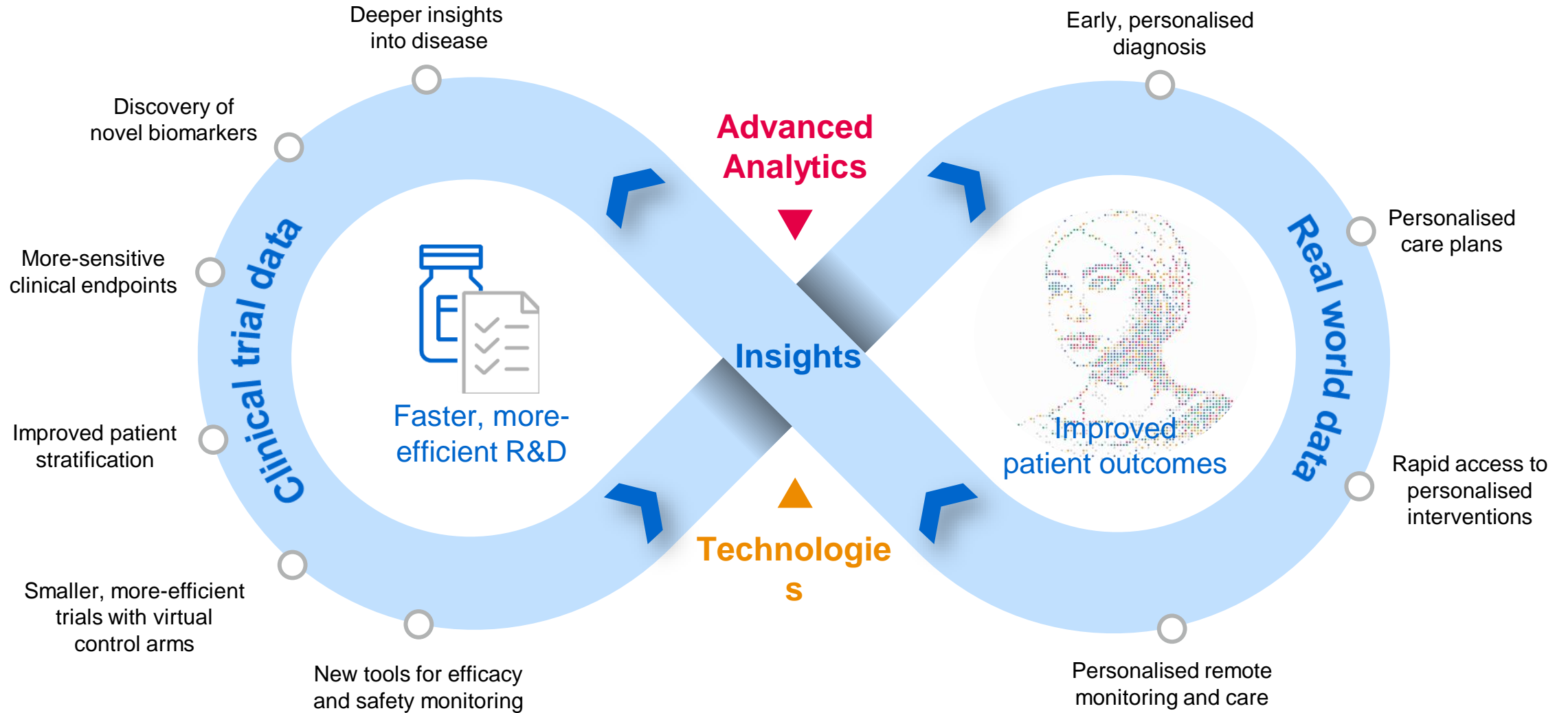
EU Beating
Cancer Plan
adopted (Q1
2021)

EU Beating Cancer Plan implementation

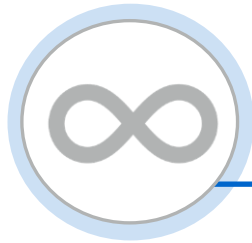
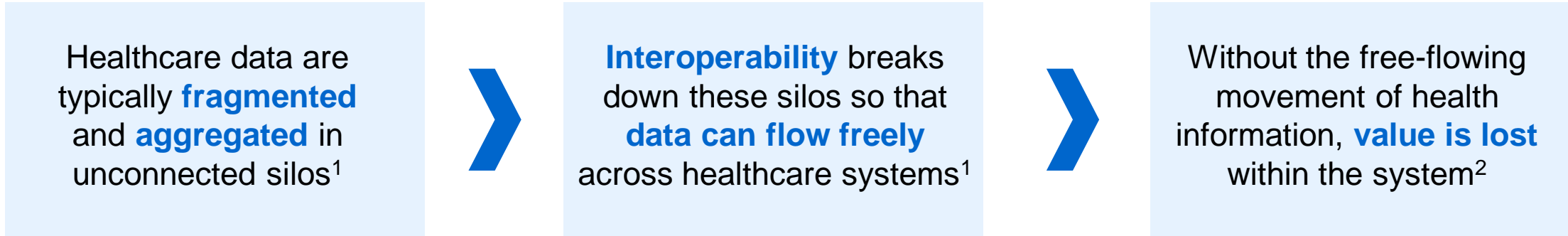
Conference on the future of Europe (healthcare at the forefront in light of COVID-19)

Health Innovation PPP Legislative Process

Data, technology and analytics can provide insights to accelerate R&D and improve patient outcomes



Why is interoperability important in healthcare?



Interoperability enables more-effective use of data, technology and analytics in clinical research and clinical practice^{1,2}

Electronic health records	Genomic data	Imaging data	Clinical trial data
Mobile health apps	Wearable technologies	Clinical decision support	Advanced Analytics