

# INTRODUCTION TO THE STUDY DAY

## *“IN HOUSE MEDICAL SOFTWARE”*

Prof. Pascal Verdonck, MSc CivEng, MScBME, MBA, Phd

# GLOBAL CONTEXT

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# “J. CAESAR” CROSSES THE RUBICON IN 49 BC



# USA VS EUROPA — LIFE SCIENCES & INNOVATION

Indicator	VS	Europa (EU + VK + CH)
Publicaties (medisch/biomedisch)	~30–35%	~30–40%
Patenten (medtech) – EPO (2022)	~5.8k	~6.6k
Pharma R&D (2023)	≈ 2× Europa	€52.4 mrd



# GLOBAL MEDICAL COMPANY MARKET CAP VS. COUNTRY GDP



Based on Financial Reports of Annual Revenue (Approx. Values)

1	 <b>Abbott</b>	~\$180 B	— ≈ GDP	 Lithuania
2	 <b>INTUITIVE SURGICAL</b>	~\$158 B	— ≈ GDP	 Latvia
3	 <b>stryker</b>	~\$129 B	— ≈ GDP	 Estonia
4	 <b>Medtronic</b>	~\$117 B	— ≈ GDP	 Liechtenstein /  close to Albania
5	 <b>Boston Scientific</b>	~\$101 B	— ≈ GDP	 North Macedonia
6	 <b>BECTON DICKINSON</b>	~\$59 B	— ≈ GDP	 Bahrain /  Luxembourg (partially)



Association Belge des Directeurs d'Hôpitaux (ABD)  
Belgische Vereniging van Ziekenhuisdirecteuren (BVZ)  
Belgische Vereinigung der Krankenhausdirektoren (VdK)

# A New Era in Belgian Healthcare:

Key Findings and Collaborative  
Insights towards Implementation of  
Value-Based Healthcare

**December 2024**

Commissioned by the Belgian Association of Hospital  
Managers to PwC Enterprise Advisory BV ("PwC") in  
accordance with an agreement signed between the Belgian  
Association of Hospital Managers and PwC ("").



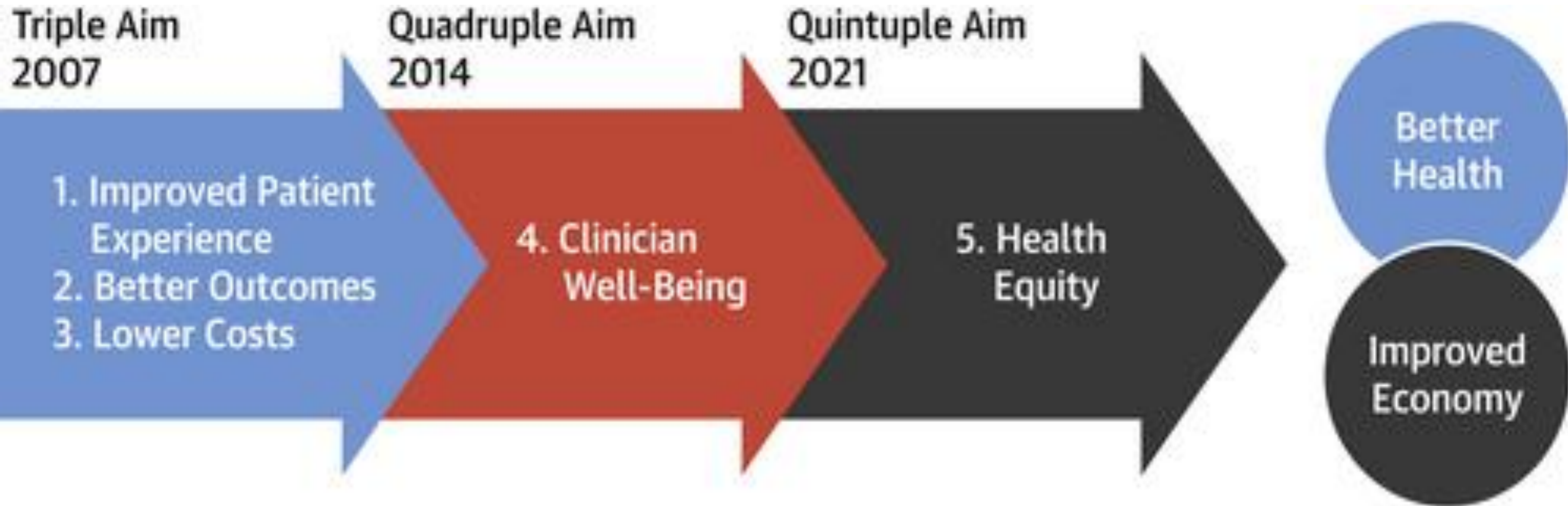
# WHY IS A TRANSFORMATION URGENT?



1. The double aging of the population
2. Structural financial pressures
3. Widespread staff shortages

The current model is not scalable without a "system overhaul"!

# CHALLENGES OF HEALTHCARE



# SOLUTION FOR OUR HEALTHCARE



# STANDPUNT 25 VAN KVAB - 2014

## MEDISCHE TECHNOLOGIE

### ALS MOTOR VOOR INNOVATIEVE GEZONDHEIDSZORG

In januari 2004 publiceerde CAWET, het Comité van de Academie voor Wetenschappen en Techniek, voorloper van de Klasse Technische Wetenschappen, zijn rapport nr. 45 met als titel 'Biomedische ingenieurwetenschappen: speerpunttechnologie van een moderne gezondheidszorg'. Dit nieuwe Standpunt over 'Medische Technologie als motor voor innovatieve gezondheidszorg' is een vervolg op het intussen 10 jaar oude CAWET-rapport.

Dit Standpunt werd voorbereid door een werkgroep die werd voorgezeten door Pascal Verdonck, bestuurder van het AZ Maria Middelares in Gent. Werkgroepleden waren Yvan Bruynseraede, departement fysica en sterrenkunde KU Leuven, Bart De Moor, departement ESAT KU Leuven, Bart Swaelens, CEO van Materialise, Erik Tambuyzer, voorzitter van het Centrum voor Medische Innovatie, Erik Vandamme, departement biochemische en microbiële technologie UGent, Jos Vander Sloten, departement biomechanica KU Leuven, Ewout Vansteenkiste, Technology Developer HyCT UGent, en Ivo Van Vaerenbergh, voorzitter Agora Metalen en Materialen.

"Health technology" is voor de World Health Organization (WHO) van het hoogste belang voor het tot stand komen van stabiele en duurzame mondiale gezondheidssystemen. Medische Technologie omvat de toepassing van wetenschappelijke kennis en technieken in het brede domein van de gezondheidszorg. In dit Standpunt echter werd de focus bewust beperkt tot 'medical devices', zoals bv. medische beeldvorming, implantaten, sensoren, etc. Medical devices hebben tot doel behandelingen te optimaliseren, de patiënt meer comfort te geven en finala uiteraard levens te redden.

Opdat Belgische bedrijven en start-ups een leidende rol zouden kunnen spelen in deze sector, pleiten de auteurs van dit Standpunt voor de oprichting van een uniek platform, (MedTechplatform Flanders en MedTech.be innovatieconsortium) waar overheid, industrie, onderzoeksweld en ziekenhuissector met elkaar in overleg kunnen treden. Een geïntegreerde aanpak en een efficiënte dialoog tussen deze stakeholders, waarbij het belang van de patiënt centraal wordt gesteld, zijn immers basisvoorwaarden voor succes.



