

25th May 2022

Life Science Webinar



DANSK
ERHVERV



Agenda

- 10.00-10.20** **Welcome and presentation of the European standardization strategy 2025**
Jeanett Fleron, Senior Consultant and Maibritt Agger, Head of department Danish Standards
- 10.20-10.40** **Why is standardization important for business and the life science industry?**
Michael Bremerskov Jensen, Functional Manager International Trade, Danish Chamber of Commerce
- 10.40-10.55** **Questions and debate**
- 10.55-11.15** **The importance of standardization for future use of diagnostics and personalized medicine**
Ulf Bech Christensen, Founder and CEO, PentaBase
- 11.15-11.20** **Short break**
- 11.20-11.40** **Standardization and innovation are prerequisites for each other**
Martin Vesterby, MD Ph.d. of Health Tech Adopter Partner, Health Tech Hub Cph.
- 11.40-12.00** **From research to practice to standardization**
Serkawt Kholá, Ph.d., CEO & Founder EvoPlexus Medics, member of S-273 Health informatics and ISO/TC 215 Health informatics
- 12.00-12.20** **Why innovation and investment in evidence-based standards are crucial for trade in the future**
Gitte Petersen, CEO & co-founder, Genomic Expression (online from USA)
- 12.20-12.50** **Panel debate and questions**
By all presenters and the chair of the DS committee, Health informatics, Frederik Endsleff, Elisabeth Erhardtson, (DVM, mBA), Senior RA Specialist, Regulatory Affairs Solutions i KLIFO A/S, representing Dansk Biotek
- 12.50-13.00** **Conclusion and next steps**
Jeanett Fleron, Senior Consultant, Danish Standards.

Welcome and presentation of the European standardization strategy 2025

Jeanett Fleron, Senior Consultant and
Maibritt Agger, Head of department
Danish Standards

About Danish Standards

What is Danish Standards?

- Denmark's official standardization organization
- Commercial foundation, founded in 1926
- 182 employees
- Corporate partnership with the Danish Ministry of Business Affairs

We are a member of:



A strong platform of solid brands:



Basic premises of Danish Standards

1. Danish Standards operates for the benefit of society

Non-profit commercial foundation, co-financed by performance contracts.

2. Danish Standards is Denmark's representative in the international organizations

- International Organization for Standardization (ISO/IEC)
- European Committee for Standardization (CEN/CENELEC)
- European Telecommunications Standards Institute (ETSI)
- Nordic and European ecolabels.

3. Danish Standards is market-driven

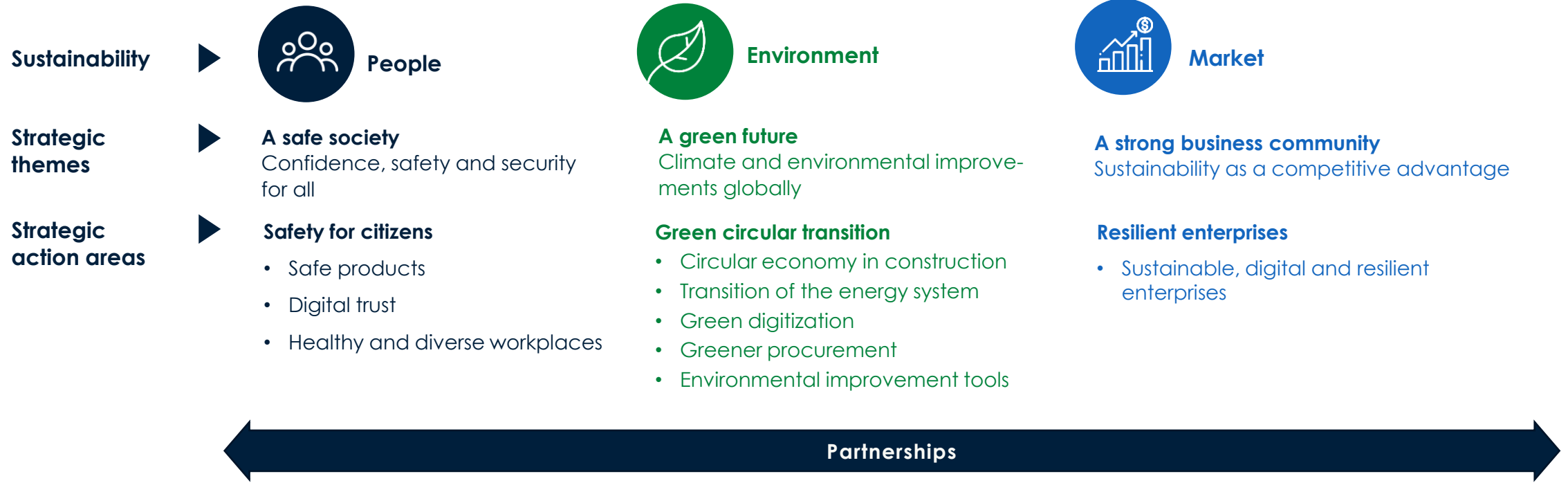
Many services are provided on regular commercial terms, with focus on customers' needs.



Vision Danish Standards wants to be a driving force of sustainable development

Ambition Our ambition is to contribute to a sustainable and safe society and business community for people, the environment and the market

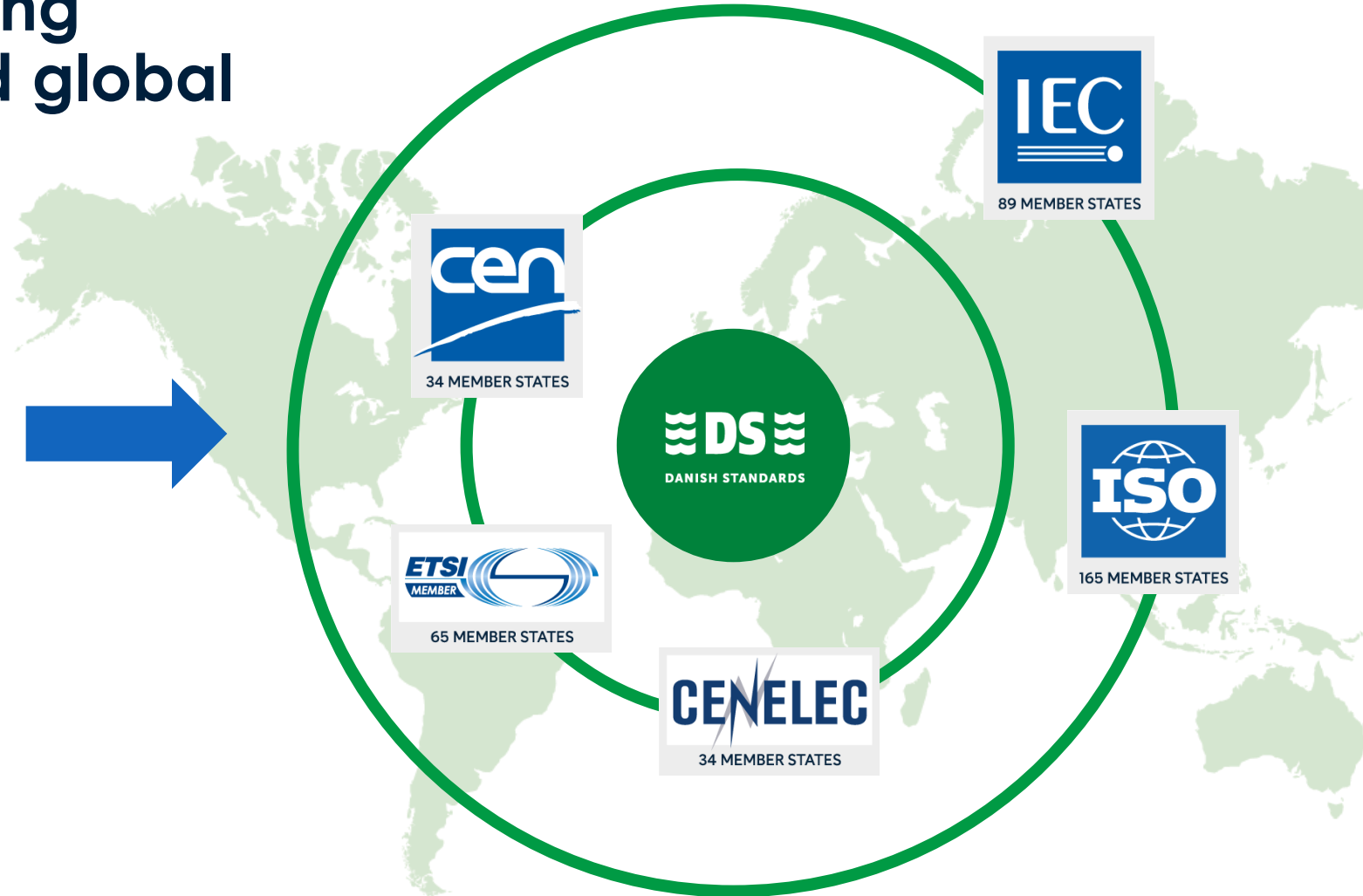
Strategic action areas



Danish Standards – a strong player in a European and global standardisation network

Everyone can make an impact:

Industries, authorities, NGOs, research and education provide input to the work of Danish Standards and participate in our standardization committees.



EU's Standardization Strategy

- Covid-19 vaccines and medicines production
- Medical devices and in vitro diagnostic medical devices
- Safety and trustworthy artificial intelligence systems

Highlights from the EU Standardization Strategy



Geopolitics of standardization

- More assertiveness by trading partners, pursue geopolitical ambitions at EU/international level (cf. Chinese standardization strategy)
- Increased complexity and need for resources
- Not only about technicalities, also about democratic values



Good Governance

- Systems will have to deliver on implementation key in EU policies – incl. an human approach to AI, cyber-resilience, defense, green technologies – and requirements to EU guidance
- Cybersecurity and tele communication



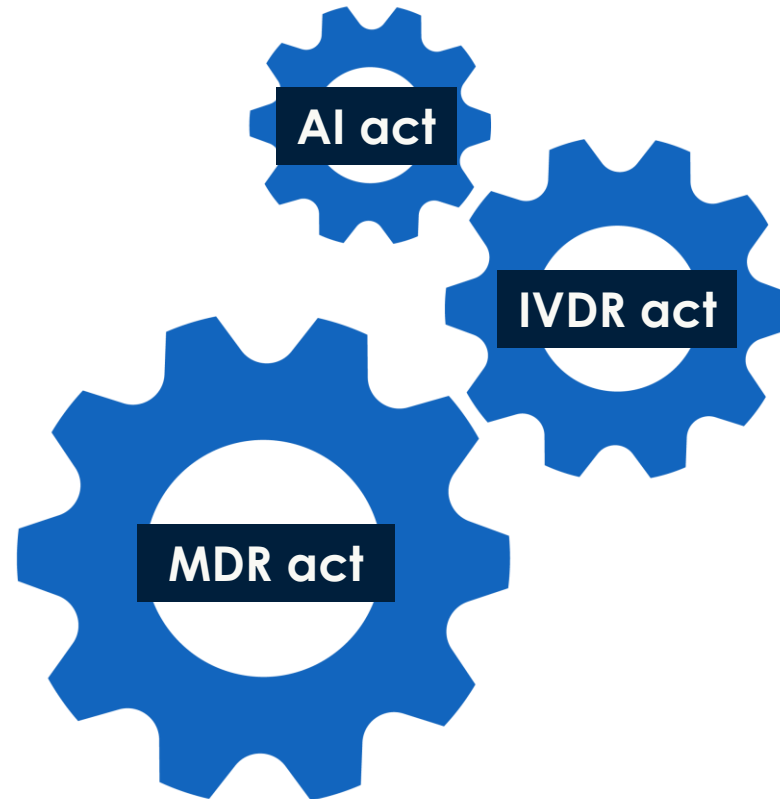
Priority setting and speed

- We need to steer the system better to deliver on our priorities; Today scattered activities and industry-driven
- Systems are not plugged into the research and innovators community, no anticipation and prioritization or sense of urgency
- Risk for Twin transition and resilience

Legislation on the strategies related to standardization in the healthcare area

Strategies:

- EU European Standardization Strategy
- CEN & CENELEC's Advisory Board for Healthcare Standards' strategy: *Mobile applications, Cybersecurity, AI, Biotechnologies and others new technologies*

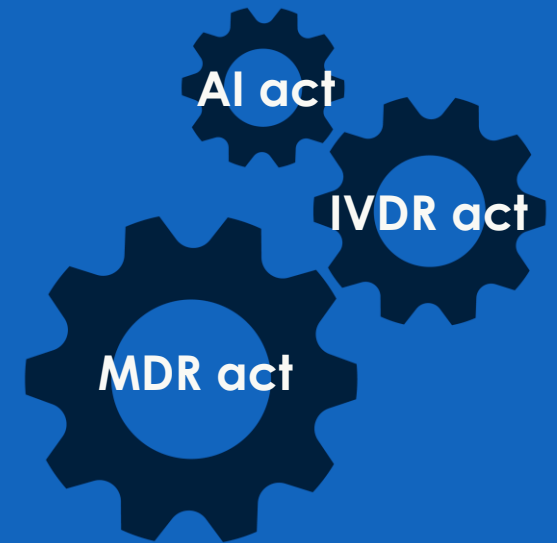


Legislation and soft law:

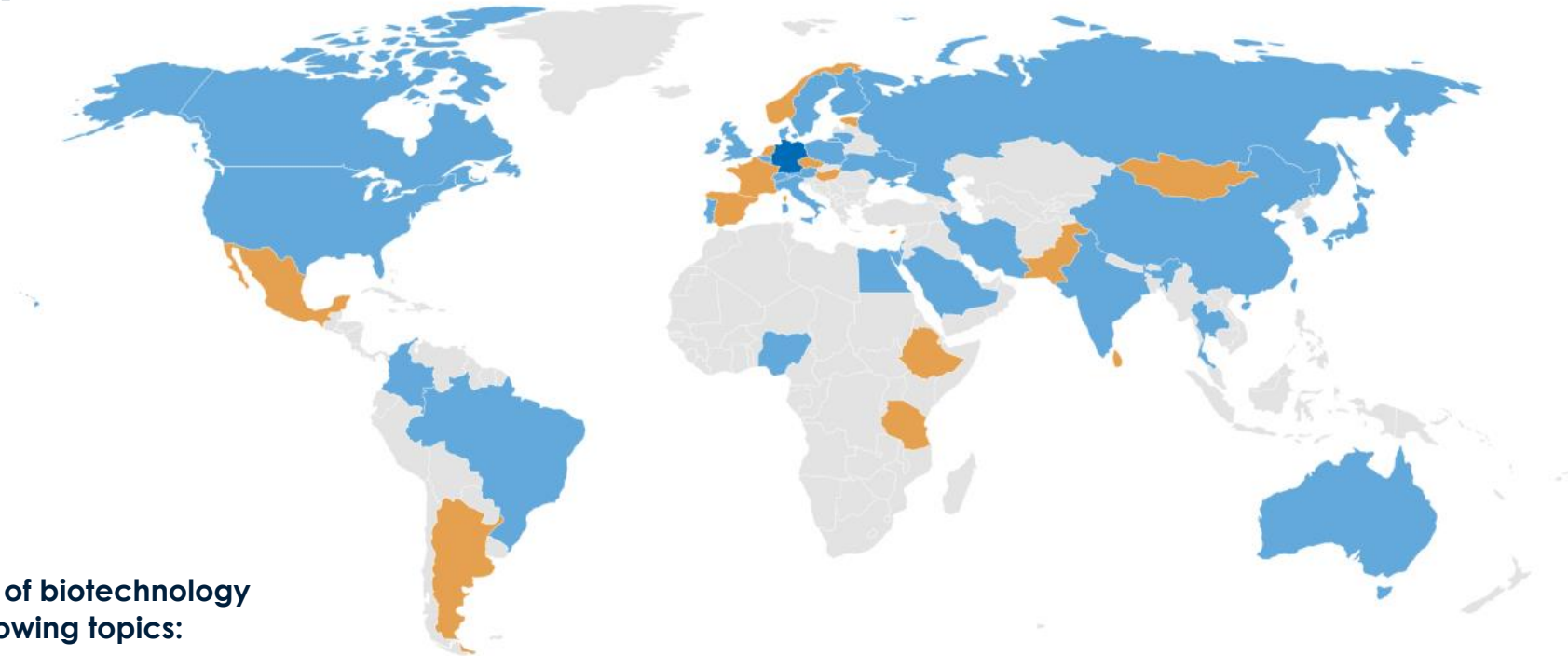
- European Data Health Space (EDHS) a proposal for the new legislation has just been published
- MDCG Guidance (Medical Devices Coordination Group)
- IMDRF (International Medical Devices Regulators Forum)

**Harmonized standards
will manage the market
of the future...!**

If you are not around
the table – You will
find yourself at the
menu...!



