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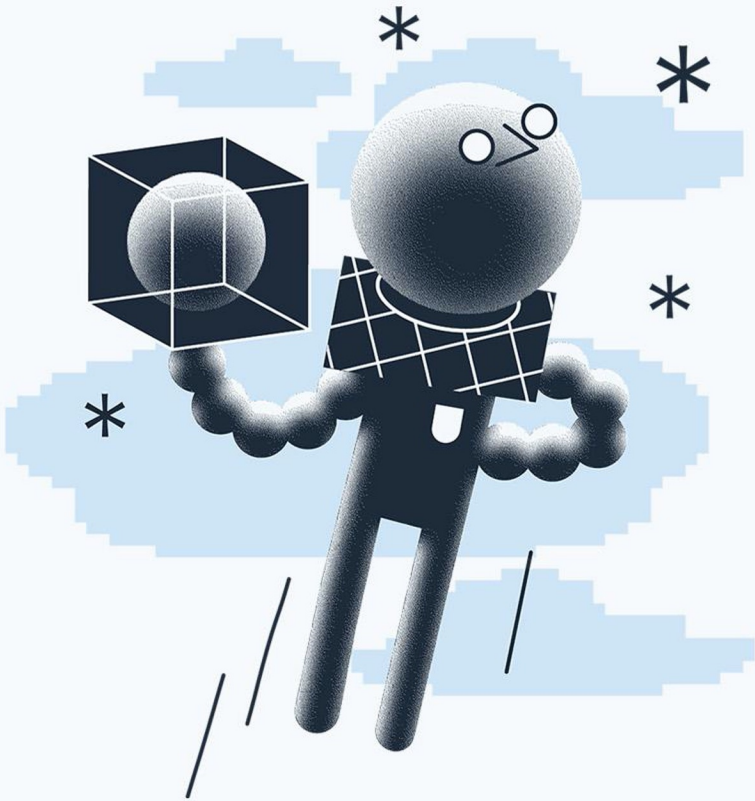

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# Advances in Digital Health