## MEDISCHE TECHNOLOGIE

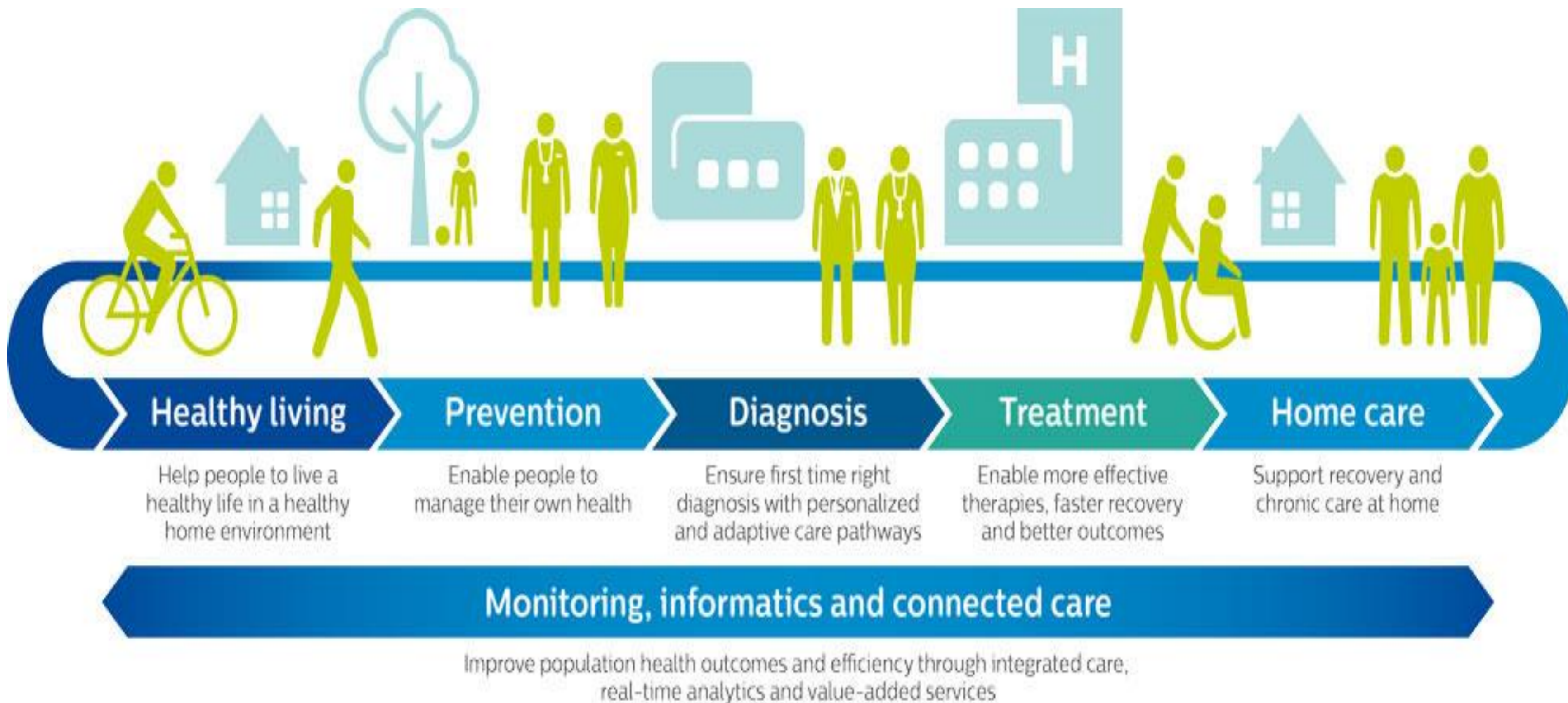
### ALS MOTOR VOOR INNOVATIEVE GEZONDHEIDSZORG

