POINT OF CARE TESTING AND DIGITAL SOLUTIONS

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DECLARATION OF INTEREST:

NONE FOR THIS PRESENTATION

- Unofficial declaration of interest

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THE WORLD HAS CHANGED

EMERGING TECHNOLOGIES AND HEALTHCARE

ADVANCES IN EMERGING TECHNOLOGIES HAVE COME TO THE RESCUE IN THE FORM OF:

- RAPID DIAGNOSTIC TESTS

- VACCINES USING NANOPARTICLES TO CAGE, STABILIZE AND TRANSPORT RNA MOLECULES

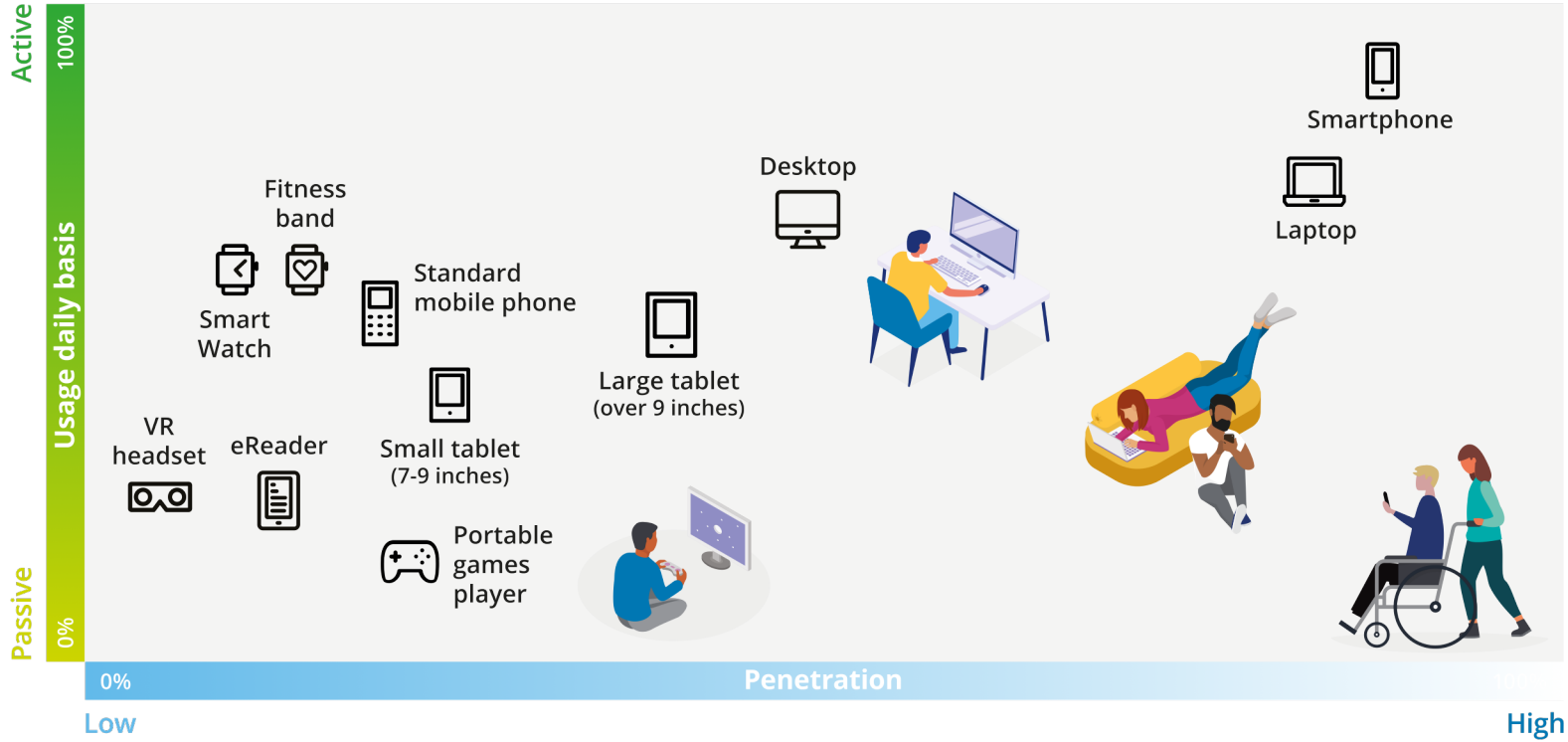
POINT OF CARE

Needs

Availability of devices

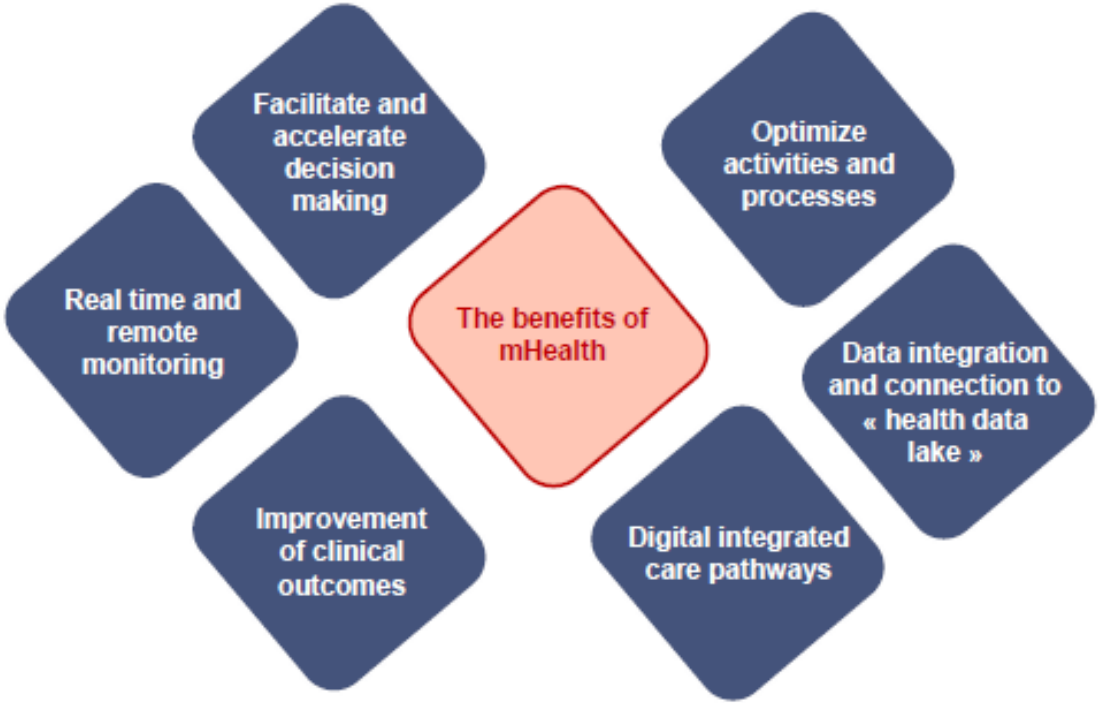
Opportunities

The digital environment

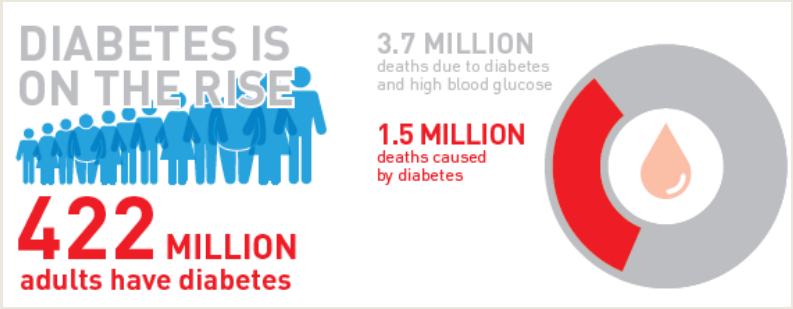


Source: Deloitte

The power of integration

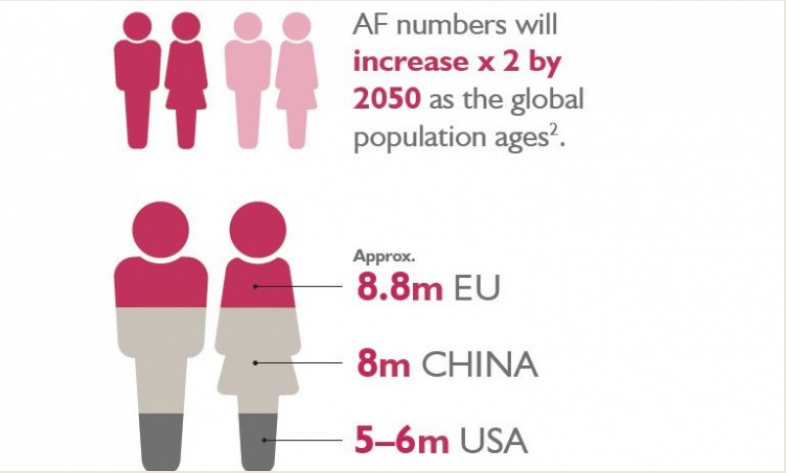


Diabetes

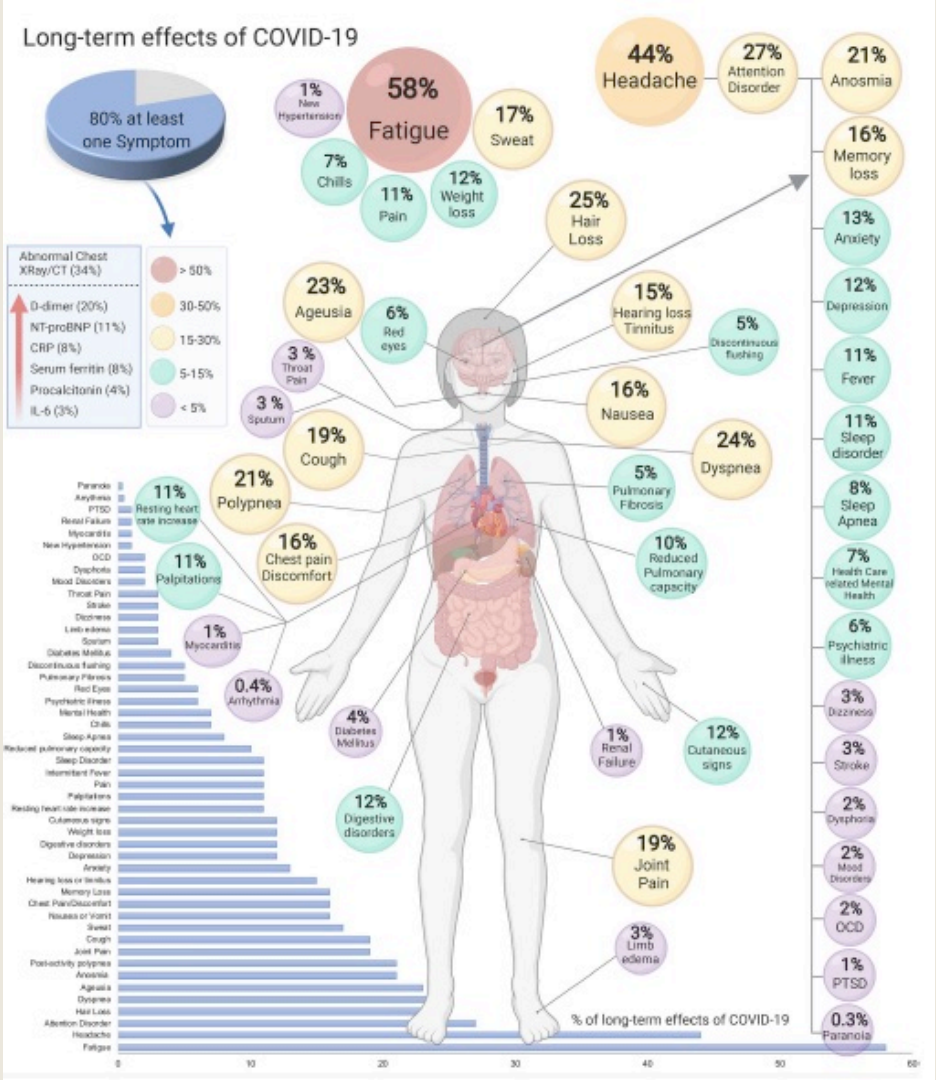


Source: WHO

Atrial fibrillation



https://healthcare-in-europe.com/en/news/atrial-fibrillation-imposes-a-high-burden-in-europe.html



Lopez-Leon et al.; 2021

- Giving users an opportunity to modify health behaviours → In a minority of individuals, this may lead to increasing anxiety about health, to device addiction, or to self-diagnosis or even to selfmedication or self-management of clinical conditions.