Biotechnology



Standardization in the field of biotechnology processes includes the following topics:

WG 1: Terms and definitions: working for harmonized standards for biomarker, biomaterial, biological material, cell, personalized medicine, regenerative medicine, medicine, synthetic biology

WG 2: Biobanks and bioresources 

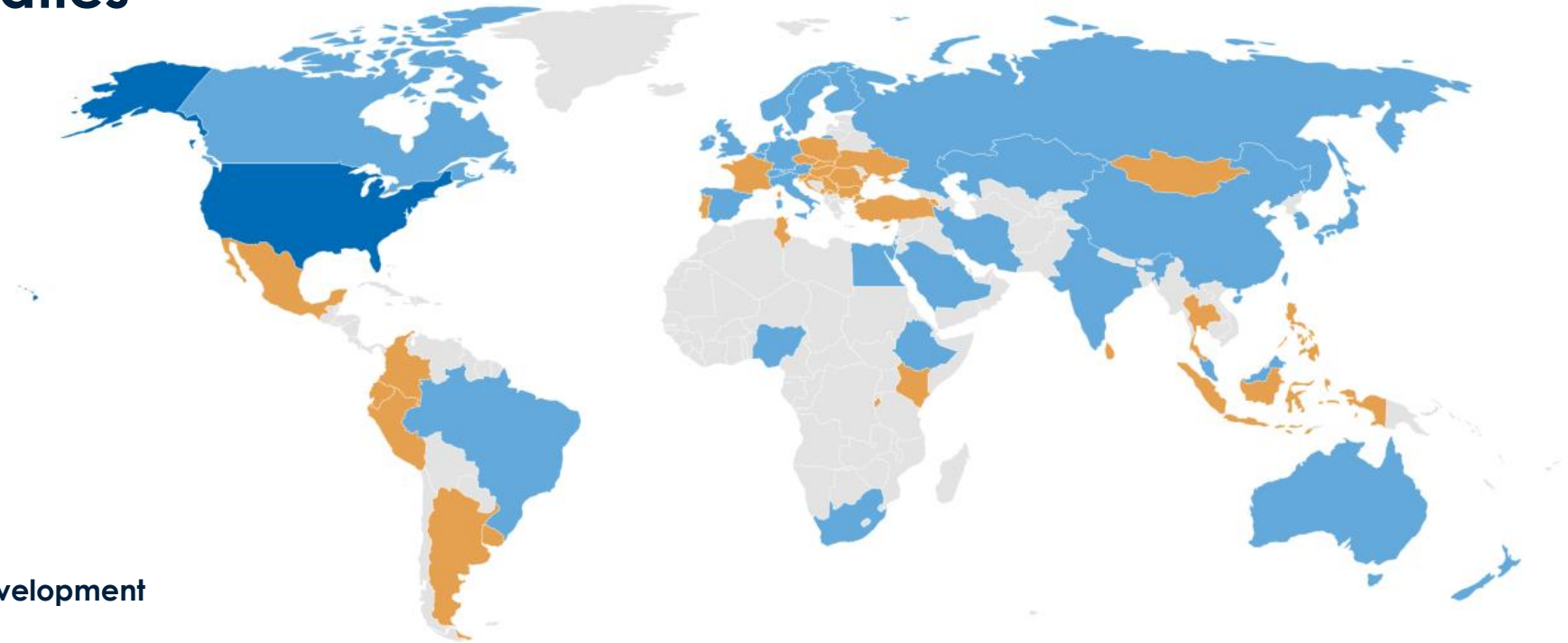
WG 3: Analytical methods, including personalized medicine & diagnostic

WG 4: Bioprocessing

WG 5: Data processing including annotation, analysis, validation, comparability and integration

WG 6: Metrology.

Health Informatics



67 ISO standards under development

SC 1: Genomic Informatics

AGH 4: Standards and conformance

AGH 5: Safe, effective & Secure Digital Therapeutics

AGH 6: Content of risk and associated terms

CAG 1: Executive council, harmonization & operations

CAG 2: Advisory group

JWG 1: Traditional Chinese Medicine (Informatics – TC 249)

JWG 7: Safe, effective & secure health software and health IT systems, including those incorporating medical devices (IEC 62A)

TF 1: Task Force on Quantities and Units to be used in e-health

TF 5: AI technologies in health informatics

WG 1: Architecture, Framework and Models

WG 2: Systems and Device interoperability

WG 3: Semantic content

WG 4: Security, Safety & privacy

WG 6: Pharmacy and medicine business

WG 10: Traditional medicine

WG 11: Personalized digital health

Action point 1

Anticipate, prioritize and address standardization needs in strategic areas

- We need standards faster and in tune with the European **innovation and policy** agenda.
- The Commission has identified standardization urgencies as regards COVID-19 vaccine and medicine production, chips certification and data standards.
- As of this year, standardization priorities will be clearly identified in the 2022 annual Union Work Programme for European standardization.
- A High-level Forum will be set up to inform future standardization priorities.
- The Commission will establish the function of a Chief Standardization Officer to ensure high-level guidance across the Commission on standardization activities, which will be supported by an EU excellence hub on standards composed of Commission services.



Action point 2

Improve the governance and integrity of the European standardization system

- European standards, which support EU policy and legislation, must be decided by European players. The Commission is proposing an amendment to the **Regulation on standardization** to improve the governance in the European standardization system.
- The Commission will further pay close attention to the **inclusiveness of the system, and the role of SMEs and civil society**. At the same time, the Commission will launch the evaluation of the Regulation on standardization.



Action point 3

Enhance European leadership in global standards

- The Commission will work through the High-Level Forum to set up a new mechanism with EU Member States and national standardization bodies to share information, coordinate and strengthen the European approach to **international standardization**.
- The Commission will also pursue more coordination between EU Member States and like-minded partners. The EU will fund standardization projects in African and the Neighbourhood countries.



Action point 4

Support innovation

- The Commission is proposing to better tap into the potential of EU-funded research to valorise **innovation projects** through standardization activities and **anticipate early standardization needs**.
- A 'standardization booster' to support researchers under Horizon 2020 and Horizon Europe to test the relevance of their results for standardization, will be launched.
- The development of a Code of Practice for researchers on standardization will be initiated to strengthen the link between standardization and research/innovation through the European Research Area (ERA), by mid-2022.



Action point 5

Enable the next generation of standardization experts

- Standards rely on the best experts and Europe is facing a generation shift. The Commission will promote more academic awareness of standards through the future organization of EU University Days and the training of researchers.





The 2022 annual EU work program for European Standardization related to Life Science

Standardization urgencies set by the Communication on the EU standardization strategy:

- COVID-19 Vaccines and medicines production
- Medical devices & in vitro diagnostic medical devices
- Safe and trustworthy artificial intelligence systems

Why is standardization important for business and the life science industry?

Michael Bremerskov Jensen
Functional Manager International Trade
Danish Chamber of Commerce

Questions and debate

The importance of standardization for future use of diagnostics and personalized medicine

Ulf Bech Christensen
Founder and CEO
PentaBase



PentaBase
- Setting new standards in diagnostics

Introduction to PentaBase



Background

- PentaBase is a Danish, science-driven company built on unique DNA technologies, creating innovative workflows and PCR analyses
- We are enabling personalized treatment using sensitive, specific and robust monitoring of genetic biomarkers



Focus

- Leading provider of COVID-19 PCR in DK
- 80+ assays for somatic mutations in cancers
- Novel workflows for MSI and epigenetic
- Unique oligonucleotide technologies



Company information

- Founded in 2006
- Head office in Odense, Denmark
- 7 laboratories in DK and 120+ employees

Introduction to PentaBase



Mission

- As a science-driven company with a unique DNA platform, PentaBase will provide customers with robust and precise genetic analyses and services.



Vision

- Every patient is unique and deserves to be individually treated.
- Our vision is to create a healthier society by personalised detection, prevention and treatment of diseases based on precise and timely genetic diagnostics.



Values

- Accountability
- Adaptive
- Caring
- Scientific excellence



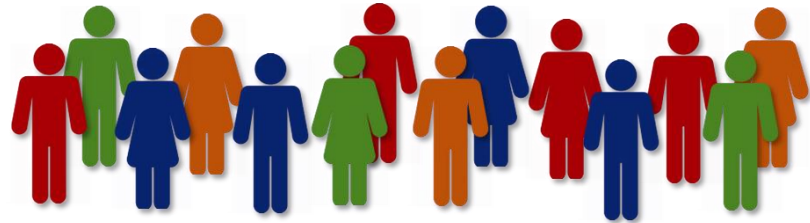
Inventors of Intercalating Nucleic Acid - INA[®]

INA[®] oligo nucleotides have higher sensitivity, specificity and affinity towards their natural DNA targets

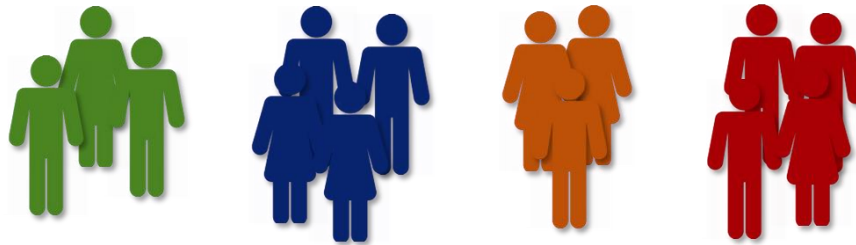
INA[®] is the only DNA platform technology that work by increasing the stacking effect

Personalized medicine

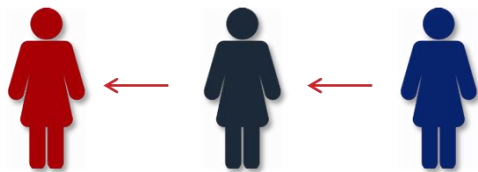
One-size fits-all medicine



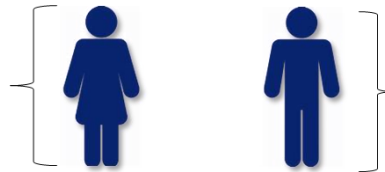
Stratified medicine



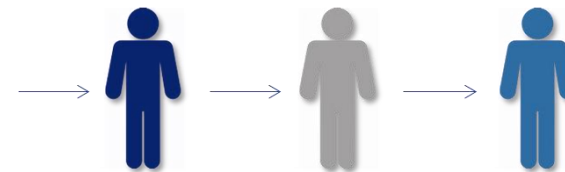
Personalized medicine



Precision medicine



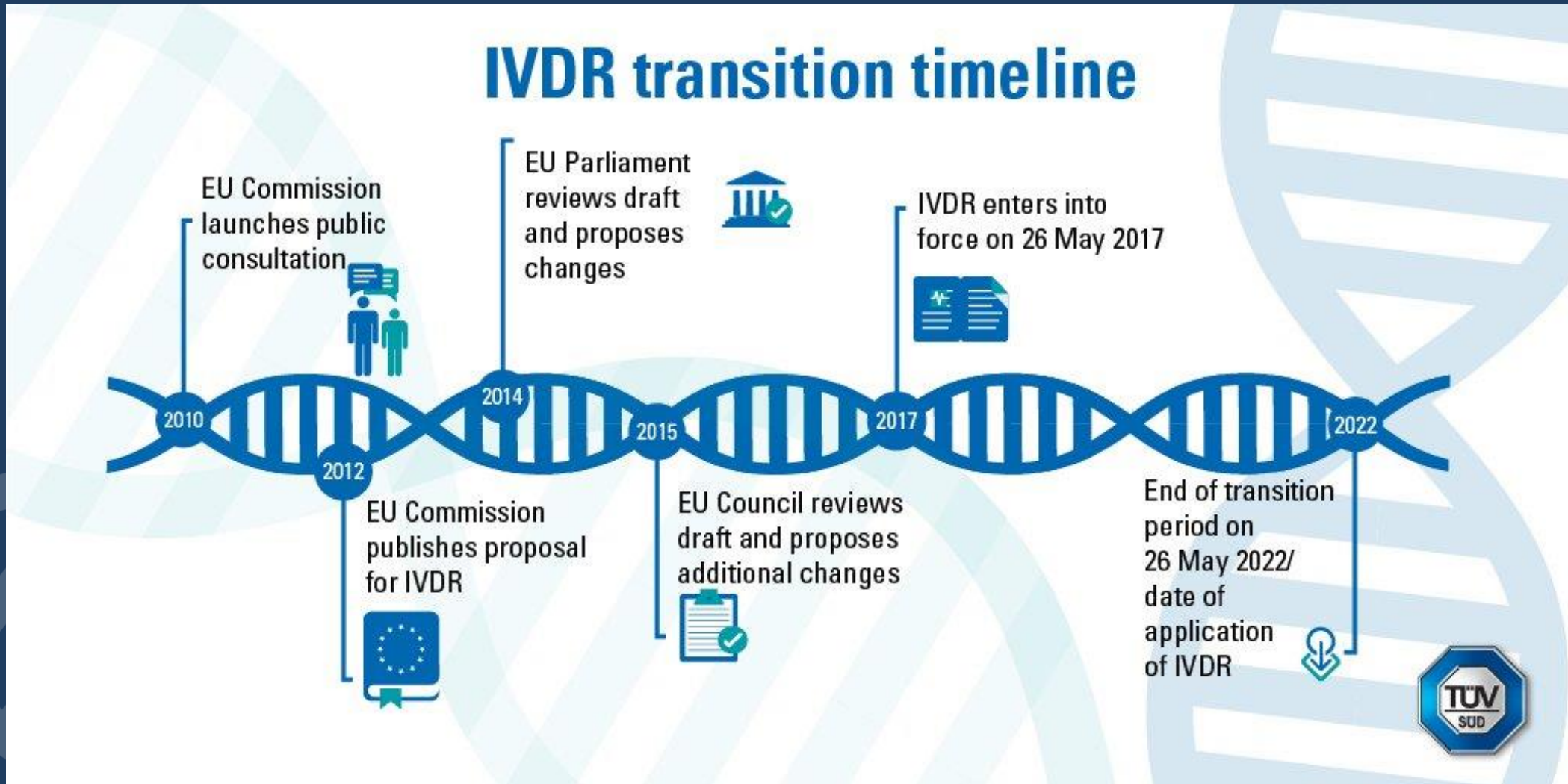
Personalized medicine





PentaBase
- Setting new standards in diagnostics

Last day of the old EU standard



Standards should be for the benefit of the patient



Scientist-to-Scientist

NGS data - Scientific exploration

Doctor-to-doctor

Patient data - changing hospitals

General practitioner to hospitals and municipalities

Patient-to-X

My data to second opinion

My data to private alternative

My data to own research

Standards should be minimum promises to patients on issues that matters for the patient

Standards should not be seen as instruments to reduce competition nor innovation

Importance of diagnostics

The right diagnosis at the right time is the most important factor to ensure the foundation for the best possible treatment.