Pascal Verdonck

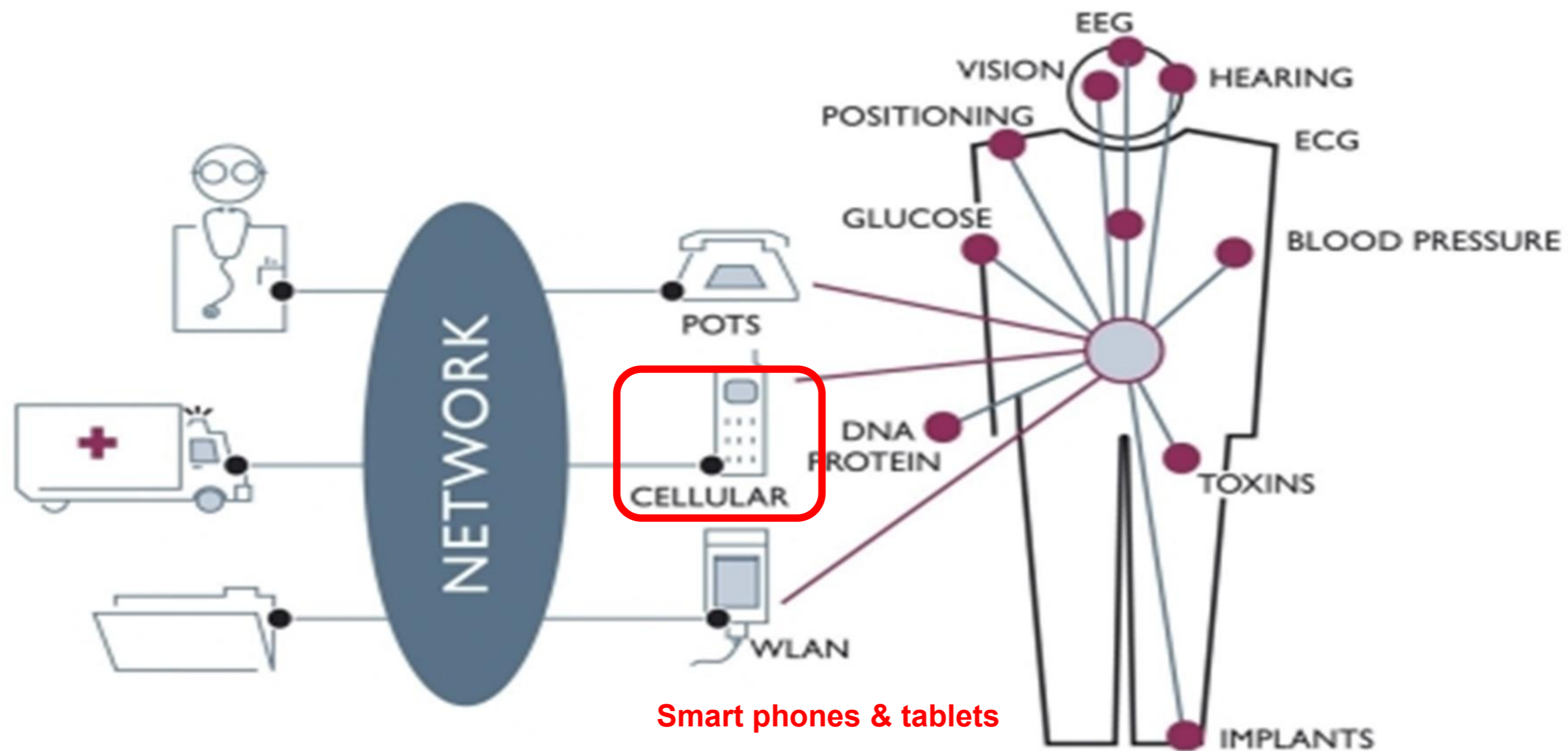
# FUTURE OF HEALTH

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# HEALTH CONTINUUM



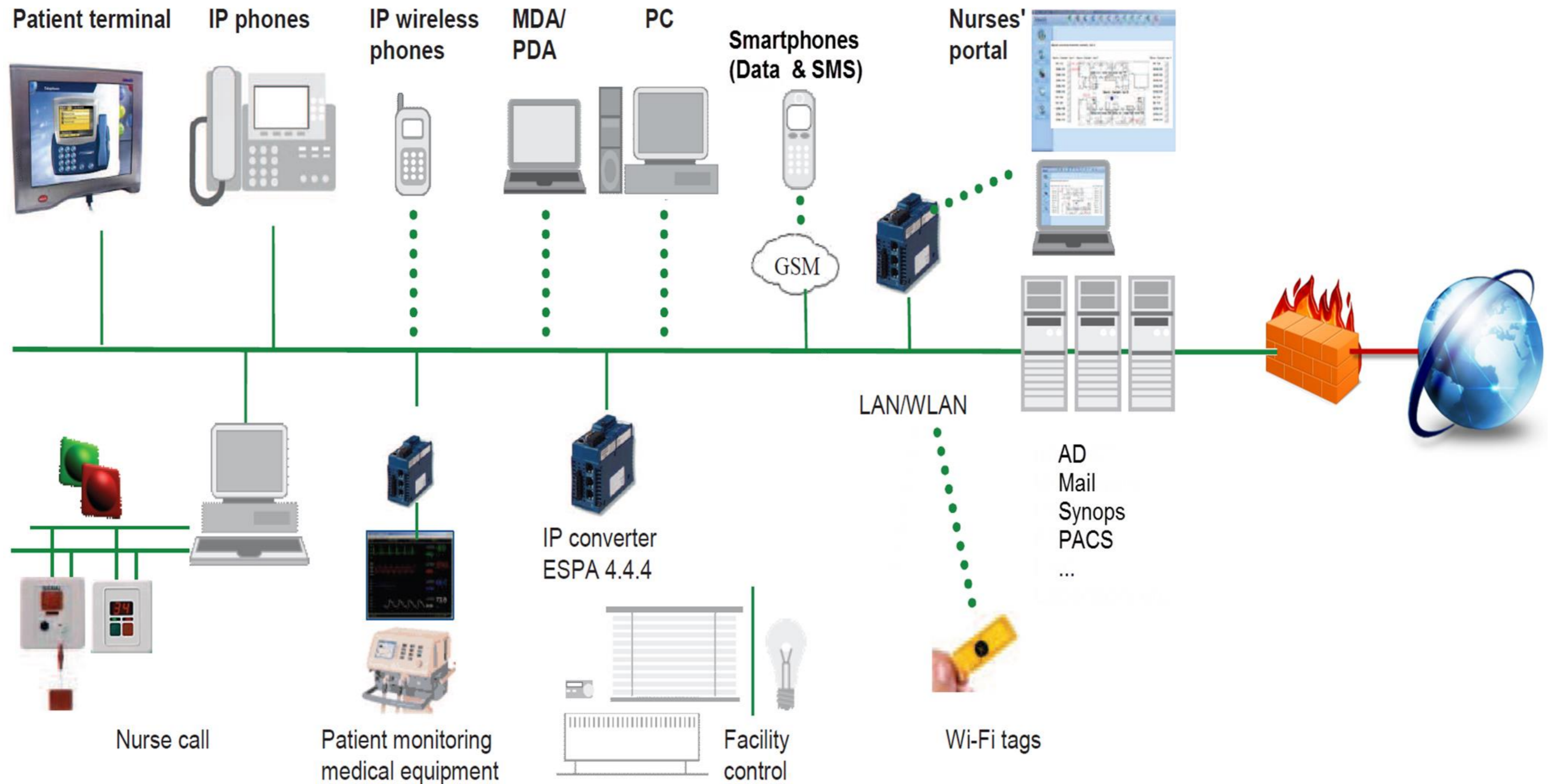
# OUR BODY IS A NETWORK



Smart phones & tablets

Wearables & insideables

# A SMART HOSPITAL IS A NETWORK



# A FUTURE PROOF HOSPITAL

An Intervention center with a command tower:  
*patient flow management for efficient and safe  
access and care for patients intra & extra muros*

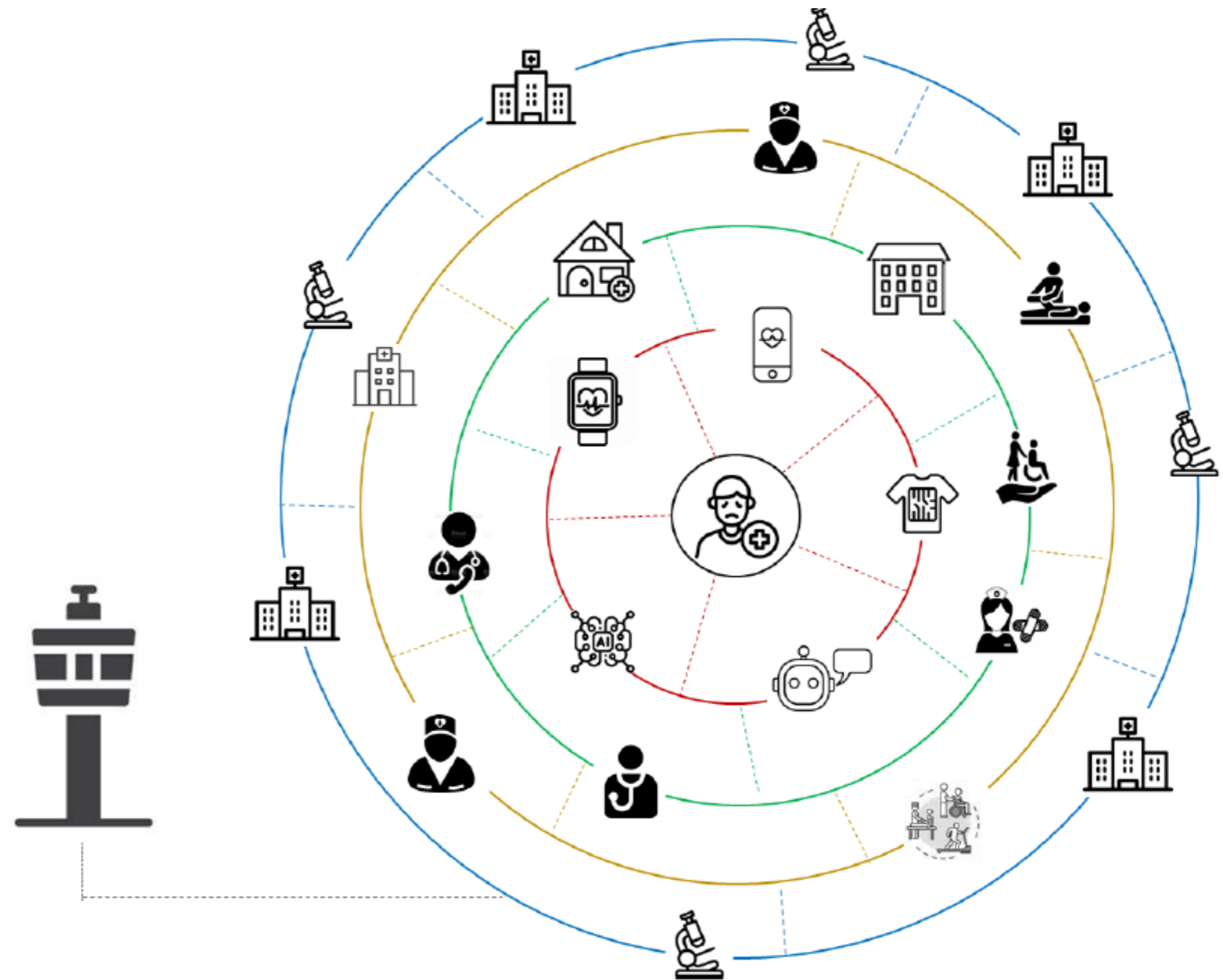


TTSH C3 Operations Command Centre



# ZERO LINE IS THE "GAME CHANGER"

0<sup>de</sup> lijns zorg  
1<sup>ste</sup> lijns zorg  
2<sup>de</sup> lijns zorg  
3<sup>de</sup> lijns zorg



# MAIN TYPES OF DATA IN HC SECTOR

Health care data

```
graph LR; A[Health care data] --> B[Clinical data]; A --> C[Administrative data]; A --> D[Patient-generated health data]; A --> E[Public health data]; A --> F[Research data];
```