- Patients could also suffer from negative consequences of excessive selfmonitoring by finding it uncomfortable, intrusive, and unpleasant

- Wearables may provide false assurances to the patient, with inaccuracy of activity trackers leading individuals to overestimate their level of physical activity, limiting the effectiveness for lifestyle interventions

Jensen et al.; 2021

RELIABILITY AND SAFETY

The value of diagnostics

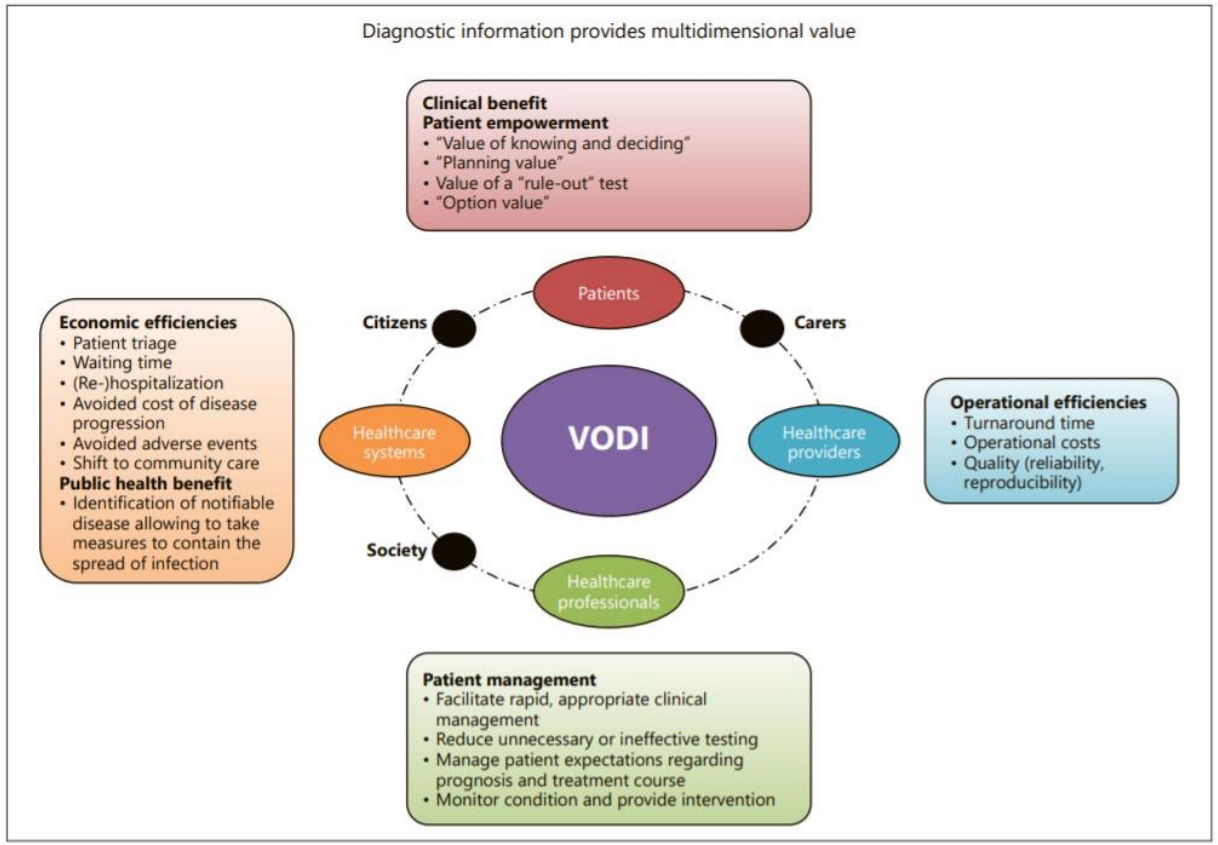


Fig. 1. VODI and its different dimensions.