## Convergence of Digital Health and MedTech

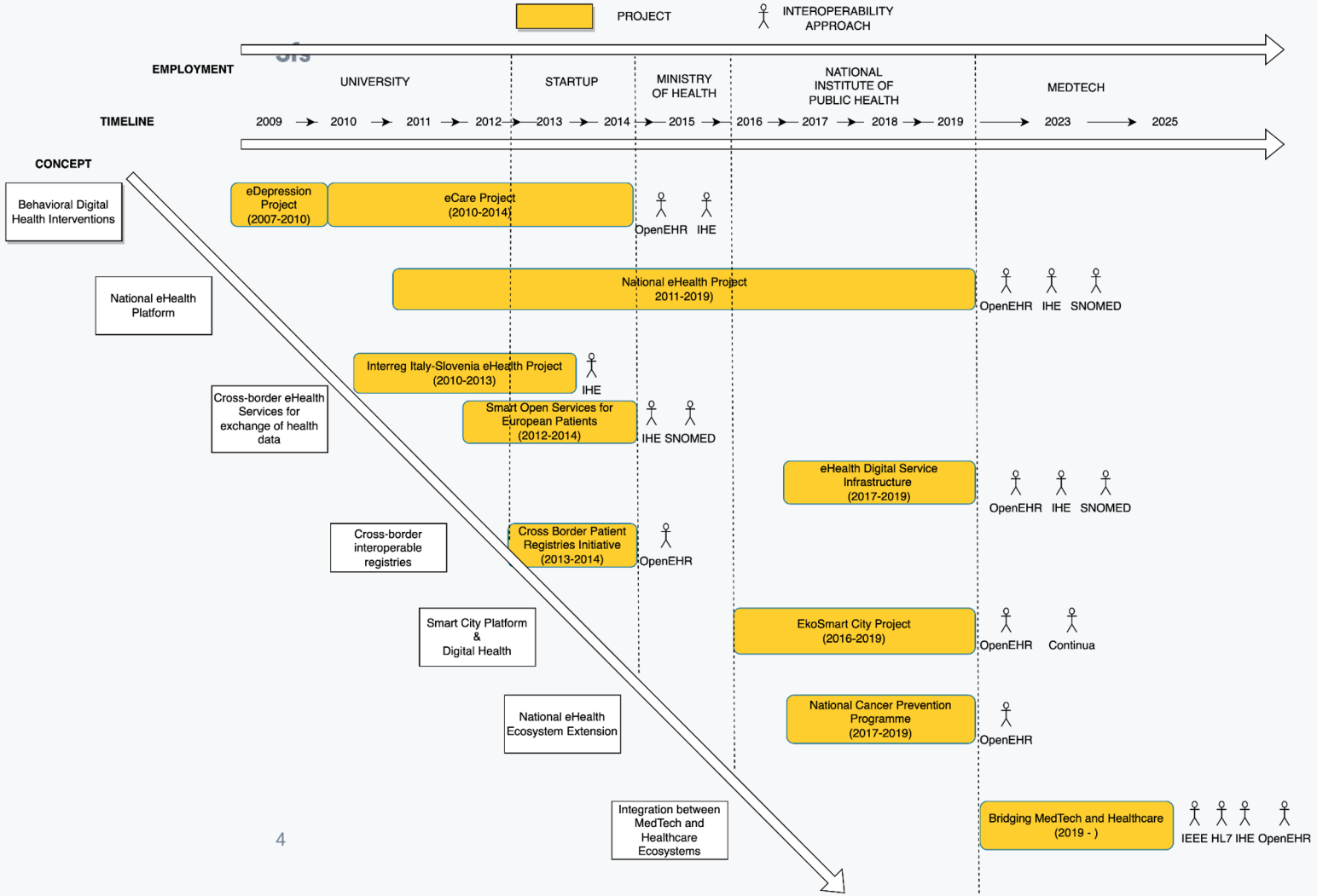
**Mate Bestek, PhD**

Head of MedTech and Digital Healthcare

VERSION 1

6 June 2023

University of Trieste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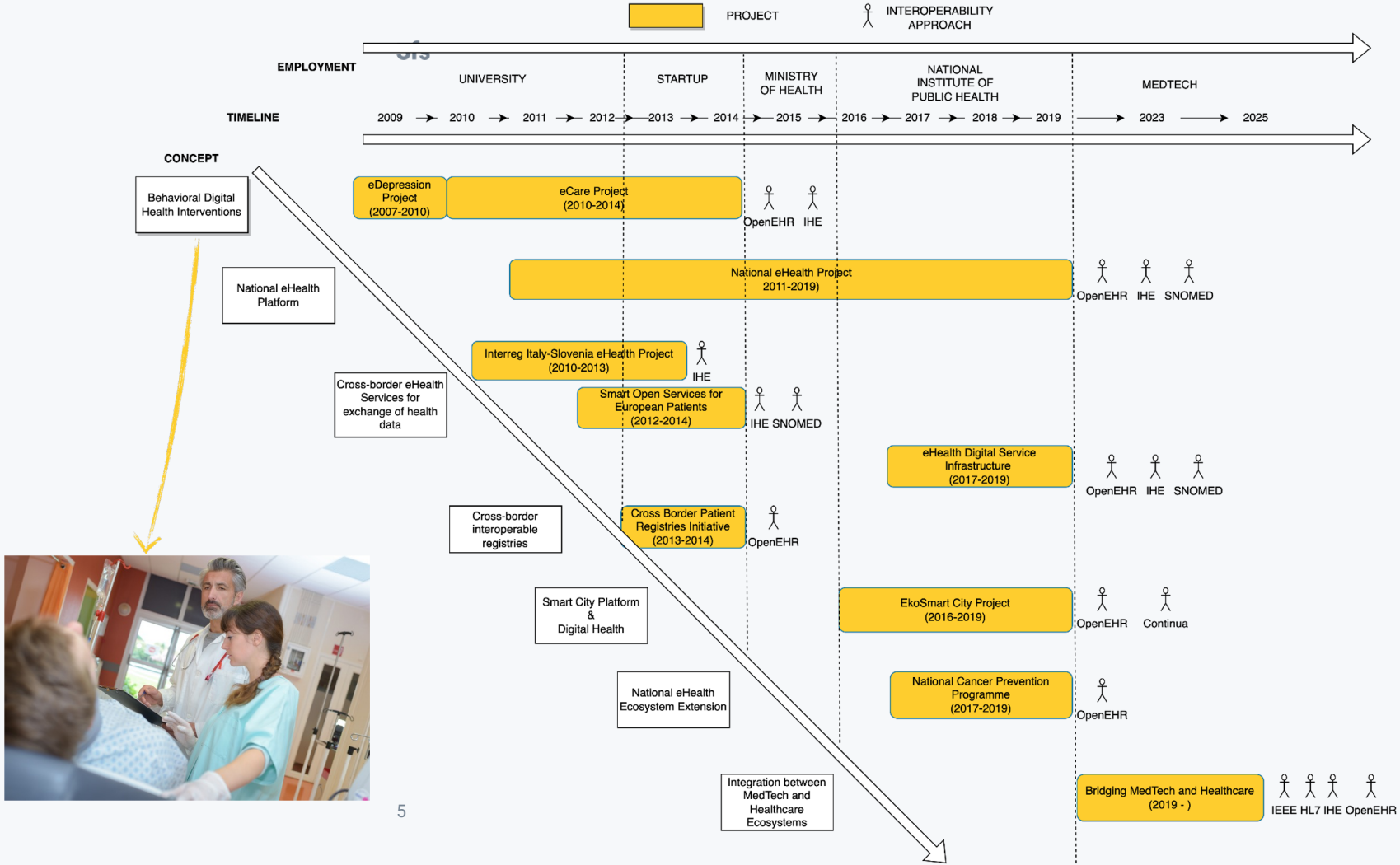
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# Digital Health
# MedTech
# Digital Health Vs MedTech
# The Convergence
# The Future