Clinical data

- EHRs
- Lab results
- Diagnostic medical images
- Medications
- Procedures

Administrative data

- Insurance claims
- Billing records
- Hospital admission and discharge records

Patient-generated health data

- Self-reported information
- Wearable devices

Public health data

- Epidemiological data
- Surveillance data

Research data

- Clinical trials
- Observational studies

# VALUE BASED HEALTH CARE

Michael E. Porter  
Elizabeth Olmsted Teisberg

## Redefining Health Care

*Creating  
Value-Based Competition  
on Results*



HARVARD BUSINESS SCHOOL PRESS

- The fundamental **goal and purpose** of health care is **to improve value for patients**

$$\text{Value} = \frac{\text{Health outcomes that matter to patients}}{\text{Costs of delivering these outcomes}}$$

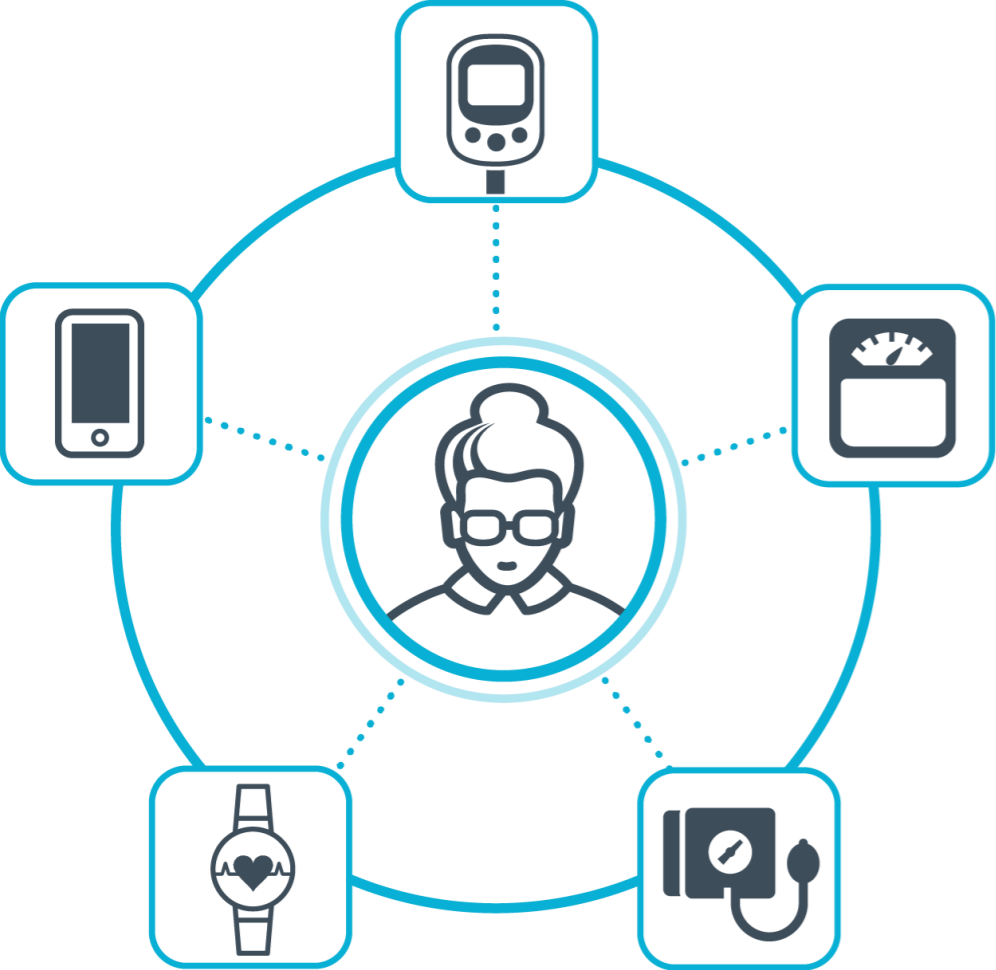
- Value is the only goal that can **unite the interests** of all system participants
- Value is created in caring for a patient's **medical condition** over the **full cycle of care**



The most powerful single lever for reducing cost and improving value is improving outcomes

Source: ICHOM 2019

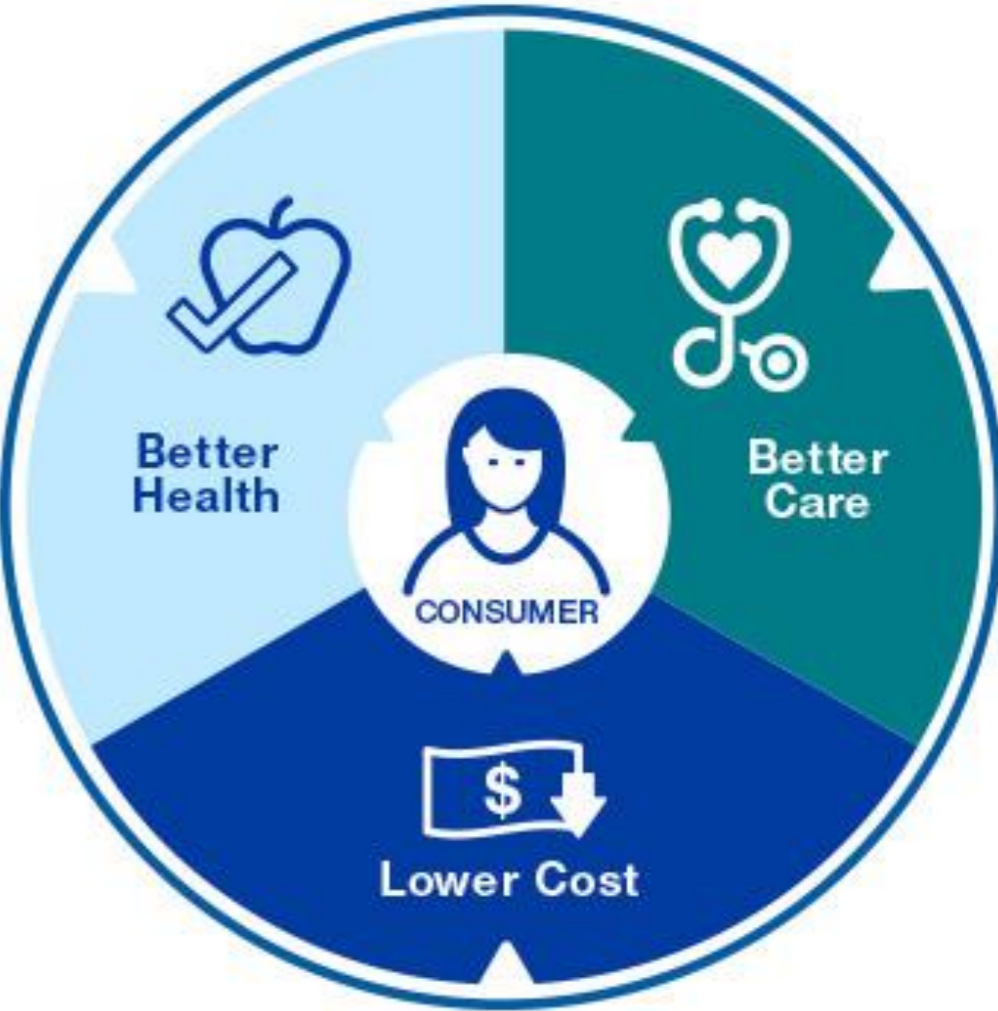
# HEALTHCARE STRATEGY TOWARDS FOH



Connected care



Integrated care



Value-based care

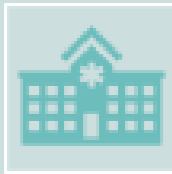
# STRATEGIC SHIFT MAYO CLINIC



Digital Adoption → digitally enabled care.