Wurcel et al.; 2019

The validation framework

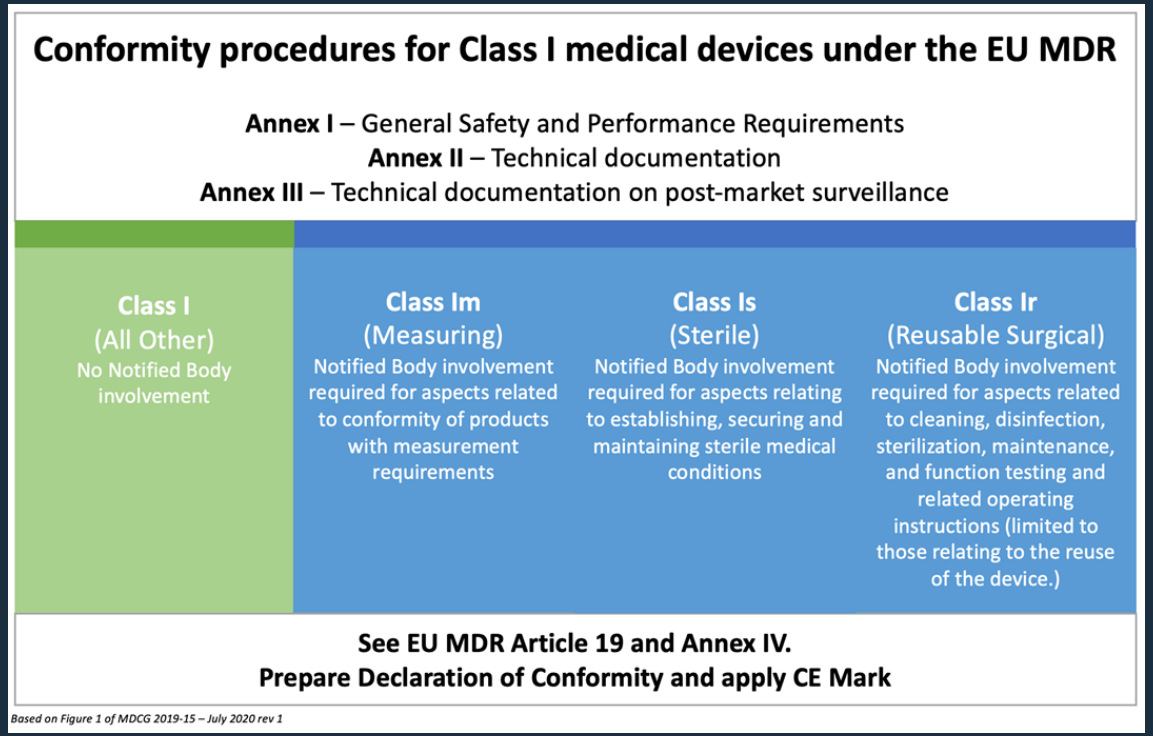
Dimension evaluated	Potential indicators
Clinical performances and clinical outcomes	Sensitivity, specificity, negative predictive value, positive predictive value, length of stay, mean time between readmission to hospital.
Behavioral	Quality-adjusted life year, symptom clusters, patient satisfaction
Technical	Limit of quantification, limit of detection, range of measurement, fault detection systems, connectivity, interoperability, usability
Organizational	Turnaround time of analysis, impact on resources, integration in care pathways
Environmental	Waste and energy consumption, impact on test ordering
Economical	Price, total cost of ownership, time for training, resources needed for implementation and management of solution, cost of management

THE LEGAL DIMENSION

EU MDR

Regulatory bodies do not regulate wearable sensors/devices designed purely for lifestyle purposes, such as smartwatches that generally promote health and fitness.

In contrast, apps with medical purposes (diagnosis, prevention, monitoring, treatment or alleviation of disease) are currently classified as 'medical devices' by both the FDA[73] and the European Union, where the new Medical Device Regulation strengthen the rules for obtaining certification.



https://www.orielstat.com/blog/eu-mdr-class-1-manufacturer-requirements/

EU IVDR

Type of clinical evidence	Definition according to IVDR Article 2	Specification of potentially applicable performances in IVDR Annex I, Section 9.1
Scientific validity	The association of an analyte with a clinical condition or a physiological state	Not applicable
Analytical performance	The ability of a device to correctly detect or measure a particular analyte	Analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limit of detection (LOD), limit of quantitation (LOQ), measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions
Clinical performance	The ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user	Diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations

The safety and benefit of each IVD, taking into account its intended purpose, should be demonstrated by means of evaluation of three types of clinical evidence (if applicable): scientific validity, analytical performance, and clinical performance.

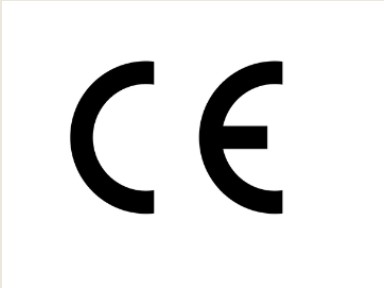
Lubbers, Bart R.; Schilhabel, Anke; Cobbaert, Christa M.; Gonzalez, David; Dombrink, Isabel; Brüggemann, Monika; Bitter, W. Marieke; van Dongen, Jacques J.M.
HemaSphere5(5):e568, May 2021.
doi: 10.1097/HS9.0000000000000568