PentaBase
Creating a healthier society

TOUR de France
GRAND DÉPART
COPENHAGUE
DANEMARK 2022



PentaBase

OFFICIAL FAN



You can't prepare every detail, but prepare how to act on every detail

PentaBase wants to replace cancer packages with person promises

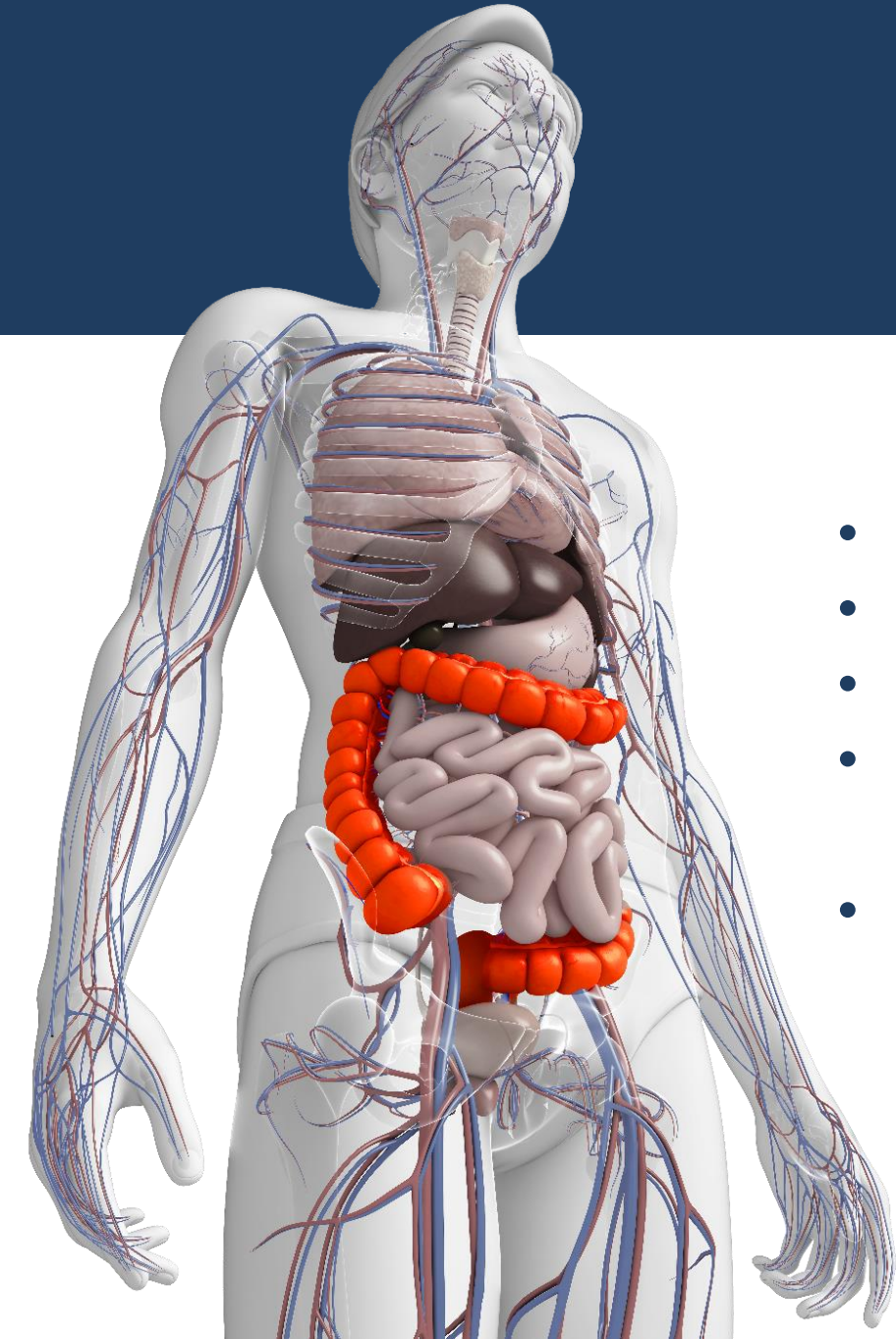


A case study

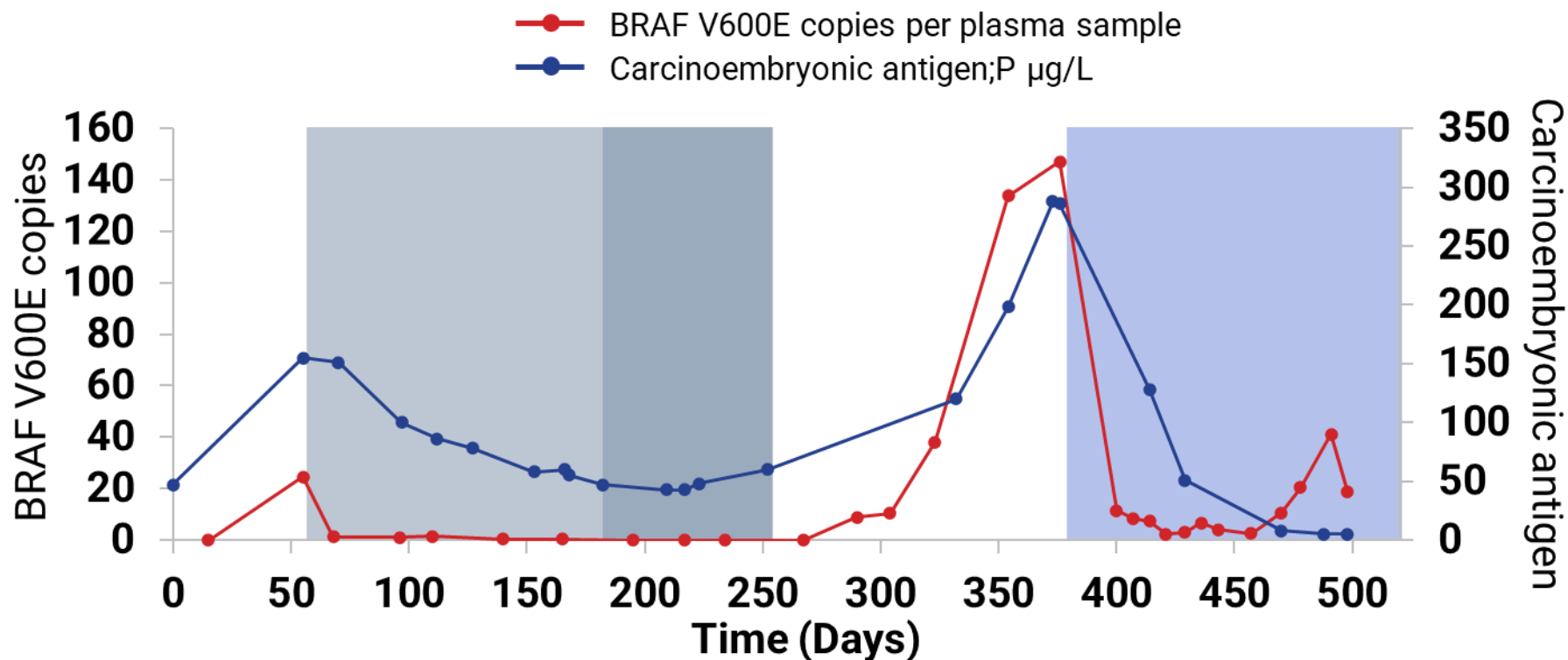
**Colorectal cancer case study
using SensiScreen[®] BRAF Liquid**

The patient

- **Male, Caucasian**
- **+60 years old**
- **Diagnosed with metastatic colorectal cancer in 2016**
- **Conventional treatment from week 7**
 - **End of first treatment regime at week 34**
- **Entered Array BioPharma clinical trial NCT02928224**
 - **Received Encorafenib, binimetinib, and cetuximab**



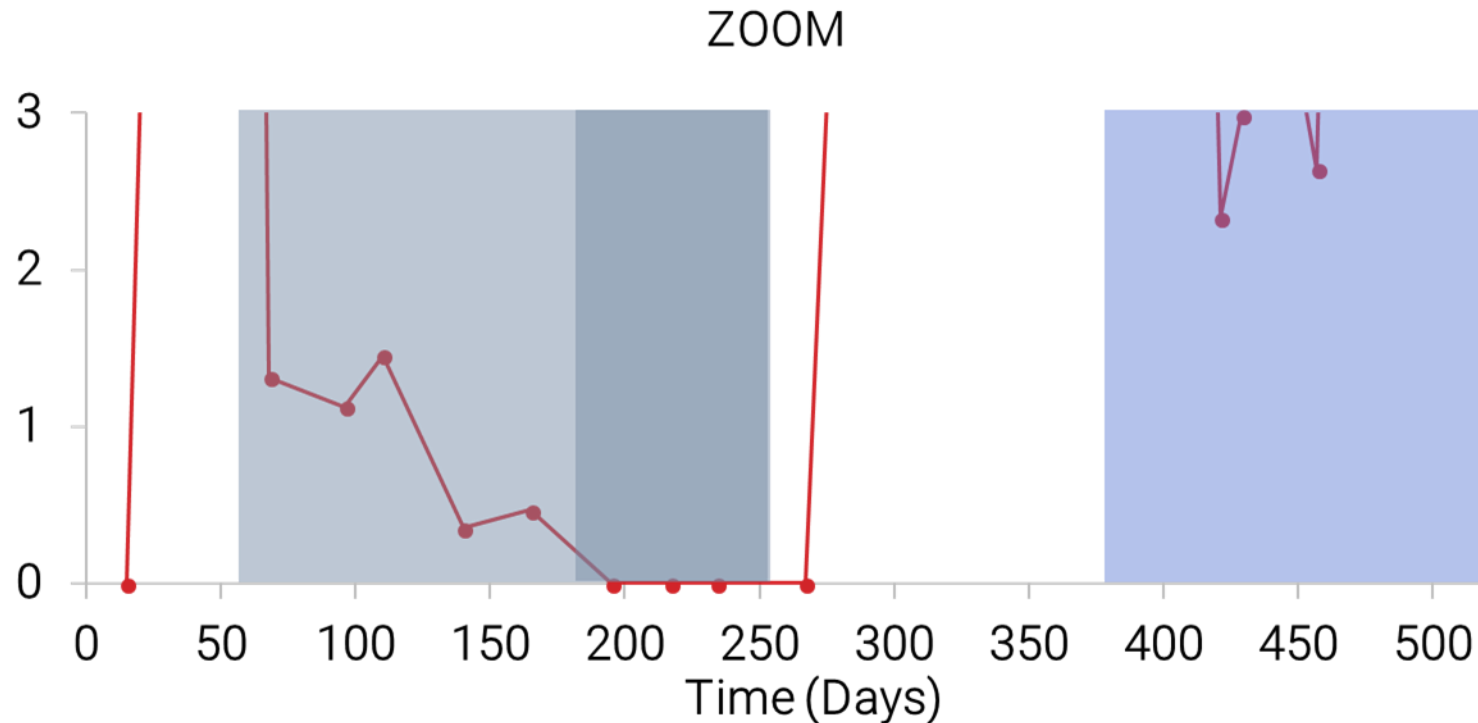
Monitoring of BRAF V600E in Liquid Biopsies