Episodic Care → Continuous Care.



Hospital Based → Platform enabled care.

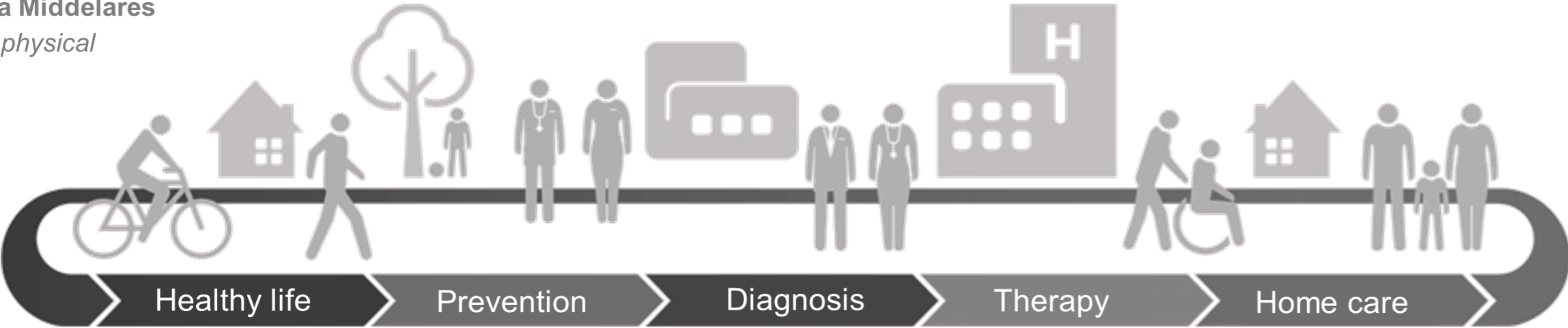


Pipeline Model → platform model .

# PHYGITAL HOSPITAL

MyHospital  
digital

Maria Middelaes  
physical



Value  
propositie

Health Coach

Innovative and high-tech  
intervention center

Continued care  
companion

Value  
architecture

- Self-care paths (with medical coaching)
- Dashboards with insights in health and measurable goals, based on consumer wearables
- Just-in-time (early) interventions
- No unnecessary physical contacts – tele services where and when relevant (save time, cost and hassle)
- 24/7 accessible and connected

- High qualitative and safe care
- Minimal time diagnosis > start treatment
- Less (long) (re)admissions

- No unnecessary physical contacts – tele services where and when relevant (save time, cost and hassle)
- 24/7 accessible and connected
- PROMs – PREMs
- Dashboards with insights in health and measurable goals, based on consumer wearables

- Reduce waiting times
- Easy appointment
- Orientation to right multi-disciplinary team

- Care coordination



# LEGAL CONTEXT

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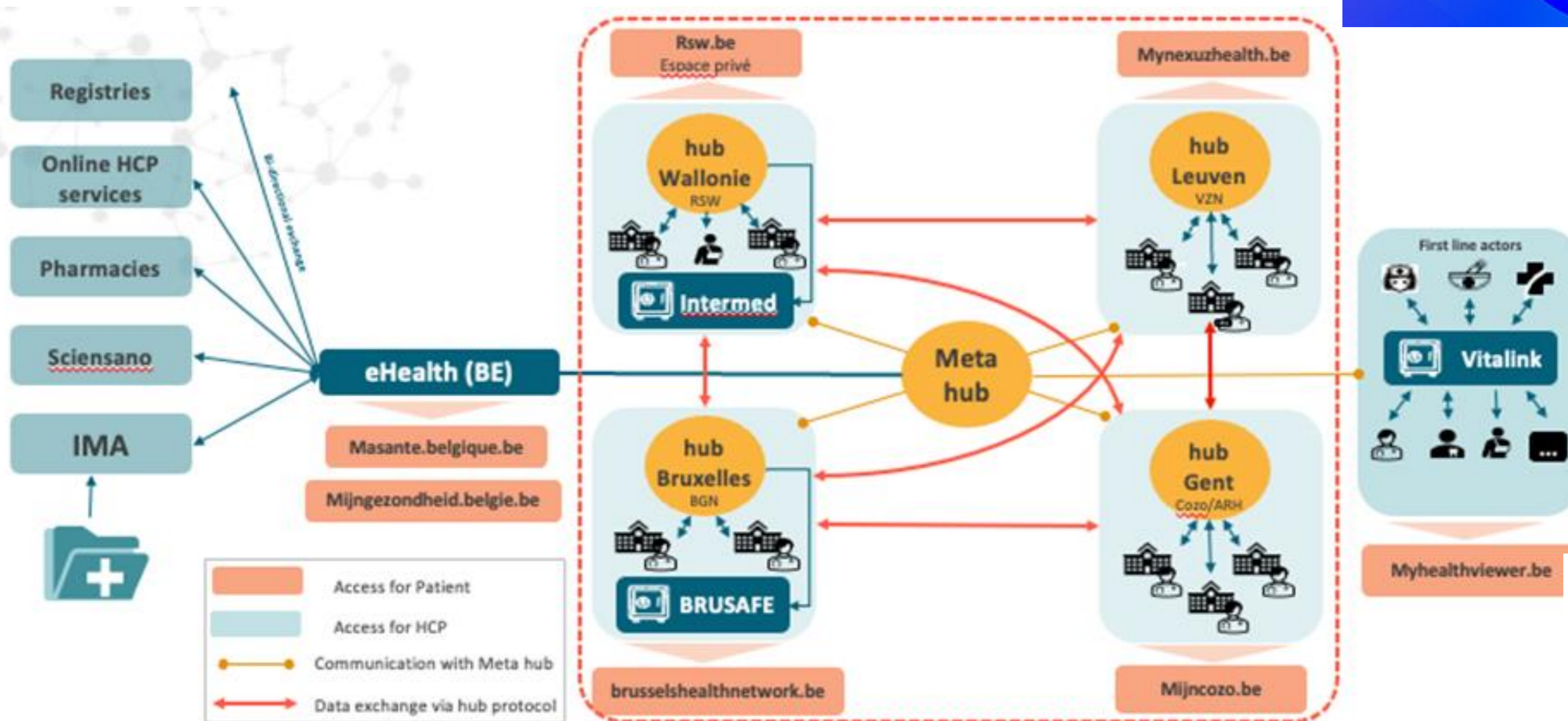
# TERMS & CONDITIONS FOR IN-HOUSE SOFTWARE

- Within a single legal entity
- Documented justification
- Requirements
  - Quality system
  - General safety and performance
  - Documentation
- Registration and declaration