- analytical sensitivity
- analytical specificity
- trueness (bias)
- precision (repeatability and reproducibility)
- and others

- diagnostic sensitivity
- diagnostic specificity
- positive predictive value, negative predictive value
- Likelihood-ratio
- expected values in normal and affected populations

→ Post-market surveillance

→ Post-market performance follow-up



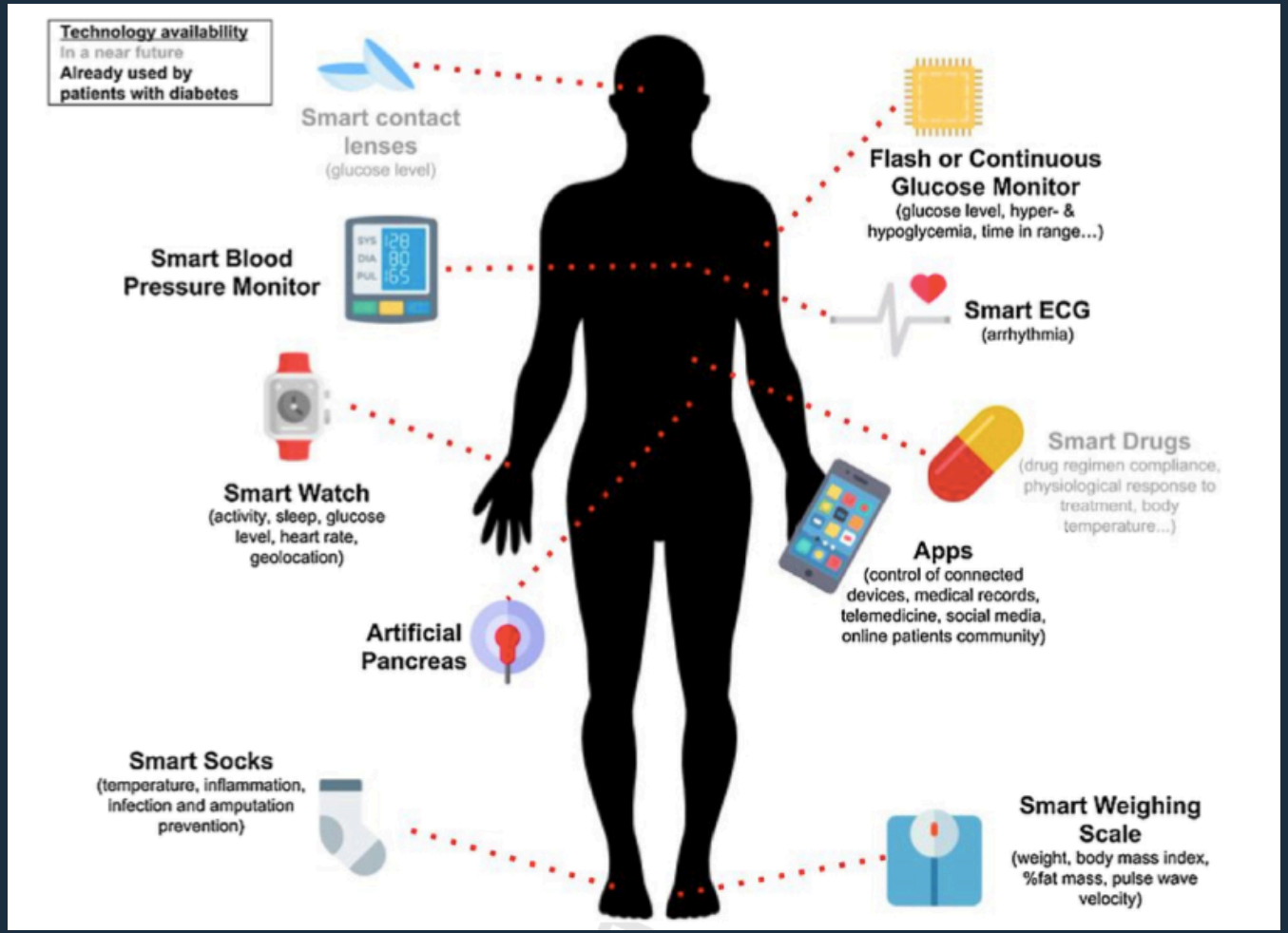
ACTA CLINICA BELGICA
https://doi.org/10.1080/17843286.2020.1868906

Taylor & Francis
Taylor & Francis Group

Organisation and quality monitoring for point-of-care testing (POCT) in Belgium: proposal for an expansion of the legal framework for POCT into primary health care