- Chemotherapy
- Targeted therapy

* Determined by SensiScreen® Liquid assay reference in approx. 200 µl plasma

Monitoring of BRAF V600E in Liquid Biopsies

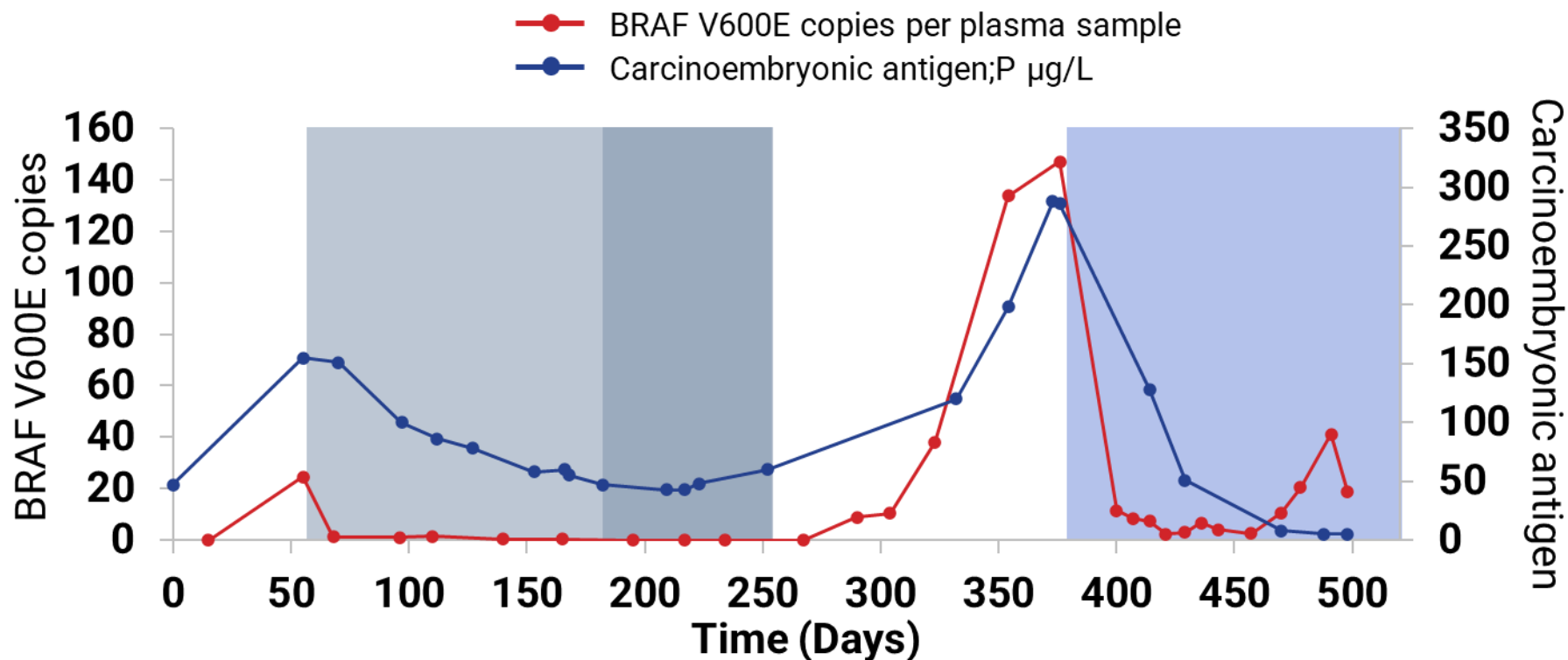


■ Chemotherapy

■ Targeted therapy

* Determined by SensiScreen® Liquid assay reference in approx. 200 µl plasma

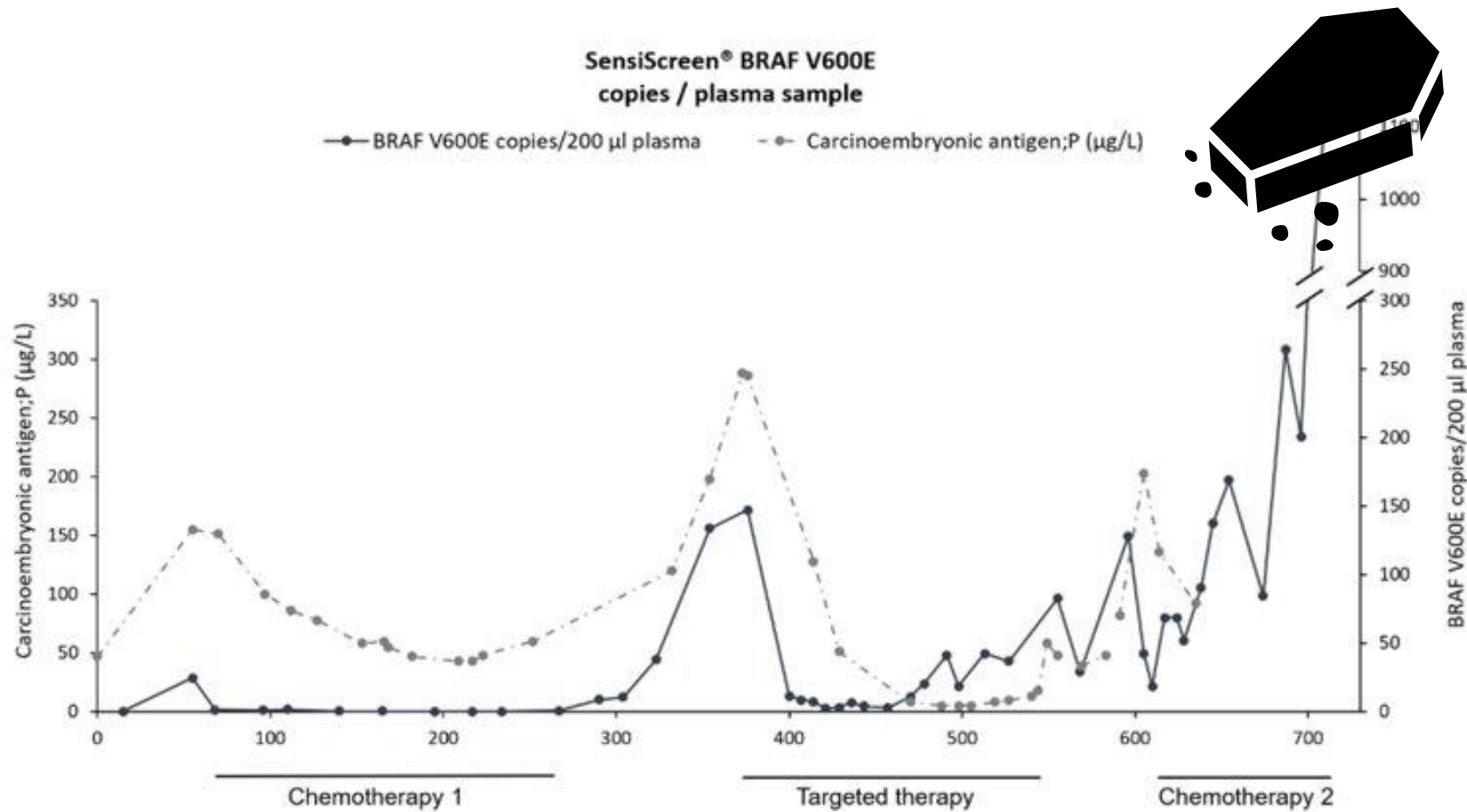
Monitoring of BRAF V600E in Liquid Biopsies



- Chemotherapy
- Targeted therapy

* Determined by SensiScreen® Liquid assay reference in approx. 200 µl plasma

Monitoring of BRAF V600E in Liquid Biopsies



Standards are called for when quality is low – but exceptions are available for some

Corona learnings

- **Governments did set their own substandard performance rules**
- **The standards changed constantly - influenced by politics**
- **Rather stick to a bad standard than admit mistakes**

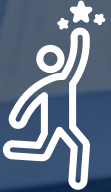
IVDR – New improved standard from tomorrow

- **Hospitals are exempted from following the same rules**
- **Class D products must be validated by reference lab – there are zero**

Summary



Patients should be in focus when making standards



Standards should support improvements and innovation



Standards should be based on science



Standards should be easily understandable and apply for all



Let's create the basis for lovable standards

The standardization dilemma
Sometimes the highest standard is to treat
people differently

PentaBase
- Setting new standards in diagnostics

Short break

Standardization and innovation are prerequisites for each other

Martin Vesterby
MD Ph.d. of Health Tech Adopter Partner
Health Tech Hub Copenhagen



**Standardization
and innovation
are prerequisites
for each other**

Or?



MAKING HEALTH TECH EVERYONE'S BUSINESS

HEALTH TECH HUB
COPENHAGEN



The Power of Collective GROWTH



1

Launch pad

For start-ups

Sustainable scaling in the Danish and global markets.

For large organizations

Launch and facilitation of internal innovation teams. Access to the global Health Tech ecosystem.

2

Catalyzer

Breaking silos

The entire system and every stakeholder in one place.

Global ecosystem access

Partnerships with global hubs enhance international mobility and start-up support.

3

Landing pad

Access to the Danish healthcare stakeholders through the hub and support on entry into Denmark as portal to the Nordic healthcare market.



MEET OUR PARTNERS

CORE PARTNERS

INDUSTRIENS FOND



Confederation of Danish Industry

netcompany



HEALTHCARE PARTNERS



INTERNATIONAL PARTNERS



ECOSYSTEM PARTNERS



TECH PARTNERS





MEET OUR PEOPLE



Jesper Grønbæk
CEO & Founder

- Team responsible
- Strategy & reporting
- Stakeholder management & lobbyist
- Fund investigation



Valentin Bejan
CIO & Co-Founder

- Adoption & collaborations
- Hub strategy & Startup acceleration
- International activities (startups, other hubs, internationalisation)



Martin Vesterby,
Ph.D
Health Tech adoption
partner

- Adoption and collaborations
- Scaling of adopted solutions
- 'Account' management



Line Rasmussen
Project coordinator

- Administration
- Project coordination
- Day-to-day tasks in the Hub



Anett Falussy
Head of Comms &
Events

- Communications
- Global & ecosystem events
- Partner events



Golda Fania
Community manager

- Community engagement
- Internal events
- Social



Felix Frahm
Business analyst

- Business tools
- Analysis
- Internationalisation



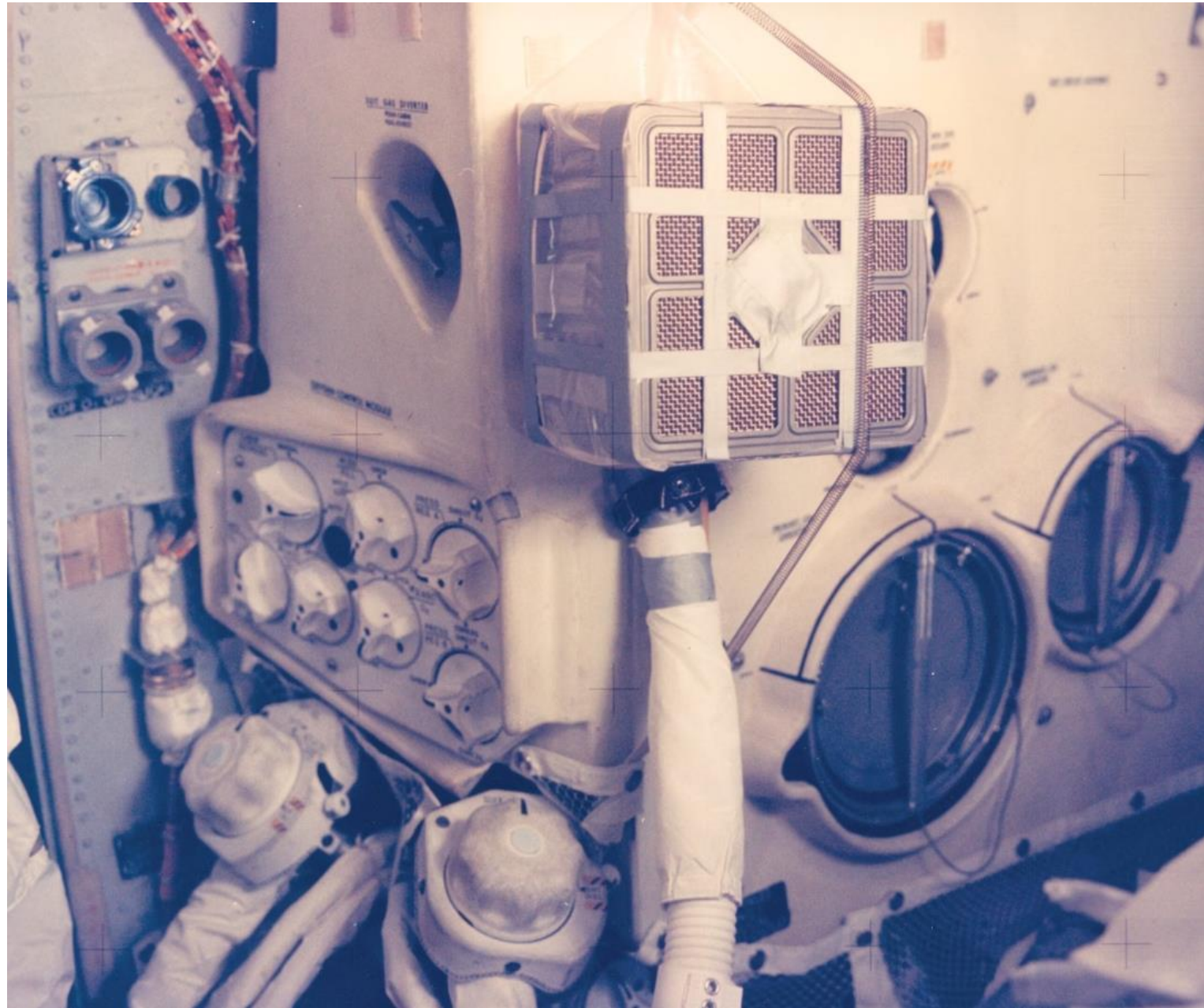
Cecilia Price
Student assistant

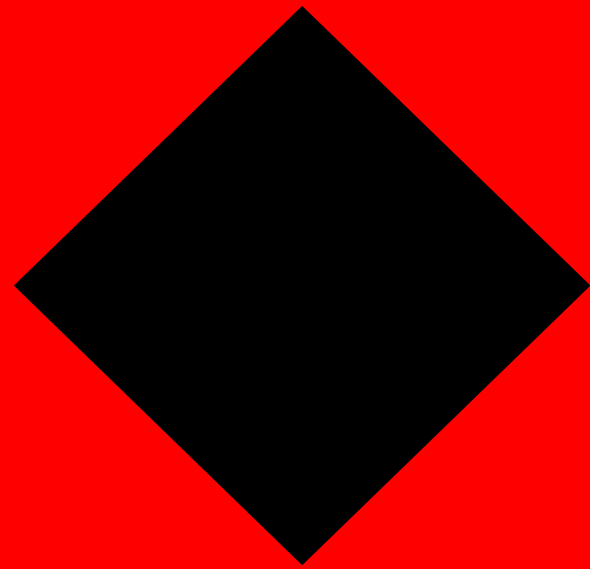
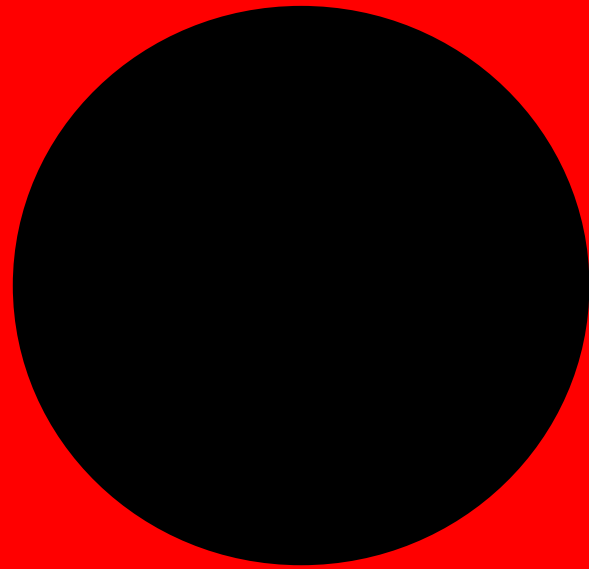
- Business tools
- Mentor network
- Internationalisation



Jannik Zeuthen
Partner Development
Manager

- Driving activities with partners
- Recruitment of partners
- Adding value to our members