# Digital Health

# Digital Health

- Digital health refers to the **use of technology to enhance healthcare delivery and improve patient outcomes**.
- It encompasses a wide range of technologies, platforms, and solutions that **leverage digital tools and data** to **enhance various aspects of healthcare**.

  - Telemedicine
  - Wearable devices
  - Health apps
  - Artificial Intelligence
  - Big Data and Analytics
  - Virtual Reality and Augmented Reality
  - Blockchain

# Example #1: Drones carrying doctors (not yet)

## Hospital of the future

20% fewer beds
8% smaller budget
…and more patients

3fs

# Example #2: AI Use Cases

## 1 Autonomous Surgical Robots

**Use cases**
- Stomach Surgery and colon and rectal surgery
- Partial knee replacement surgery
- Heart Surgery
- Gynecological surgery
- Head and neck surgery
- Back Surgery
- Urological surgery

**Benefits**
- Fewer complications or infections
- Less pain and blood loss
- Faster recovery
- Smaller, less noticeable scars

## 2 Virtual Nursing Assistants

**Use cases**
- Treatment events can also be performed outside the clinical setting
- Monitor adherence to treatment plan between treatment visits or appointments
- Allows recurring treatment events or inspections without straining existing resources
- Receives real-time alerts that can be used to perform treatment or planning.

**Benefits**
- Improves quality of care and medical results
- Fewer repeat visits (Care Angel study)
- Allows savings compared to the traditional model

## 3 Diagnostics

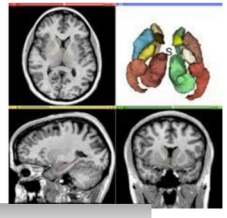
**Use cases:**
- Oncological diagnosis
- Cardiological diagnosis
- Psychiatric diagnoses
- Diagnosis of the most common infectious diseases

**Benefits**
- Improved speed and accuracy in the overall diagnosis of the disease.
- Diagnostics can be provided in remote locations with AI.
- Allows for more detailed pathological results based on tissue analysis
- Diagnosis of many types of cancer with accuracies that match and even exceed the accuracy of a trained physician / radiologist.
- Lower costs in diagnosis


## 4 Image Analysis

**Use cases**
- Enhanced 2D and 3D imaging provides valuable information on the condition of the heart, liver, lungs and other organs.
- Cloud-based computing allows various AI software to analyze the same medical images for more detailed diagnoses.
- Diagnostic scoring allows you to assess the likelihood of illness
- Applications include skin analysis, eye analysis

**Benefits**
- Artificial intelligence reduces the time it takes to perform medical imaging
- Automated workflows reduce errors and improve the effectiveness of medical image diagnostics.
- Diagnostic accuracy even better than that made by healthcare professionals (including skin cancer, breast



## 5 Drug Design, Drug Safety and Drug Manufacturing

**Use cases in pharmaceutical industry:**
- Pfizer and IBM partners use Watson AI to accelerate drug discovery for immuno-oncology treatments.
- To find new drug candidates.
- Using AI to find new drugs and other therapies.