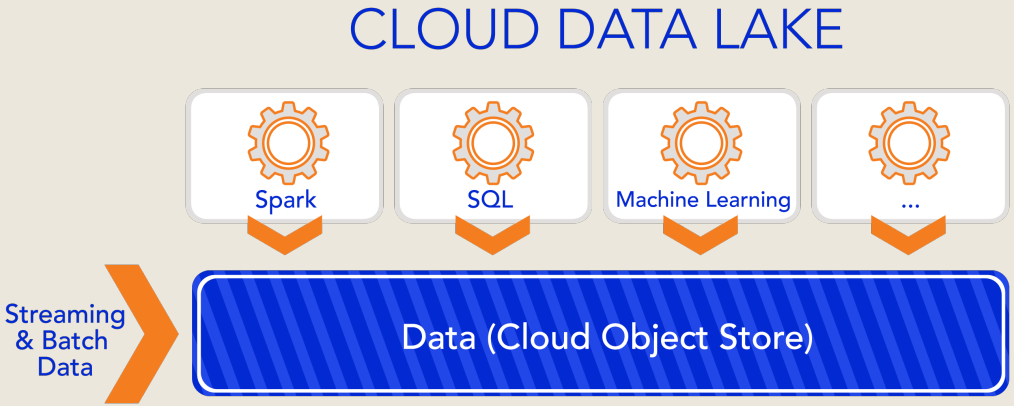
Viviane Van Hoof[a*], Dragos Barglazan[b#], Laurent Blairon[c#], Bob Braekevelt[d#], Regis Debois[e#], Nathalie Véronique J. De Vos[b#], Damien Gruson[f#], Jef Jonckheere[d,g#], Katrien Lanckmans[h#], Marc Moens[i#], Bart Peeters[j#], Joris Penders[k,l#], Alain Roman[m,n#], Lieve Van Hoovels[o#], Florent Vanstapel[p#], Jan Y. Verbakel[q,r#], Ann Verdonck[s#] and Alain G. Verstraete[t#]