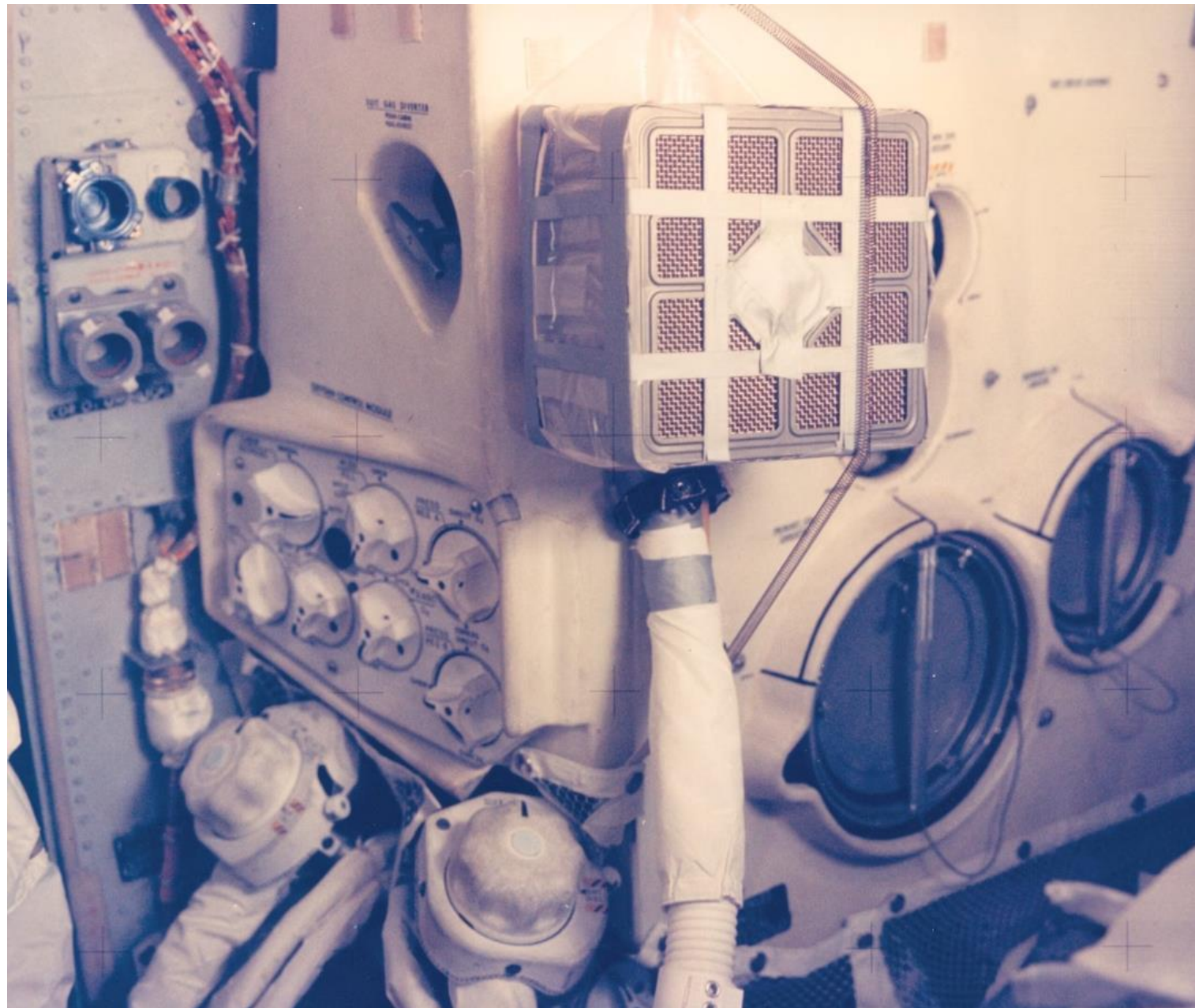






\$257 billion

when adjusted for inflation
to 2020 dollars





Standards

might have a
branding issue?
In the world of
entrepreneurship



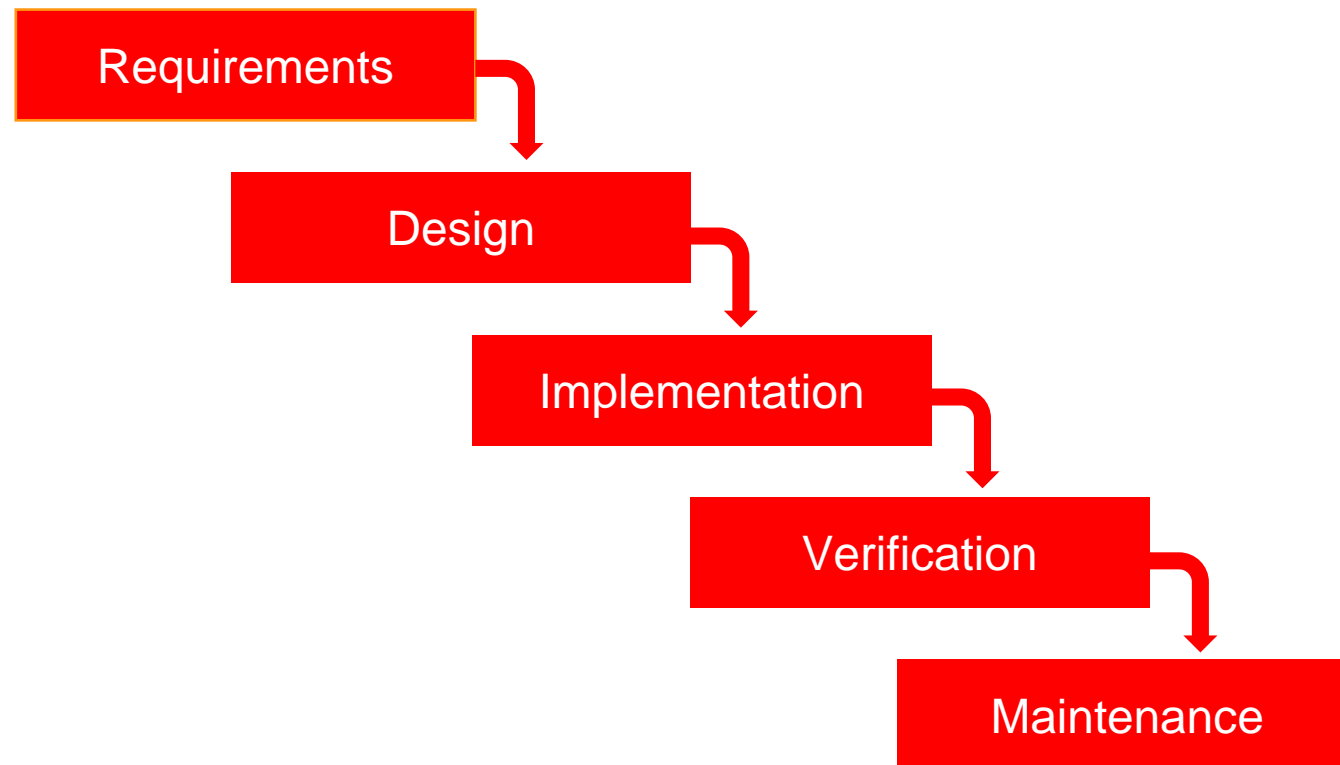


**Assumption is the
mother of all
f***ups**

**Standardization
vs Innovation**



Agile development came as a counter-reaction to the sequential development process called "The Waterfall Model" developed by Winston Royce in the 70s.





A Cry for more Creativity

“The worlds private and public sector leaders believe that rapid escalation of complexity is the biggest challenge confronting them. They expect it to continue, indeed to accelerate in the coming years.”

Capitalizing on Complexity, IBM 2010



The definition of Agile Development:

-a set of principles for development under which requirements and solutions evolve through the collaborative effort of self-organizing cross-functional teams. It advocates adaptive planning, evolutionary development, early delivery, and continuous improvement, and it encourages rapid and flexible response to change.

These principles support the definition and continuing evolution of many development methods.



Manifesto for Agile Software Development:

- 1. Individuals and interactions** over processes and tools
- 2. Working solution** over comprehensive documentation
- 3. Customer collaboration** over contract negotiation
- 4. Responding to change** over following a plan



The Prototyping Manifesto

Innovators beat ideas

Prototypes beat product-types

Building beat talking

Simplicity beats features

Now beats later

Commitment beats committees

Data beats opinions

Don't finish what you've started

Failure is an option

Scarcity bring clarity

The more the messier

Reinvent the wheel

Play with fire



Working solution over comprehensive documentation

The more the messier

Failure is an option





Formal definition of a standard

Document that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results. The document is established by consensus and approved by a recognized body. The aim is the achievement of the optimal degree of order in a given context





INNOVATION

RESEARCH



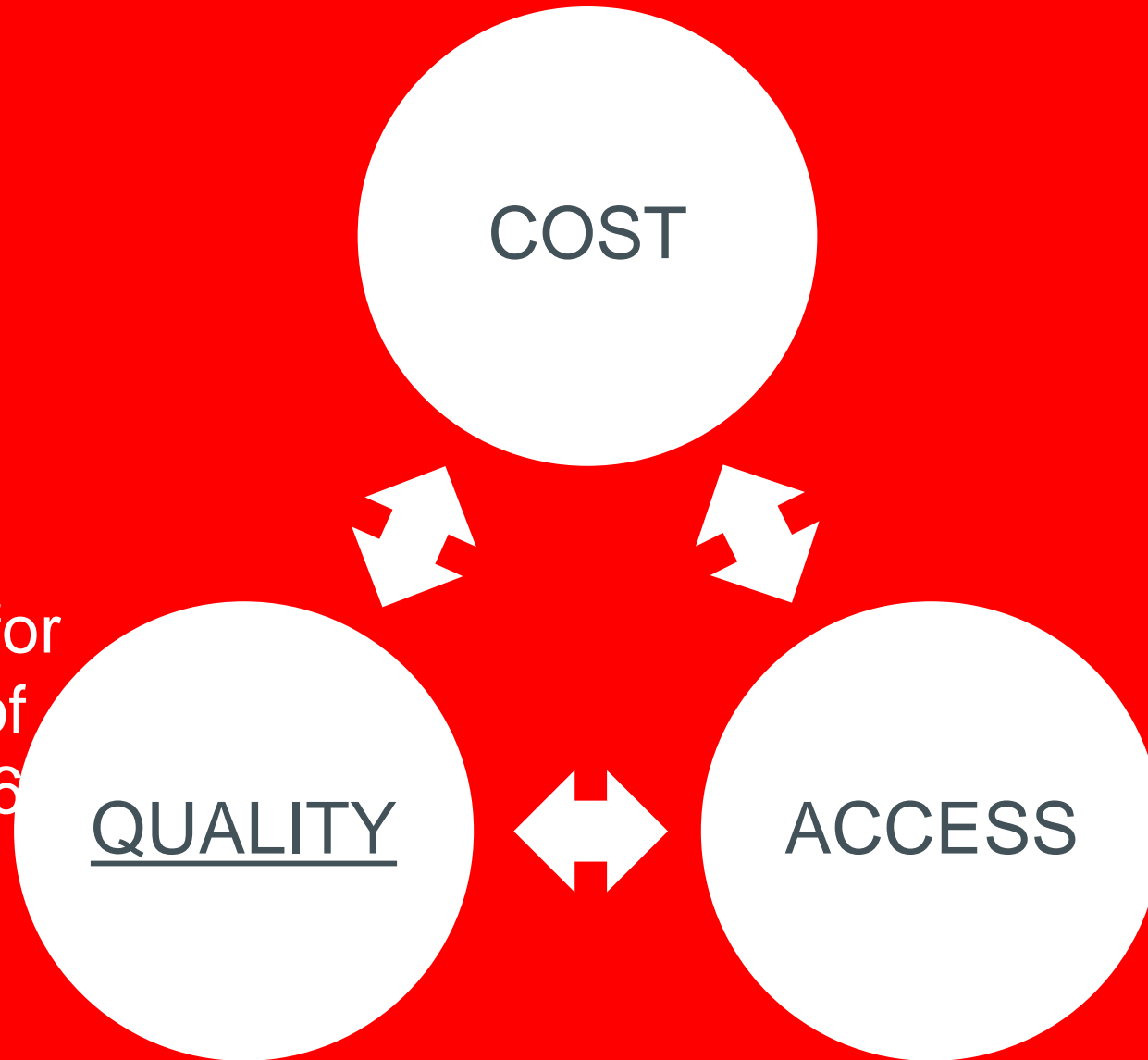
INNOVATION
WITHOUT
CHANGE IS JUST
RESEARCH



Valley of
Death



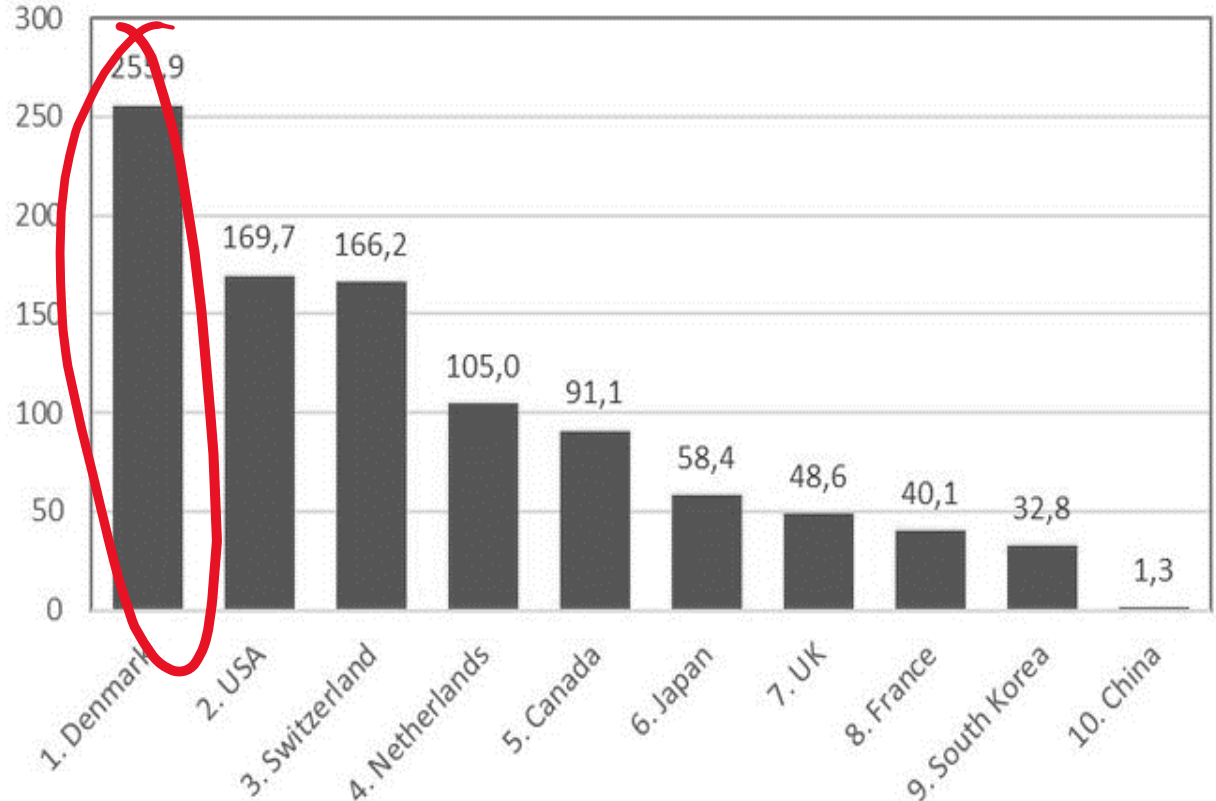
The “Iron Triangle” in healthcare



Denmark ranks among the top 5 OECD countries for scientific impact of publications (2016)

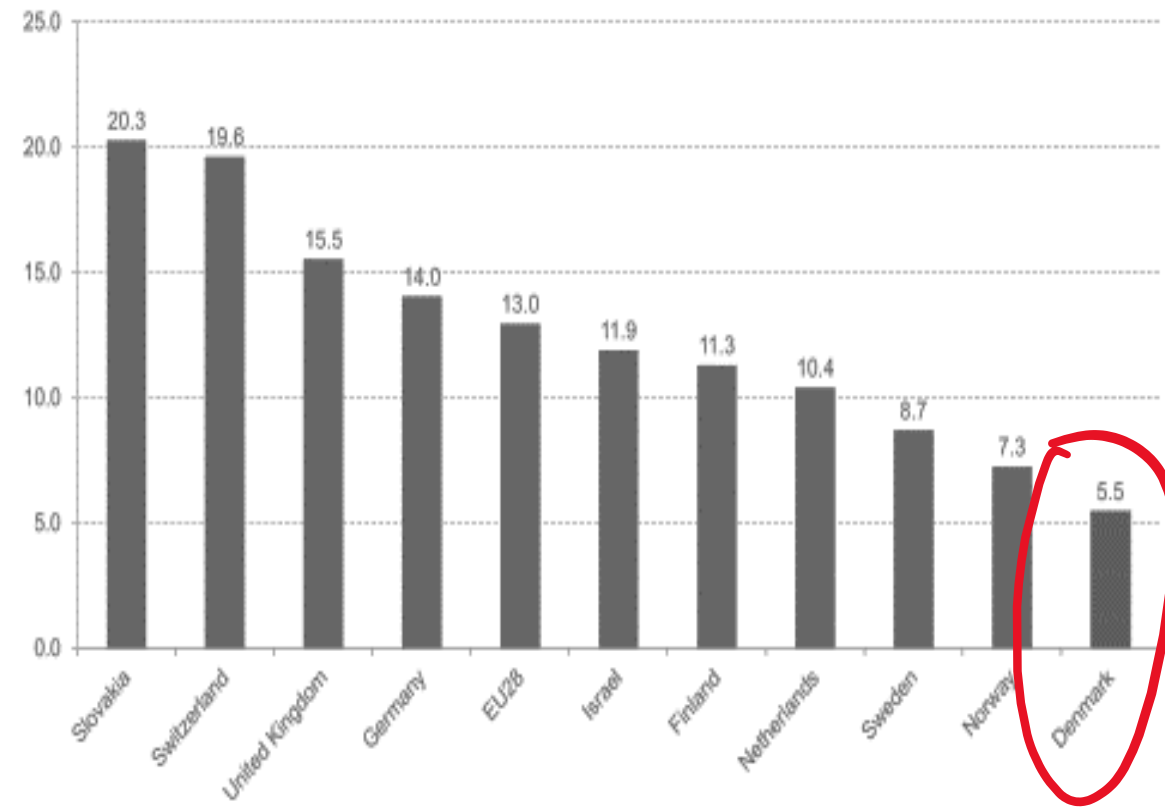
Top 10 countries with most patents in biotechnology

Ranked by patents per million inhabitants, 2021



Source: Copenhagen Capacity on basis of fDi Benchmark, Financial Times Limited 2021

Figure 16: Sales of new-to-market and new-to-firm innovations as a percentage of turnover, 2018



Source: European Commission- European Innovation Scoreboard 2019

Note: Indicator is calculated as sum of total turnover of new or significantly improved products, either new-to-the-firm or new-to-the-market, for all enterprises.