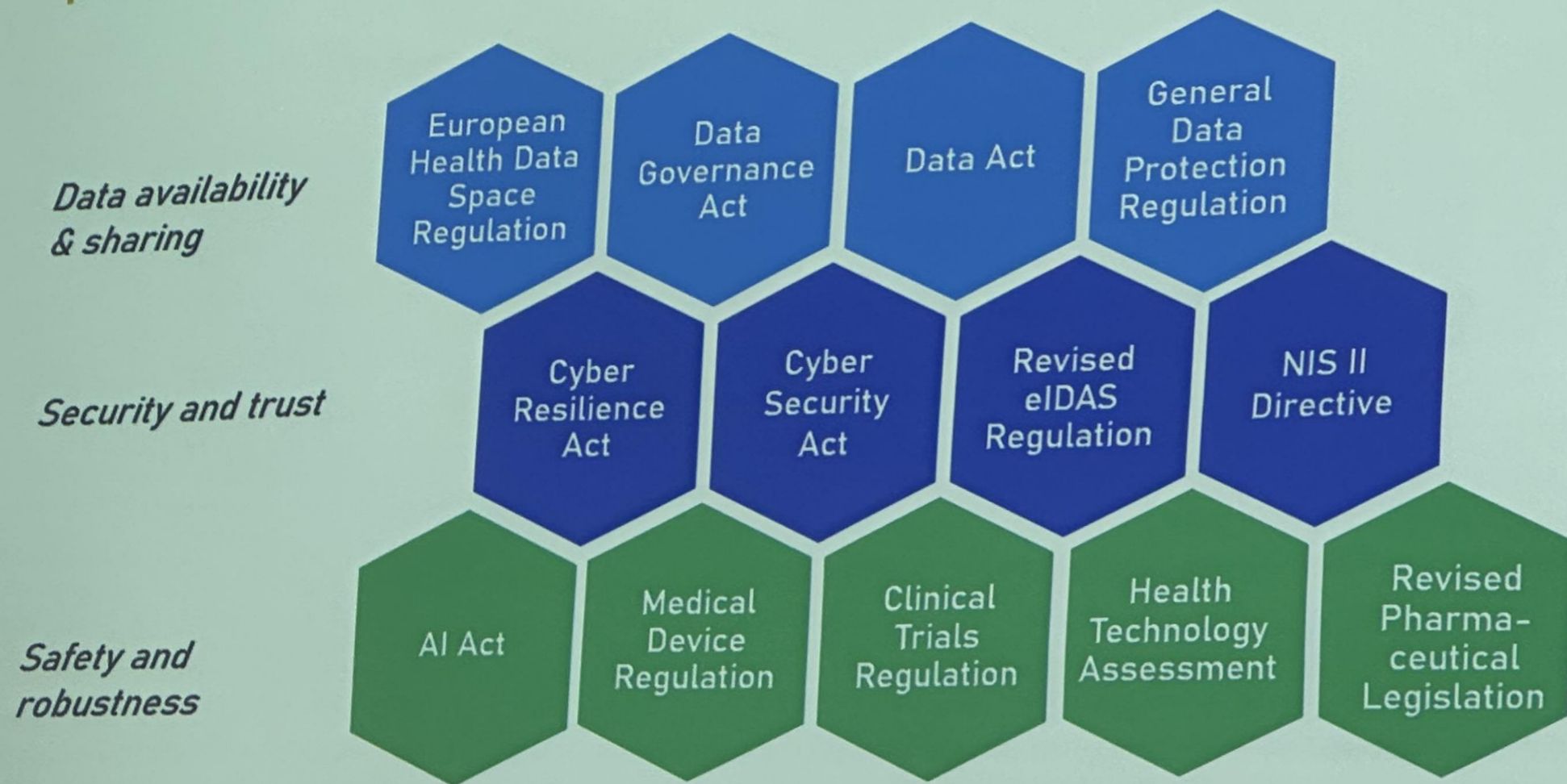
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# HEALTH DATA SPACE



# A STABLE & SECURE REGULATORY FRAMEWORK

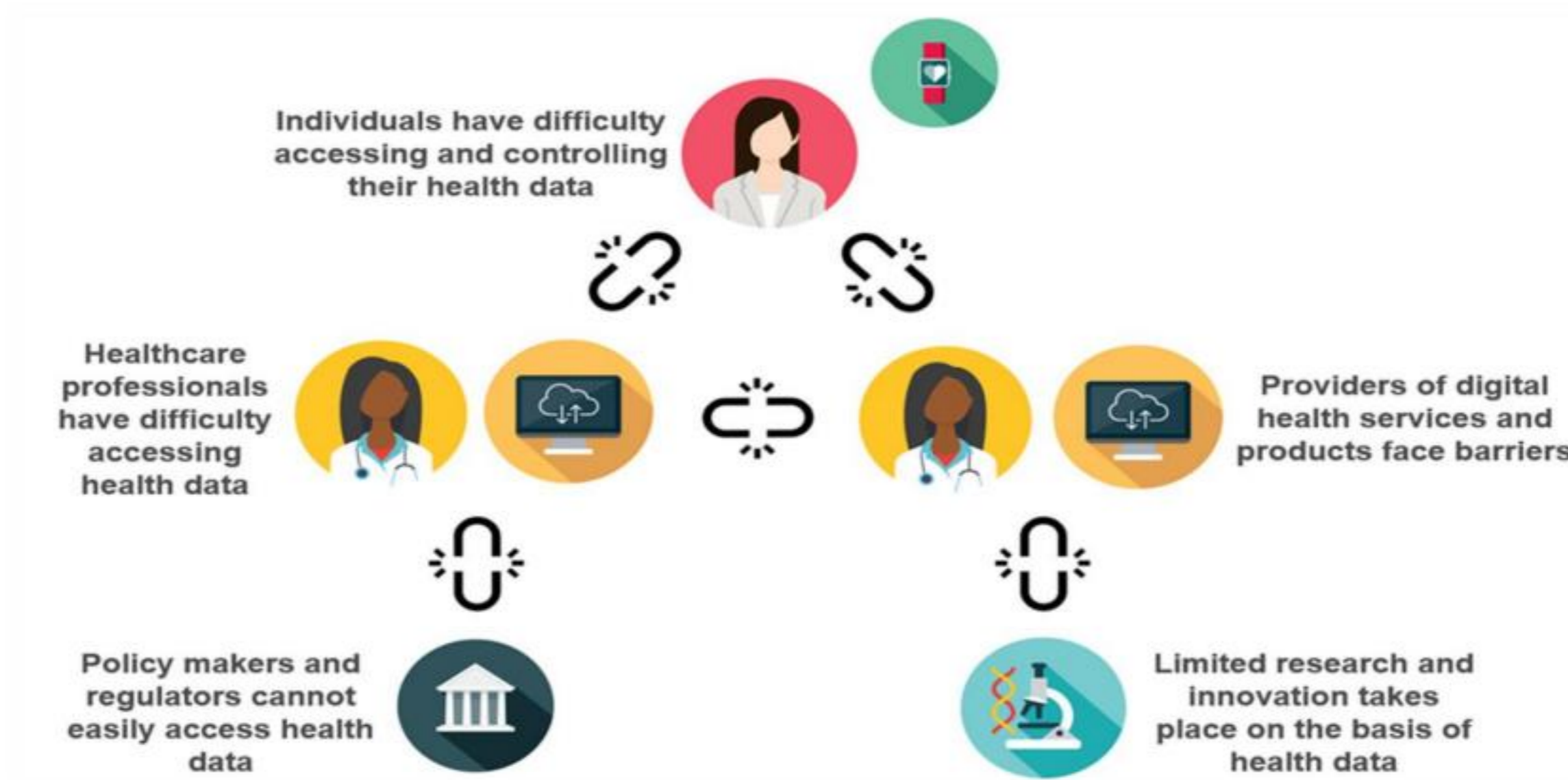
## A stable and secure regulatory framework



e-Health target: 100% of EU citizens access to electronic health records by 2030

## Implementation!

# LIMITATIONS & DIFFICULTIES



**Primary use:** Care delivery



**Secondary use:** Research, innovation

# DIGITAL OMNIBUS

## AI Act

- Extension of application timeline to 2 August 2029
- Single conformity assessment and Notified body procedure
- Exemption of investigational devices / devices for performance studies from the scope of the AI Act
- Align 'substantial changes' definitions

## Cybersecurity

- Cybersecurity Act: Reground voluntary aspects within EU cybersecurity certification
- Network and Information Security Directive II (NIS2): Support harmonised transposition, implementation and application across EU Member States

## Data Act

- Establish a coherent framework for health data sharing
- Extend timeline for the Data Act's application
- Exclude legacy devices and avoid ad-hoc changes to products
- Reduce high burden to protect trade secrets

## European Health Data Space

- Limit the overly broad "EHR systems" definition



# THE DILLEMA OF THE REGULATOR



MDD → MDR (2009 - 2017 – 2021 - 2027)