**Use cases in drug safety:**
- Detection and prevention of medical errors / dosing errors
- Medication design individually


## 6 Clinical Trials

**Use cases**
- Ability to use and handle faster and more specifically, real-world data.
- Predictive analytics that can predict test results based on a variety of criteria.
- Wearable measuring devices provide real-time access to measurement data that allows participants to be monitored and analyzed in real time throughout the study.
- Ability to identify small factors that may affect research results but remain unnoticed by humans.

**Benefits:**
- Clinical trials can now be performed cheaper, more efficiently and with more accurate results.
- Successful research will lead to the development of new drugs and the introduction of new therapies


## 7 Risk assessment

**Use cases:**
- Prediction of the occurrence of cancer, diabetes, osteoarthritis, cardiological diseases, and psychiatric problems

**Examples of forecasts:**
- How long do patients stay in hospital
- Possibilities for patients to return to hospital
- The likelihood of the disease occurring in both the short and the long term
- The success rate of different management plans
- Patient mortality probability


**The Google Medical Brain team developed an artificial neural network that analyzes patient data and makes many predictions. Google's research shows AI's ability to detect and predict disease, for example by scanning the retina which Google AI analyzed and provided effective early diagnosis of diabetes retinopathy and cardiovascular events.**

Example #3: Health App

# Information - APP - "My Hospital"

- Information to patients and relatives about treatment and examinations.
- Patient Reported Outcome.
- Research
- Questionnaires
- More than 130 different pathways.

# Digital Transformation of Healthcare

- Hospitals are working on their master data creation as part of proper **data governance** - and in e.g. Germany they estimate this to last for the next 5 to 7 years
- Future hospitals are seen as connected care without walls which will be possible only if **interoperability** is achieved
- Digital solution providers need to **align better with healthcare** - by digging into processes and showing how their solutions help optimize them and by becoming aware of how healthcare evaluates solutions (e.g. MAST methodology)
- Digital solutions can propose **new ways of working** but adoption of clinicians is crucial.

# Medical Technology - MedTech

# MedTech

- Refers specifically to the use of technology, devices, and instruments to diagnose, monitor, treat, or manage **medical conditions**.
- It involves the development, production, and application of medical devices, equipment, and solutions used by healthcare professionals and patients.
- MedTech encompasses a wide range of technologies and devices

# MedTech technologies and devices

- **Medical Imaging**: X-ray machines, MRI scanners, CT scanners, and ultrasound systems
- **Surgical Instruments**: These include a variety of tools and devices used during surgical procedures, such as scalpels, forceps, retractors, and laparoscopic instruments.
- **Implants and Prosthetics**: Medical implants, such as pacemakers, joint replacements, and artificial organs, as well as prosthetic limbs
- **Diagnostic Devices**: simple handheld devices like glucometers and blood pressure monitors, complex diagnostic equipment like genetic analyzers and laboratory testing platforms.

Source: https://www.freepik.com/free-vector/medical-equipment-isometric-icons_6438575.htm#query=medical%20ventilator&position=2&from_view=keyword&track=ais

# MedTech Digital Transformation

- Connectivity
- Data Management
- Digital Twins
- Software as Medical Device (SaMD)

# Digital Health VS MedTech

# Digital Health vs MedTech

- Product Development Methodology
- Quality Management System (QMS) - helps ensure quality and compliance

# Digital Health Product Development

- Agile Development - iterative and incremental development
- User-centric approach - focus on user needs and experiences
- Software Development - mobile apps, web platforms,...
- Data-driven decision making - use of data analytics to get insights
- Regulatory Considerations - data privacy and security regulations e.g. GDPR

# MedTech Product Development

- Regulatory Compliance - strong emphasis to ensure safety and efficacy
- Clinical Trials - to demonstrate safety and effectiveness
- Hardware Development  - make up typical medical devices which adds complexity
- Long Development Cycles - due to the above

# Digital Health QMS

- A digital health QMS focuses specifically on the quality and safety of digital health technologies and services, which include software applications, telehealth platforms, wearables, and remote monitoring systems.