DATA AND CONNECTIVITY



Fagherazzi et al. 2018

Expecting benefits from the data lake



INTELLIGENT CONNECTIVITY

The Fusion of 5G, AI and IoT

INTELLIGENTLY CONNECTING EVERYONE AND EVERYTHING TO A BETTER FUTURE

TOMORROW

5G ERA: INTEROPERABLE NETWORKS

5G / 4G / 3G / MOBILE IoT / WIFI / FIXED BROADBAND / SATELLITE

Flexible, reliable, high-speed, low latency, high capacity networks

ARTIFICIAL INTELLIGENCE

COMPUTER IQ: **10,000+**

Smarter platforms for enhanced decision making & automation

INTERNET OF THINGS

25 BILLION CONNECTED DEVICES

Everything will be securely connected enabling rich new products & services

TODAY

4G / 3G / MOBILE IoT

HUMAN GENIUS IQ: **140+**

9 BILLION CONNECTED DEVICES

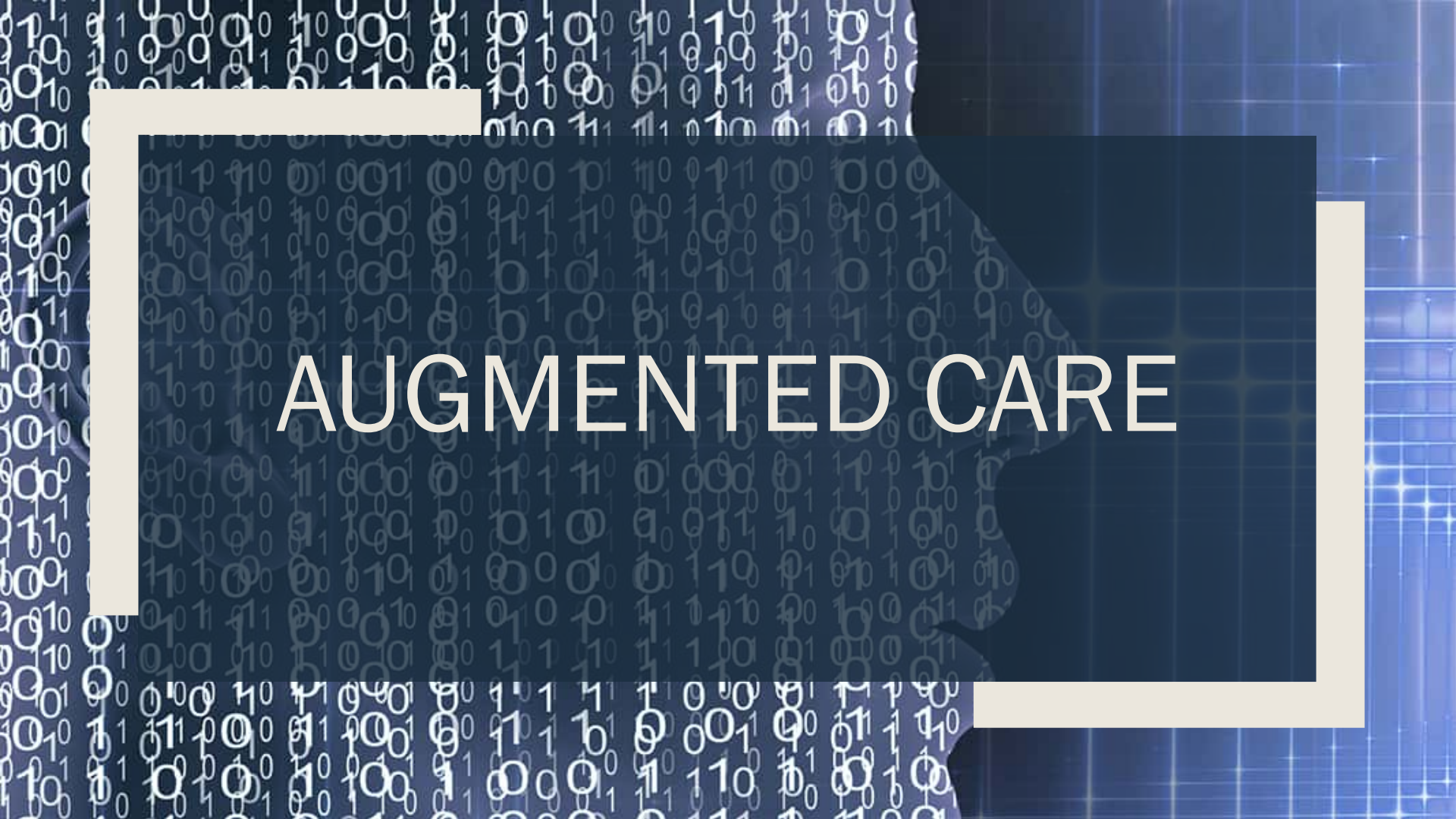
Sources: GSMA Intelligence, 2018 | Science Trends, 2018 | Softbank, 2017

Security and privacy

- Include user-informed consent and privacy/policy information
- Carry out user authentication in a continuous manner to guarantee an allowed use of the device while protecting authentication data.
- Explore a combination of biometric features with privacy-preserving approaches.
- Introduce risk assessments protocols and audits of the security system
- Combine multiple private blockchains to provide users with stronger location privacy protection without reducing the quality of service


18:33
74%
The Pegasus Project

Security:	**Guarantee of secure storage, secure communication and secure content**
Identity Management:	Ensure authentication for users, devices, applications and associated services
Privacy:	Maintain privacy
Scalability:	Capacity of evolution to sustainable and scalable solutions
Reliability:	Solutions should support identification of fault and self-repairing
Data integration:	Real-time data collection, analytics, aggregation and transmission


AUGMENTED CARE

HOW EMERGING TECHNOLOGIES CAN CREATE A MORE EQUITABLE WORLD

‘Equity’ and Global Health

- Incorporate ethical, environmental, economic, legal, social and cultural considerations

Lack of equity

- For example, the COVID- 19 nanovaccines require storage at very low temperatures

- Consider that developing countries could pay exorbitant fees for the use of emerging technologies created and patented in the industrialized world

- Most patents related to emerging technologies focus on medical conditions common in rich countries at the expense of neglected diseases prevalent in LMICs,

Fabio Salamanca-Buentello and Abdallah S. Daar, 2021

« THE WIDE RANGE OF NANOMEDICAL APPLICATIONS FOR GLOBAL HEALTH CAN IMPACT NEARLY EVERY MEDICAL SPECIALTY AND CAN IMPROVE THE QUALITY OF LIFE OF PEOPLE, EXTENDING LIFE EXPECTANCIES, AND REDUCING OVERALL COSTS OF HEALTHCARE »

Fabio Salamanca-Buentello and Abdallah S. Daar ; 2021

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THANK YOU

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