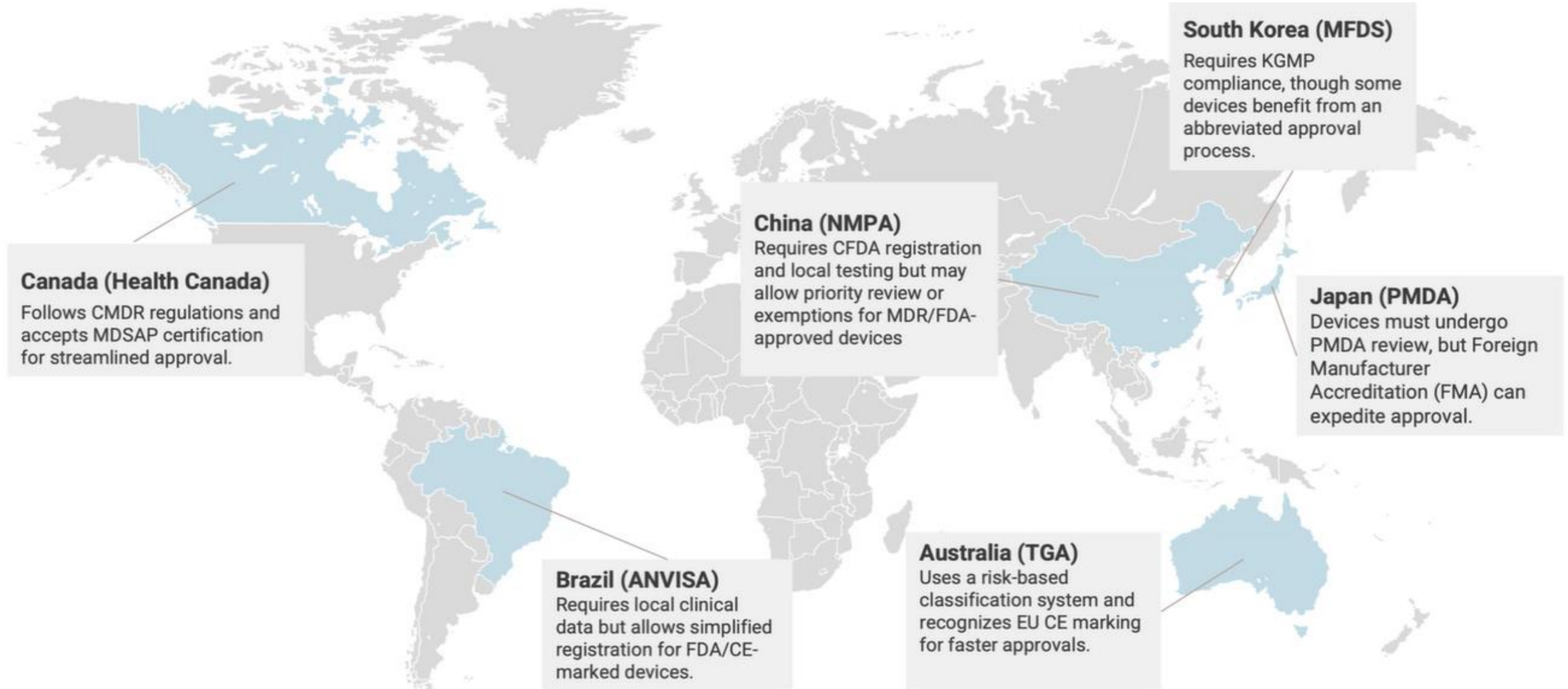


Accelerated pathway for Breakthrough Devices



PMD Act, 2014

# INTERNATIONAL REGULATORY LANDSCAPE



**Canada (Health Canada)**  
Follows CMDR regulations and accepts MDSAP certification for streamlined approval.

**Brazil (ANVISA)**  
Requires local clinical data but allows simplified registration for FDA/CE-marked devices.

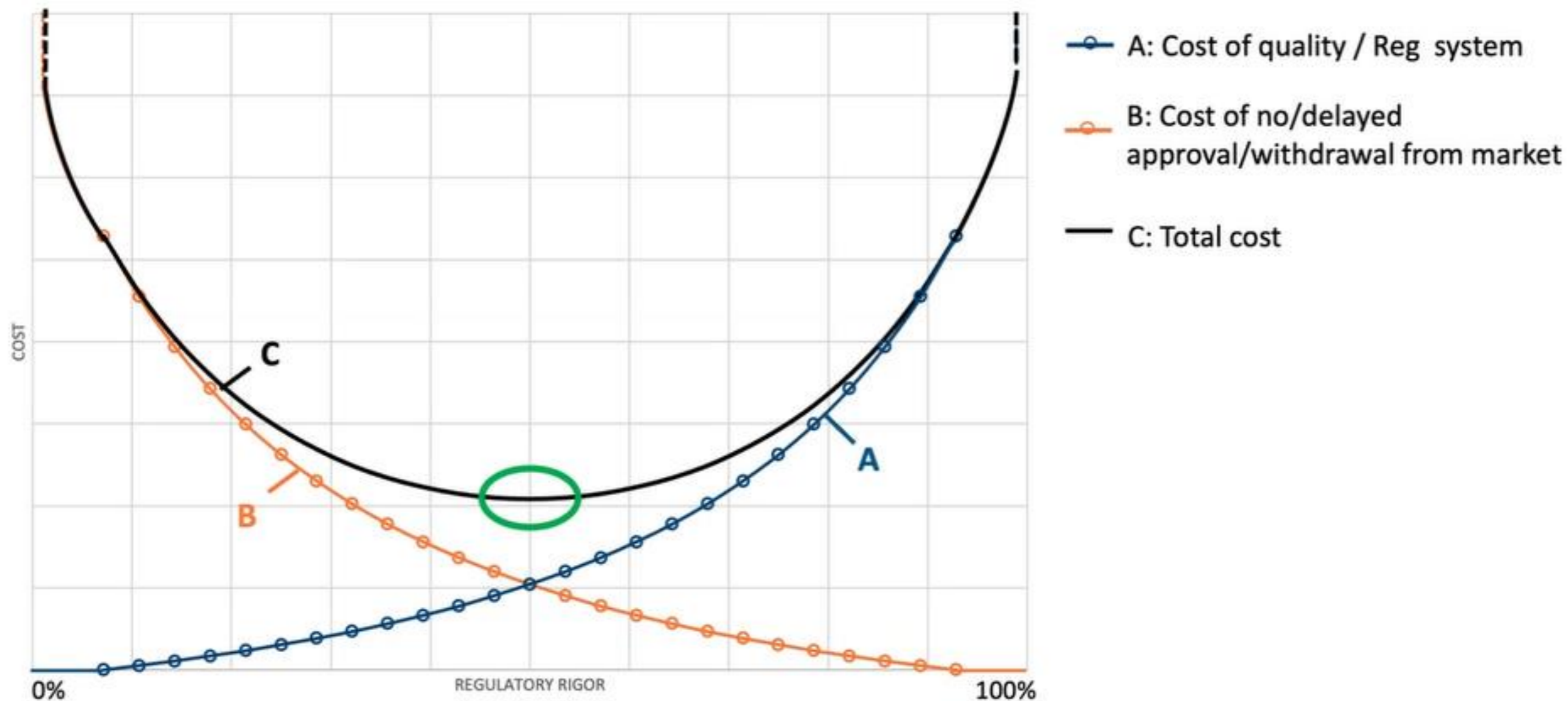
**China (NMPA)**  
Requires CFDA registration and local testing but may allow priority review or exemptions for MDR/FDA-approved devices.

**Australia (TGA)**  
Uses a risk-based classification system and recognizes EU CE marking for faster approvals.

**South Korea (MFDS)**  
Requires KGMP compliance, though some devices benefit from an abbreviated approval process.

**Japan (PMDA)**  
Devices must undergo PMDA review, but Foreign Manufacturer Accreditation (FMA) can expedite approval.

# COST OF REGULATORY STRATEGY



Be pro-active in defining your Regulatory strategy !