“The excellent outcomes in science insufficiently translate into commercial innovation, in particular in SMEs, start-ups and scale ups.”

Peer Review of Denmark’s R&I System 2020

“Sales of products from new-to-market and new-to-firm innovations are significantly lower, as a share of total revenue, than the EU average and most of the peer economies.”

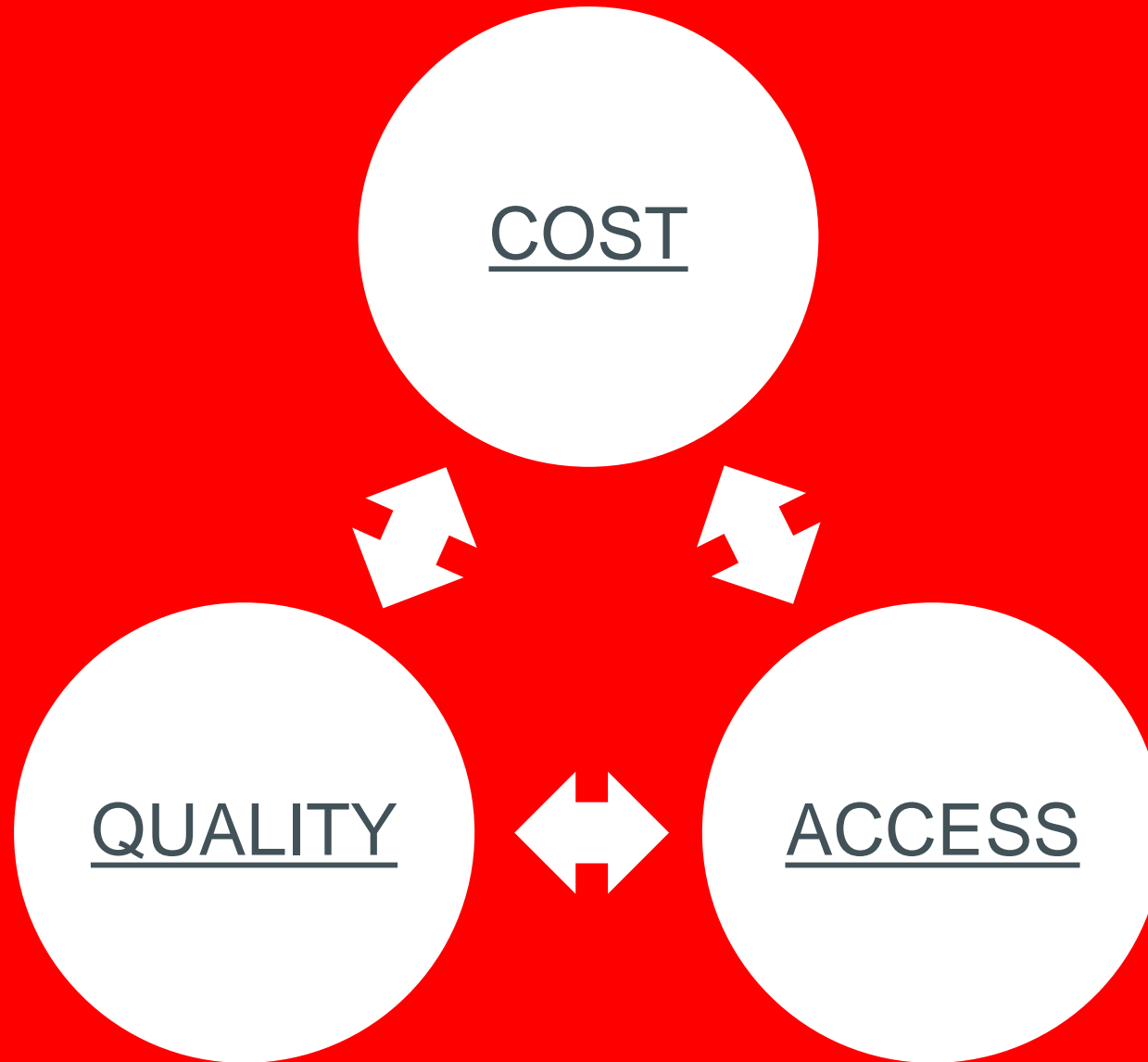


Valley of
Death





The “Iron Triangle” in healthcare





CHANGE



To achieve CHANGE at scale
We need ADOPTION



Successful implementation of telemedicine depends on personal relations between company representatives and healthcare providers: A qualitative study of business models for Danish home telemonitoring



Valley of
Death

Lack of Adoption





To get adoption we need standards.





THANK YOU

Martin Vesterby

**HEALTH TECH HUB
COPENHAGEN**

THE POWER OF COLLECTIVE GROWTH

From research to practice to standardization

Serkawt Kholá
Ph.d., CEO and Founder
Evoplexus Medics



Helping You Empower Precision Healthcare

EVOPLEXUS MEDICS

Serkawt Khola, PhD
CEO & FOUNDER



s.khola@evoplexusmedics.com
+45 4277 2851

CONTACT

Fruebjergvej 3, 2100 Copenhagen OE, Denmark
www.evoplexusmedics.com

- Our advanced solutions:

- Support both clinicians and patients to better manage complex conditions
- Improve quality of care to more patients
- Optimize resources and time
- More precise treatments for individual patients



OVERVIEW

- Our journey
- The wild west!
- Cases:
 - Academic Research - AI
 - First Patient: MS (Asperger, Dyslexia)
 - ESRD
 - Heart Failure
 - VAD and CKD
 - NawaQlinik for Precision Medicine
 - Current Collaborations and Representatives

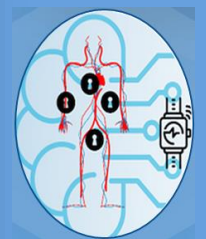


Our Journey: T - 20X Years

Dawn of Academic AI Research (T-20X Years), ca.1998



First Medical Device Project: Fingertip Pulse Oxymeter with AI/PR – the 'Science Fiction'!



AI for MS Patient – 21 Y

AI for: Dyslexia, Asperger,

The Time-Data-Space Machine Learning Algorithm Optimisation Problem

Autonomous Vehicles

JPL: The Space Project

Gene Expression Biomarkers

EvoPlexus AI (R&D)
AI for Healthcare market less ready (T-10X Years)



Projects: Heart Failure, NEC, AAA, ESRD, (COPD)



EvoPlexus Medics ApS (Sep 2019 -)



Precision Healthcare: VAD, CKD, PD (Multiple Providers and Countries)



Standards:
-TC215
- DS273

T = 2022

The Evolution





The Lack of Standards and Guidelines: Cases

The Research ... The Wild West (almost!)... The Standards and Guidelines.

T-20X Ys: Academic Research

- Labs
- Fragmented
- Collaborations
- Standards and Guidelines: Too few, or lack of, or unapplied etc.
- AI - Too Early!



The Lack of Standards and Guidelines: Cases

- First Patient – MS (21 years ago):
 - Multiple Sclerosis (disease of the central nervous system)
 - Rapidly disabling
- Asperger and Dyslexia:
 - Data
 - Analytics

Standards and Guidelines:

- Use of AI - Too Early!



The Lack of Standards and Guidelines: Cases

- ESRD:
 - Multi-provider, Multi-centre project
 - Concesus on methods, practices and rules
 - Data

Standards and Guidelines:

- Data: identification, coding, collection, storage, sharing
- Privacy, Security, Safety
- Interpretations, Interoperations, Integrations
- AI – definitions, methods, algorithms, presentations, interpretations



The Lack of Standards and Guidelines: Cases

- Heart Failure:
 - Single centre project
 - Multi-target stakeholders
 - Unseen methods
 - Data: collection, merging, values, types etc.

Standards and Guidelines:

- Smoother processes
- Better Outcomes
- AI – Concensus on definitions, methods, algorithms, presentations, interpretations – lesser problem!



The Lack of Standards and Guidelines: Cases

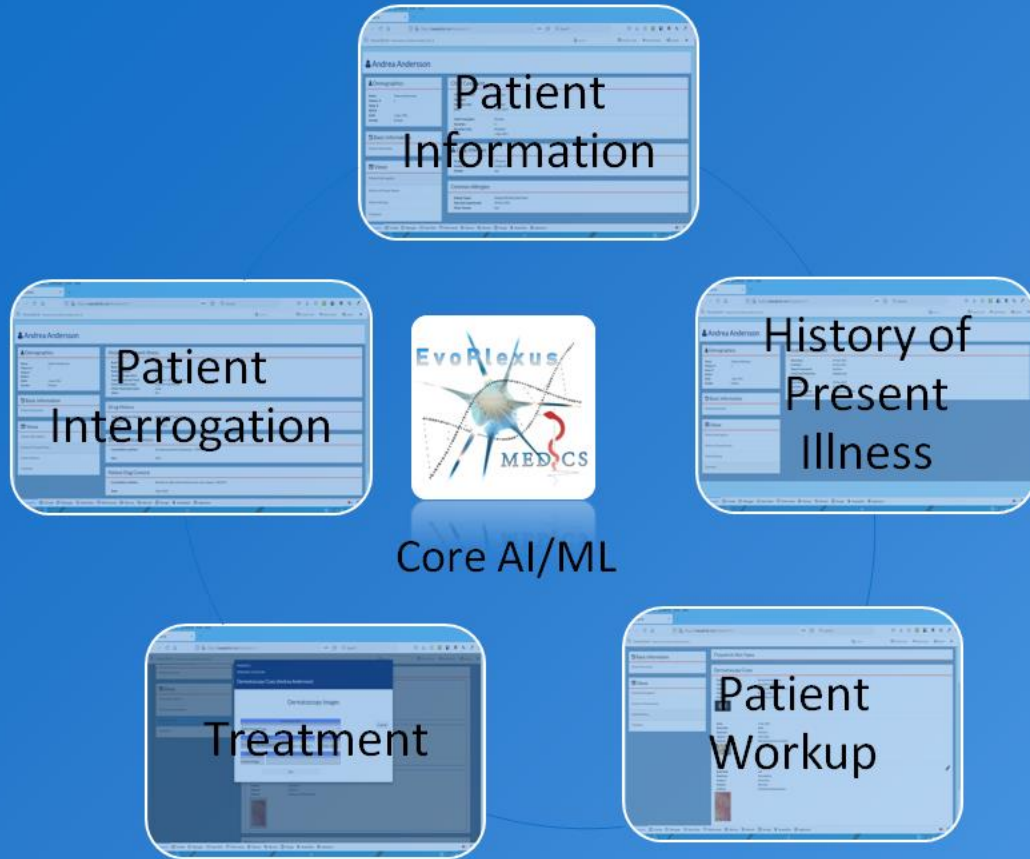
- VAD and CKD:
 - Main partner, but multiple providers/collaborations
 - Multiple countries
 - Highly varying data sources, collection methods, storage, consent, sharing, timelines etc.

Standards and Guidelines:

- Help streamline processes
- Common grounds, common understandings
- AI – Difficulties!

NawaQlinik

AI-Enabled Platform for Complete Patient Pathway



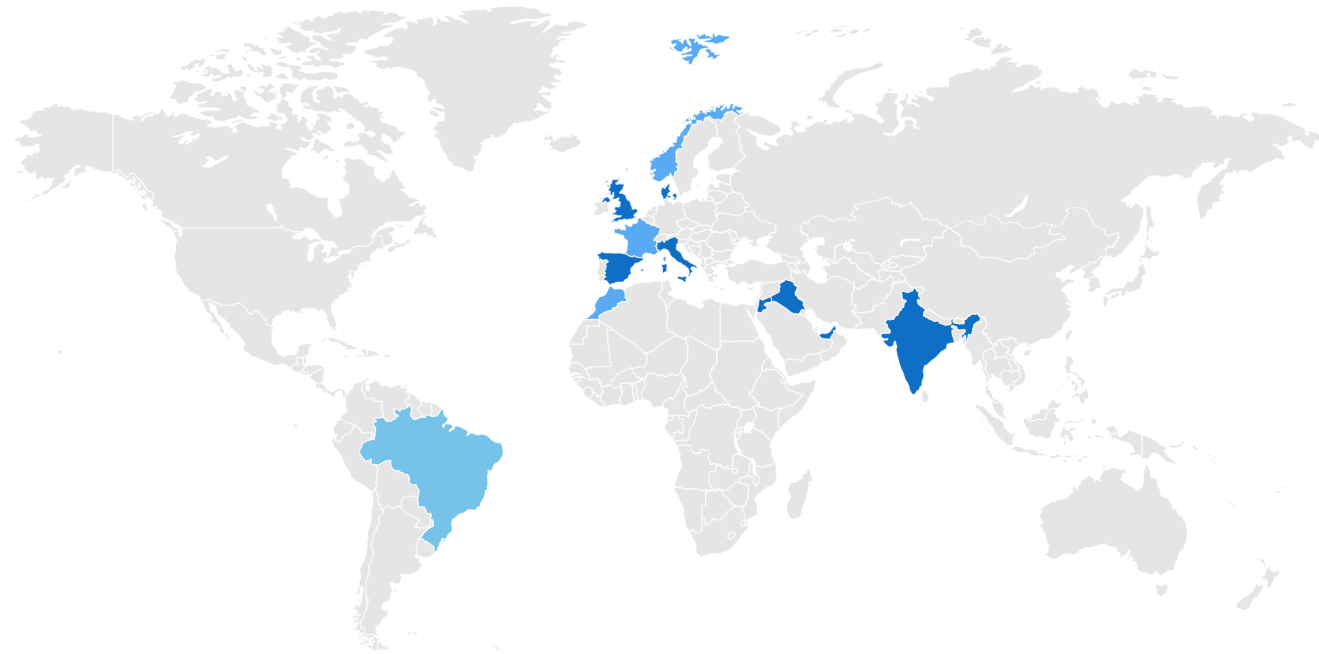
An AI-Enabled
smartphone application
for users/patients

Track
Vascular Access
Conditions



Time Track
Patient Health
Changes

OUR CURRENT COLLABORATIONS AND REPRESENTATIVES



INVESTORS - PARTNERSHIPS - COLLABORATIONS

Please contact us:

info@evoplexusmedics.com

hr@evoplexusmedics.com

THANK YOU

WE LOOK FORWARD TO HEARING FROM YOU

Why innovation and investment in evidence-based standards are crucial for trade in the future

Gitte Petersen
CEO and co-founder
Genomic Expression



Dansk Standard: 2022/05/24

By Gitte Pedersen, CEO and co-founder and
member of ESIR2

Mission: to save lives and make healthcare more effective

Vision: By analyzing **RNA** we can monitor **health**, detect **disease** and design next generation **cures**

Who pays for healthcare ?