# Digital Health QMS specifics

- Software Development Lifecycle - requirements handling, software testing and validation. IEC 62304 might be followed
- Data Security and Privacy - encryption, access control, compliance with GDPR or HIPAA
- User Experience and Usability - gathering user feedback and iterative design improvements
- Interoperability - focus on different systems and devices so that coordination of care can be supported
- Software updates and maintenance - to ensure ongoing performance, security and compliance
- Cybersecurity - measures to protect against threats and vulnerabilities

# MedTech QMS

- A MedTech QMS refers to the **processes**, **policies**, and **procedures** implemented by medical technology companies to maintain quality and regulatory compliance throughout the product life cycle.
- The QMS typically covers areas such as design and development, manufacturing, distribution, and post-market surveillance.

# MedTech QMS key components

- Design Control - regulatory requirements and customer needs
- Risk Management - identify and mitigate risks
- Document Control - SOPs, …
- Supplier Management - evaluate, select and monitor
- Corrective and Preventive Actions - identify, investigate and resolve quality issues
- Complaint Handling - identify, document, investigate and resolve customer complaints

In summary, while both MedTech QMS and digital health QMS share common goals of ensuring quality and compliance,
the digital health QMS has specific considerations related to software development, data security, user experience, interoperability

# Convergence of Digital Health and MedTech

# Convergence example

- A traditional MedTech firm had to decide to add digital products on top of their medical devices offering
- Digital products included Digital Twins that enable use cases such as:
  - remote view (remotely looking at the devices parameters)
  - remote control (future)

**Getinge**

#digital-twin #design-workshop
#user-testing #product-validation


# A breath of fresh air

We helped a global MedTech leader ideate and validate a value-added digital service for their Servo line of ventilators, a significant step towards delivering modern software solutions for clinicians.

## Connectivity

We helped make point-of-care medical devices in Intensive Care Units effectively and efficiently communicate and exchange clinical data with the surrounding ecosystem of Internet of Medical Things (IoMT) and existing Healthcare Environments.

## Data Management

Helped architect data governance and the supporting solutions that align with existing regulatory requirements including privacy and security. This includes combining on-prem and cloud solutions.

## Digital Twins

Product design of digital twins that leverage connectivity and high quality data management to allow future proofing the toughest healthcare environments such as ICUs by adding capabilities of remote view for medical devices and eventually remote control to support growing issue of lack of medical professionals.

# The transformation

- New software development capabilities and infrastructure (DevSecOps)
- Changes to the existing QMS to include software development and Software as Medical Devices
- Convergence of Product Development to include Software as the main product
- New established strategy on interoperability
- …

All while still continuing the production of traditional hardware medical devices…

# The Future

# MedTech 2.0, 3.0,...

- MedTech firms are becoming software development firms
  - Similarly to how Pharma firms became IT consultants
- Their internal digital transformation is happening and will increase their capabilities to deliver digital products and Software as Medical Devices
- The supporting connectivity and data management digital products help with deploying new Digital Products to a global network of hospitals

# Potential Synergy?

- Digital Health could leverage the existing commercial networks of large MedTech firms to implement their own digital products
- MedTech firms have are trusted as they often provide life-saving equipment to hospitals so it is easier for them to offer new digital products
- MedTech firms will evolve their QMSs to ensure high enough degree of compliance, safety and efficacy - as this is what they have been doing all along
- Digital Health is trying to re-invent a new type of QMS that would require less resources to be put in place

# Pitfalls?

- MedTech would partner but often Digital Health providers are not mature enough and the main issues are with QMS
- So while the digital provider is trying to improve its QMS, the large MedTech can focus on developing its own new digital products

# Thank you for your attention!

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