# OUR BURNING PLATFORM

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# FUTURE VALUE: INNOVATION & DATA

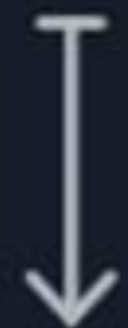
**FV = ID**

**Future value**

= [ **Innovation**  
Outcomes x Personalization ]



For people  
For physicians  
For payers  
For policymakers



Participatory  
Precise  
Predictive  
Proactive

**Data**

(Connect + Combine + Share)



Data streams



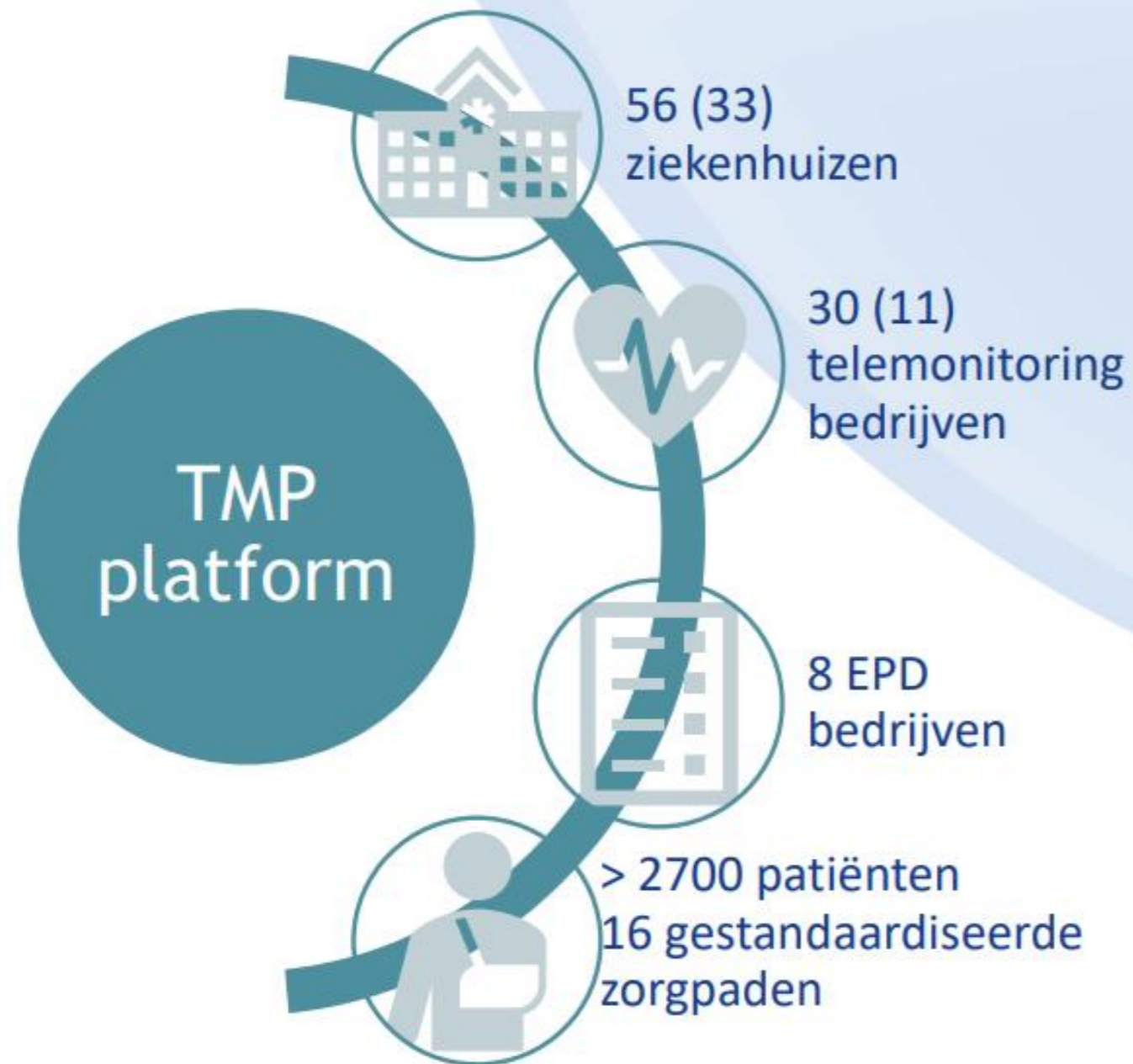
Traditional and  
non-traditional  
partners



Platforms  
of care

# INNOVATION OF A TRANSMURAL PLATFORM

## Status publiek-private samenwerking



## Financiering stopgezet

- ❖ continuïteit platform
- ❖ transitie periode



CONVERSATION



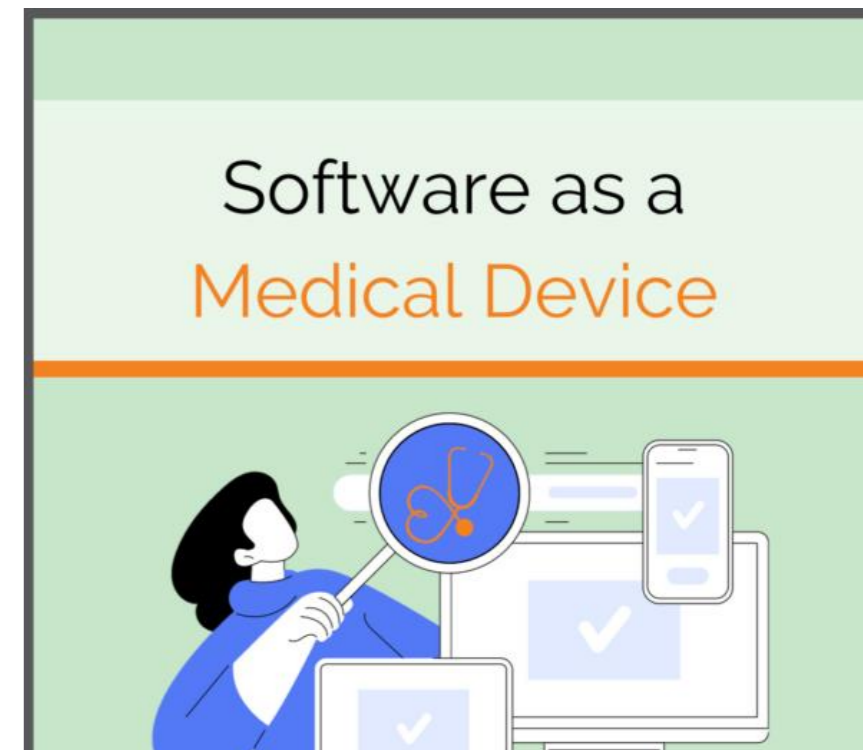
# Building a Global Innovation Ecosystem to Transform Health Care from Within

Health care transformation requires more than isolated innovation efforts — it demands a global ecosystem where institutions become engines of entrepreneurship, spinning out solutions from within while collaborating across borders to scale impact and achieve financial sustainability.

**Authors:** Eyal Zimlichman, MD, MSc, and Thomas H. Lee, MD, MSc [Author Info & Affiliations](#)

# ROLE OF MEDICAL DEVICE SOFTWARE

- Software intended for medical purposes (diagnosing, monitoring, or treating diseases and conditions)
- Software as a Medical Device (SaMD): “Standalone”  
example: a mobile app that uses AI to detect skin cancer from photos.
  - Software in a Medical Device (SiMD): “Embedded”  
examples: firmware in a pacemaker



# KEY QUESTIONS FROM HOSPITAL PERSPECTIVE

- Actual qualification and classification?
- What is the EU regulation framework?
- What are future proof pathways for in-house developed medical software?
- ...



# Prof. Pascal Verdonck

gewoon hoogleraar medische technologie  
biomedische ingenieurswetenschappen

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