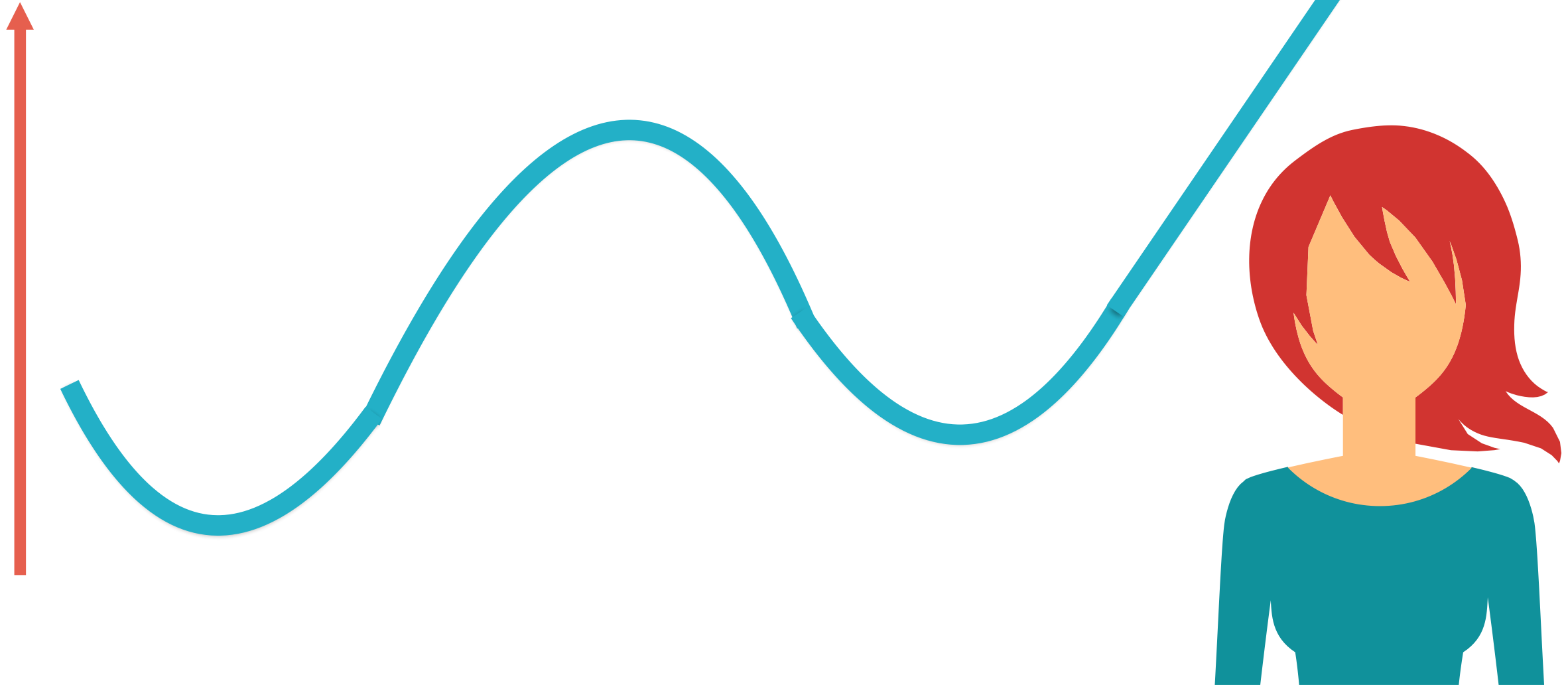


YOU



U.S. health care spending grew 9.7 percent in 2020, reaching \$4.1 trillion or \$12,530 per person/year
Europe, the average cost of international health insurance in 2018 is spread out between USD 8,786 in the UK
and USD 6,585 in Romania, Croatia, and Slovakia.

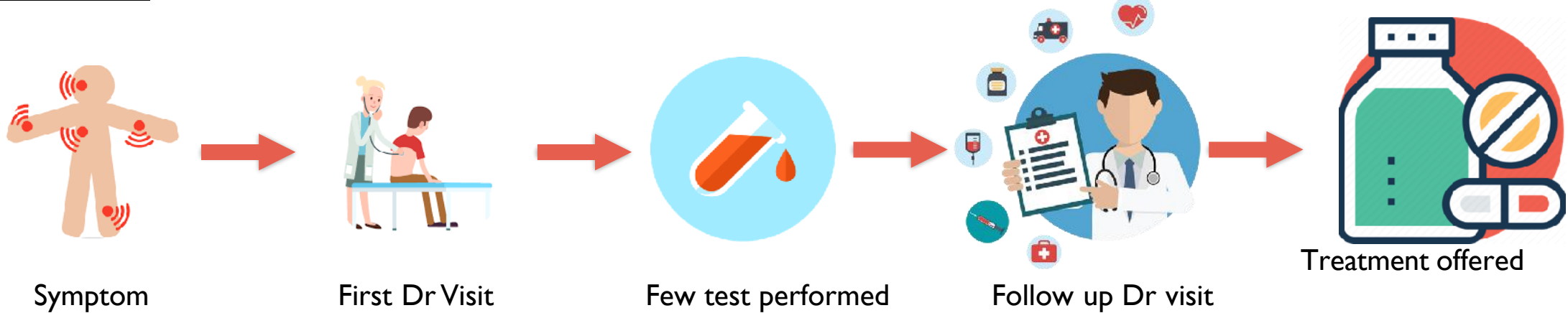
Health is Dynamic and not binary



COVID-19 has transforming delivery of health care

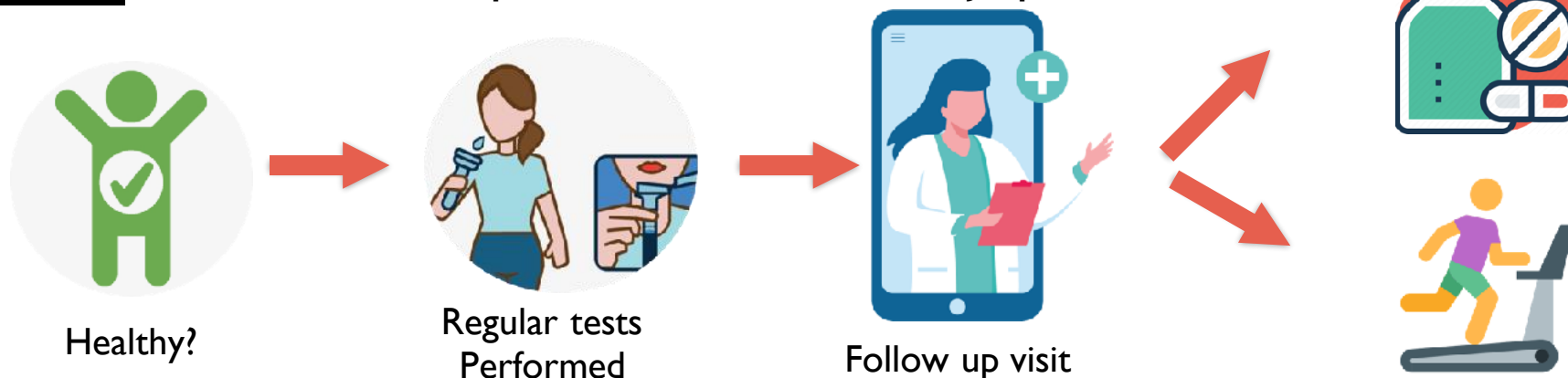


Yesterday: Pre COVID-19 it could take weeks to a month from onset of a symptom to entering into treatment



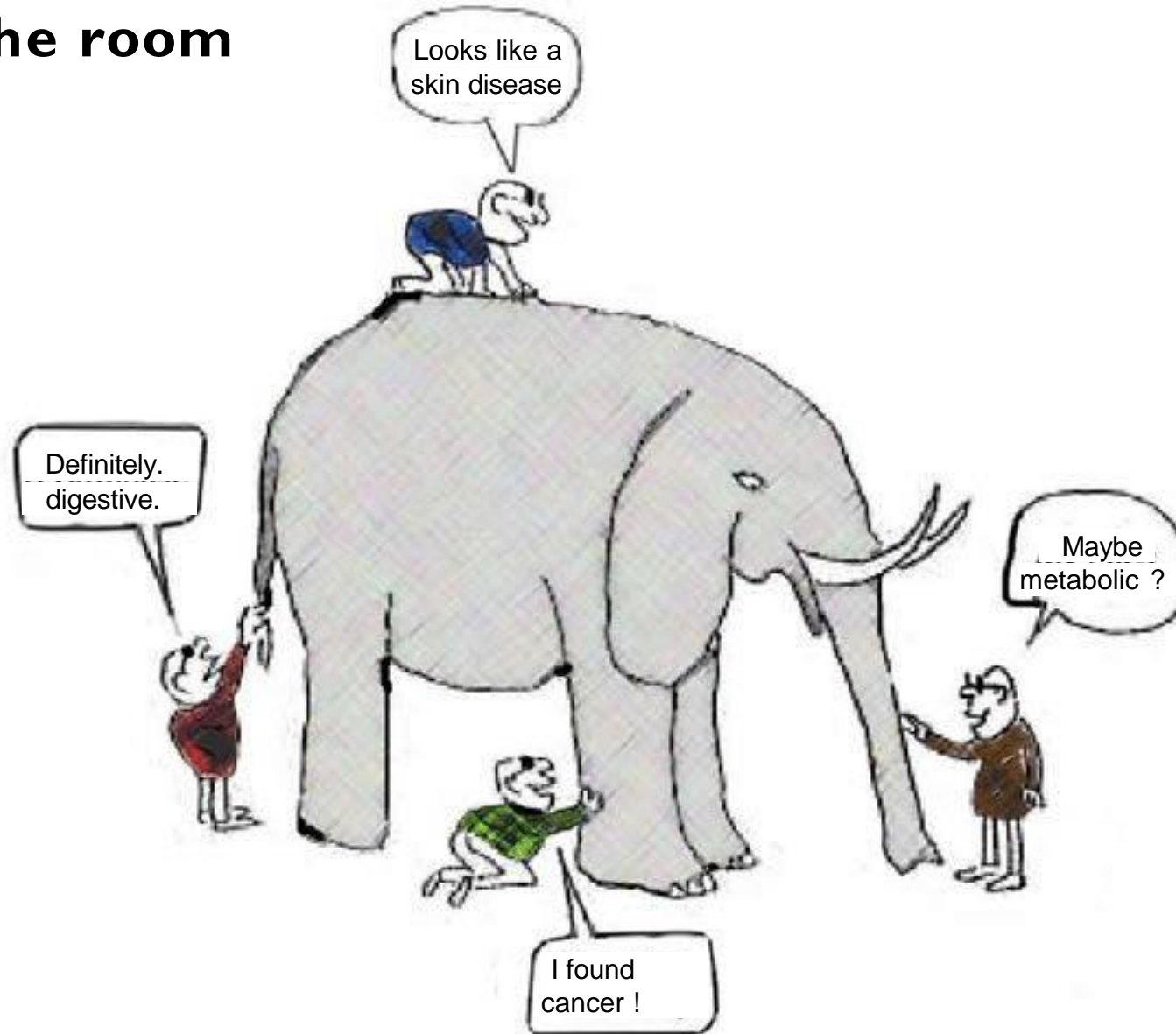
85% of older adults have at least one chronic health condition, and 60% have at least two chronic conditions

Today: We detect disease prior to manifestation of symptoms in 24 hrs



Most chronic conditions are life style related and can be reversed with non-pharmaceutical Intervention

The elephant in the room



People living with diseases in the USA

Mental
70M

Bi-polar: Borna disease virus, Borrelia species bacteria. Impairment, herpes simplex virus

ADHD: Bacteria borrelia burgdorferi and streptococcus, and with HIV and enterovirus. Viral infections during pregnancy, at birth, and in early childhood are risk factors

Autism: rubella virus or cytomegalovirus and Clostridia bacterial

Anxiety: cytomegalovirus, Epstein-Barr virus, bacterium helicobacter pylori.

Dementia: herpes simplex virus, cytomegalovirus, West Nile virus, Borna disease virus, and HIV. Borrelia species bacteria.

Depression: Cytomegalovirus, West Nile virus, Epstein-Barr virus, Borna disease virus, as bartonella and borrelia species bacteria.

Auto Immune
23M

Enteroviruses, **Epstein-Barr virus**, cytomegalovirus, parvovirus B19, HIV,

bacterium mycobacterium tuberculosis
helicobacter pylori

Alzheimer
5.7M

Herpes simplex virus
bacteria porphyromonas gingivalis, chlamydia pneumoniae and helicobacter pylori

Cancer
16M

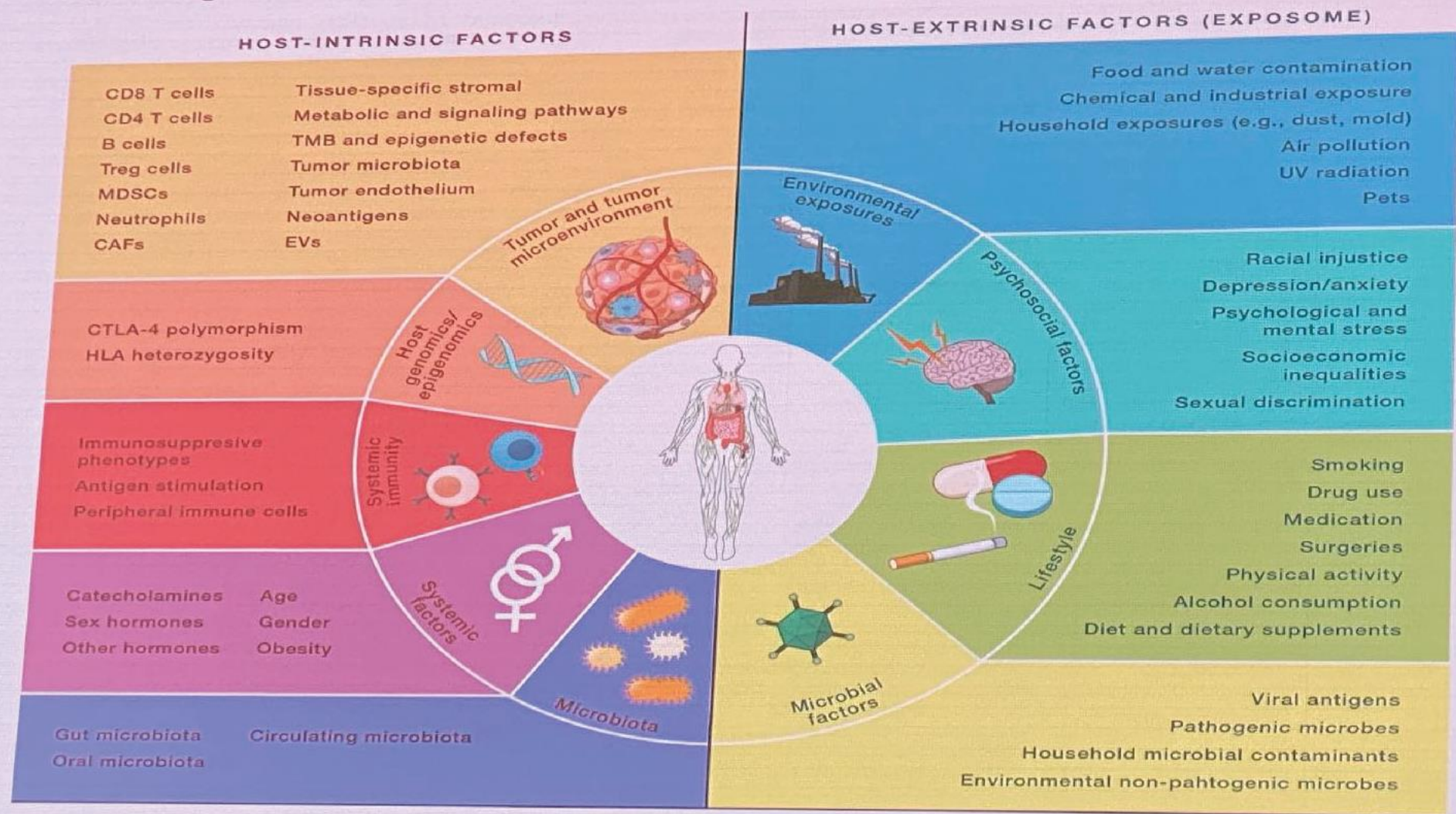
20-30% of cancers are caused by Infectious agents and 30% due to life style (smoking, drinking obesity)

Respiratory
50M

35M or 10% of US population has Asthma: associated with rhinovirus, human respiratory syncytial virus, and the bacterium chlamydia pneumoniae.
17M or 5% COPD, emphysema, chronic bronchitis

108M or 31% of US population is Obese: associated with adenovirus 36, which is found in 30% of obese people, but only in 11% of non-obese people

Through these types of approaches, we have identified a number of factors that impact tumor growth and response to cancer treatment that may be targeted



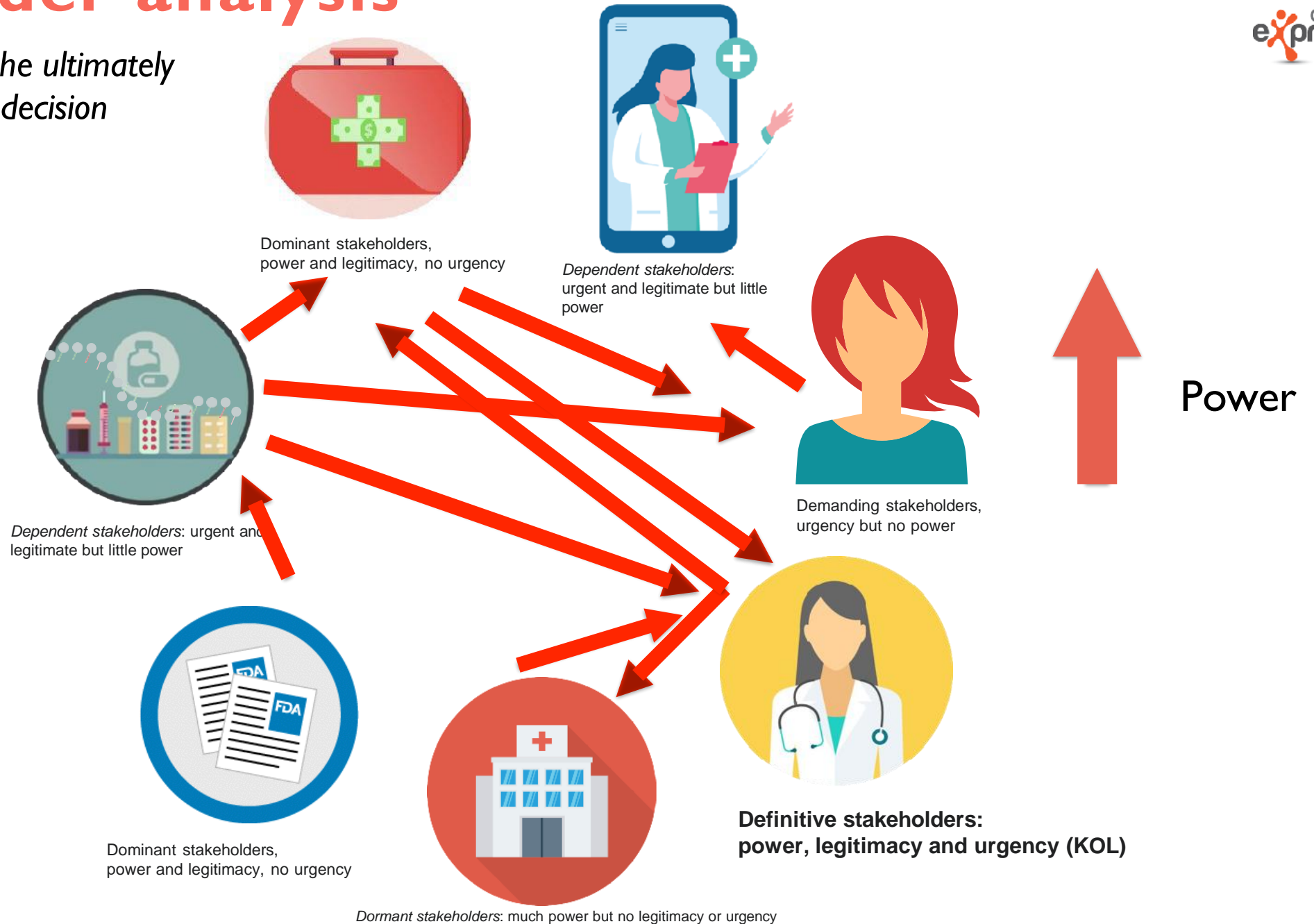
Vitamin D Benefits

1. **Promotes Immune Health**
2. **Promotes Bone Health**
3. **Promotes Dental Health**
4. **Promotes Tissue Health**
5. **Supports Colon Health**



Stakeholder analysis

Only industry where the ultimately beneficiary is not the decision maker nor the payor



"In the future, most healthcare decisions will be based on collectively-derived insights that are synthesized in real-time and delivered at the point of care."

Chris Klomp, CEO
Collective Medical



As a result of the digitization and increasing liquidity of healthcare data, today, we're seeing record amounts of innovation and investment in the industry from a variety of participants, such as startups and large tech companies, as well as big-box retailers and traditional healthcare organizations.

The background of the image is a reproduction of Michelangelo's 'The Creation of Adam' fresco. It shows two hands reaching towards each other, with a significant gap between them. The text is overlaid on this image.

RNA/DNA

Health Data

AI

LifeStyle Data

Less than **1% of biomarkers** discovered gets implemented

OneRNA®

Exponentially scalable platform for Next Generation Cures

ONE assay

ALL +20,000 mRNAs



Isolate RNA



Panel-free OneRNA sample prep



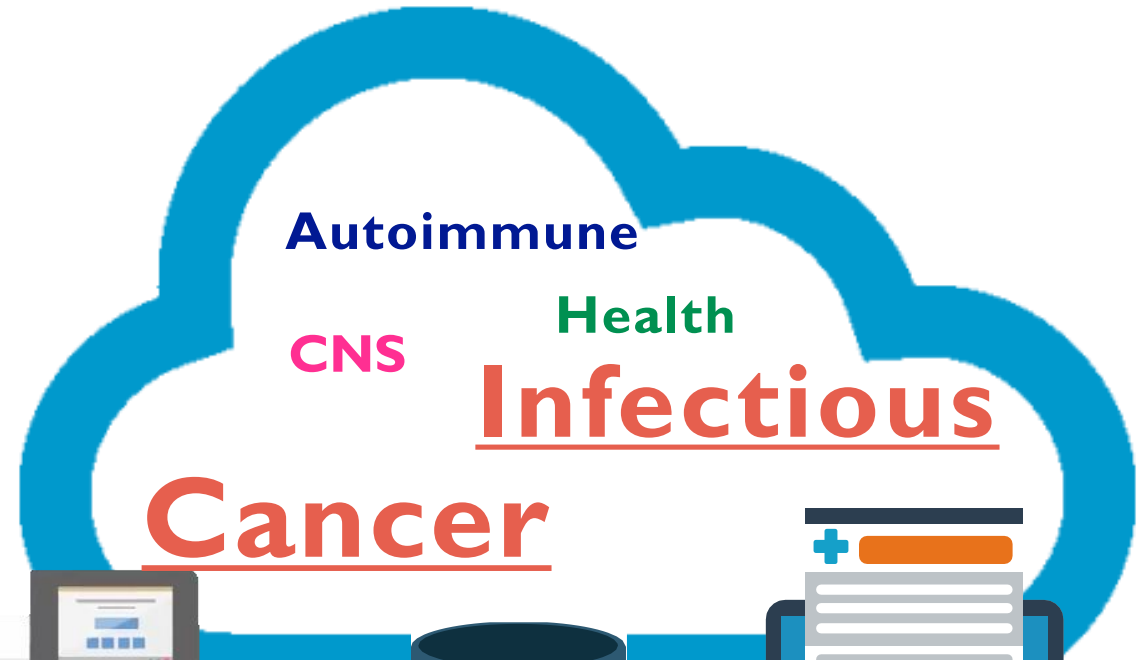
Sequence and analyze data



Match profile to actionable genes



Generate OneRNA report



OneRNA® could save lives NOW



We identify 5 already approved drugs in 100% of the patients

Paradigm shift from static standard of care model to dynamic truly Individualized treatment



ONE Disease

Her2

ONE Marker



ONE Drug

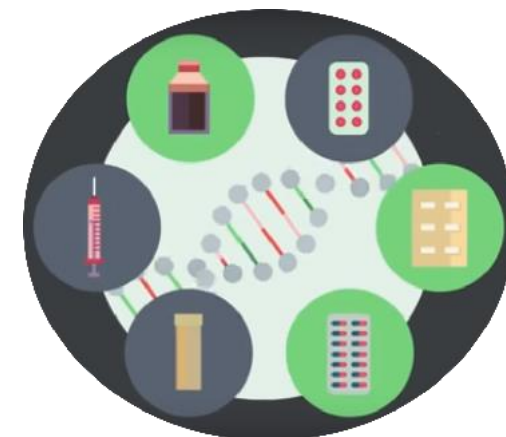
50%
↓
20%



ONE Patient

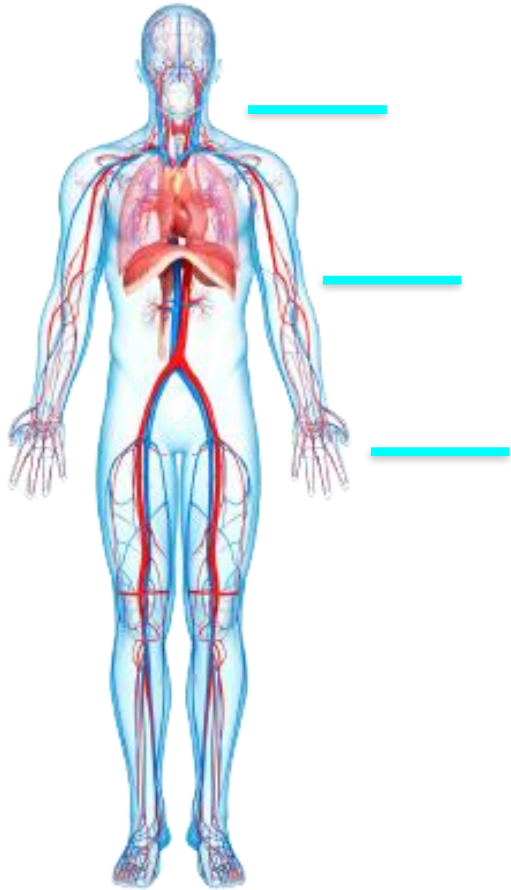


Many Markers

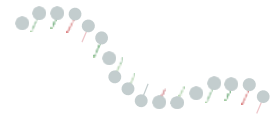


Multiple Treatments

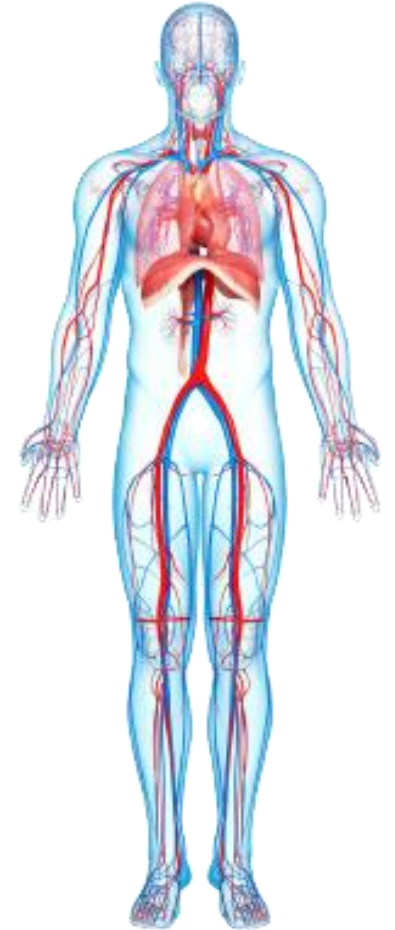
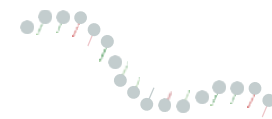
From RNA code to drug 12 month



RNA



**RNA
Vaccine**



12 month compared to 10 years

Important standards moving into health 2.0



- 1) Protection of consumer health data e.g. GPDR, HIPAA etc
- 2) Standardization of consent to use data and biological information
- 3) Standardization of regulatory procedures US<>EU
- 4) Standardization of disease definitions and codes
- ~~5) Standardization of data structure and programs for EMR (HL7)~~
- ~~6) Definition of health as the absence of detected disease~~

HL7



HL7 standards are healthcare-specific formatted messages that support a variety of system integrations and interoperability—and enable EHRs to communicate with a variety of systems that operate outside the EHR

HL7 Vision

A world in which everyone can securely access and use the right health data when and where they need it.

HL7 Mission

To provide standards that empower global health data interoperability.

Google sued for using the NHS data of 1.6 million Britons 'without their knowledge or consent'

The Royal Free NHS Trust in London, which gave Google the patient data, was previously told the move was illegal following an investigation by the Information Commissioner's Office.



Alexander Martin

Technology reporter @AlexMartin

🕒 Monday 16 May 2022 13:45, UK



Conclusions

- 1) Our healthcare system have dramatically changed during COVID19 -> we learned that we can deliver care using the internet Telehealth and diagnostics
- 2) We can leverage this change to continue improving on delivering of care using Telehealth and accurate diagnostics
- 3) The consumer is the key stakeholder and willing (in the USA) to spend \$1.5/pa on wellness
- 4) Healthcare systems need to spend more \$\$ in monitoring health to reduce cost of care
- 5) People and patients have to be involved and sharing of data is necessary to achieve the improvements that data technology provides and develop next generation drugs



Panel debate and questions

Conclusion and next step

Jeanett Fleron
Senior Consultant, Danish Standards

Why participate?

- Gain influence on the national strategic direction for standardization
- Gain influence on the framework and on the requirements of the future standards within the life science field
- National and global network
- Knowledge of e.g. future requirements, trends and new research & development
- Get inspiration to innovation and new partnerships
- Strengthen Denmark's and the Danish society's position in this field



Examples of national committees

- Health Informatics (S-273 Sundhedsinformatik)
- Biotechnology (S-809 Bioteknologi)
- Quality management and corresponding general aspect for medical devices (S-257 Medicinsk udstyr – ledelse og kvalitet)
- **New DS Task Force for life science & standardization!**



Next step

- The presentations and recording from the webinar will be made available at Danish Standards' webpage (ds.dk)
- Contact Danish Standards for general information
- Contact Danish Standards (Jeanett Fleron) if you wish to participate in the work or learn more about the ongoing standardization work



Contact



Jeanett Fleron
Senior Consultant
E: jef@ds.dk
T: 39 96 61 72

