

Integrating digital health technologies in clinical trials

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29 October 2024 - Outsourcing in Clinical trials
DACH 2024

digital**switzerland**

TRANSFORMING SWITZERLAND
INTO A LEADING DIGITAL NATION



Integrating digital health technologies (DHT) in clinical trials

Agenda



- 1 Introduction
- 2 Challenges and considerations of DHTs in clinical trials
- 3 DHT selection process
- 4 Impact of DHTs in clinical trials
- 5 Use cases
- 6 Future impact of DHT on clinical trials
- 7 digitalswitzerland

Introduction



Digital Health Technologies are revolutionising Clinical Trials

SPONSORED INSIGHT

REGENERON
SCIENCE TO MEDICINE™

Transforming clinical trials: how innovation is revolutionizing drug development

Unleashing Their Potential: The Evolving Landscape of DHTs

April 19, 2024

By Jill Sommerville

Lauren Flood

Advancing sleep health: Wearable technologies revolutionize clinical trials and patient care

By Liza Laws

02-Jul-2024 - Last updated on 26-Jun-2024 at 10:59 GMT

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Data-Driven Devices: Powering Healthcare's Digital Revolution



Suruchi Kothari Forbes Councils Member

Forbes Business Development Council

COUNCIL POST | Membership (Fee-Based)



Jul 9, 2024, 07:00am EDT

DATAcc by DiMe Awarded FDA Grant to Boost Use of Sensor-Based Digital Health Technologies in Clinical Trials

DATAcc
Digital Health Measurement
Collaborative Community



NEWS PROVIDED BY
Digital Medicine Society (DiMe) →
Oct 03, 2024, 05:45 ET

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Digital Health technologies (DHTs)



Wearables



Mobile health apps



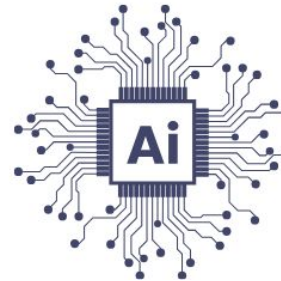
Telemedicine platform



Electronic health record



Sensors



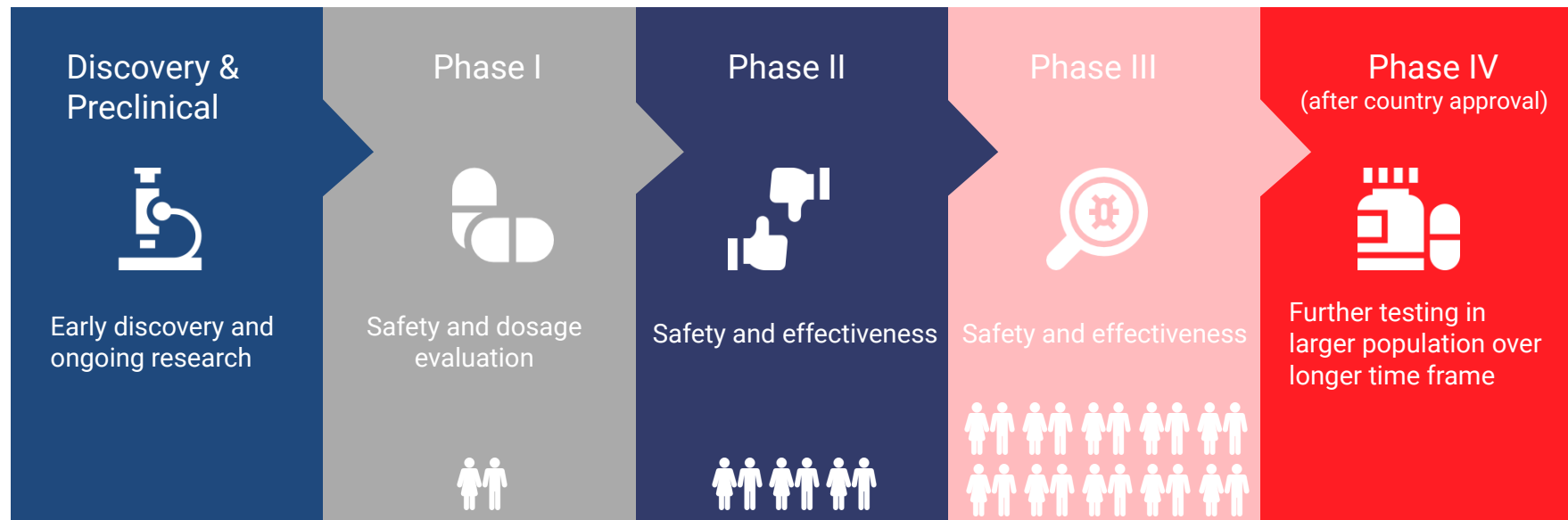
AI & Machine Learning



Blockchain

Clinical Trials

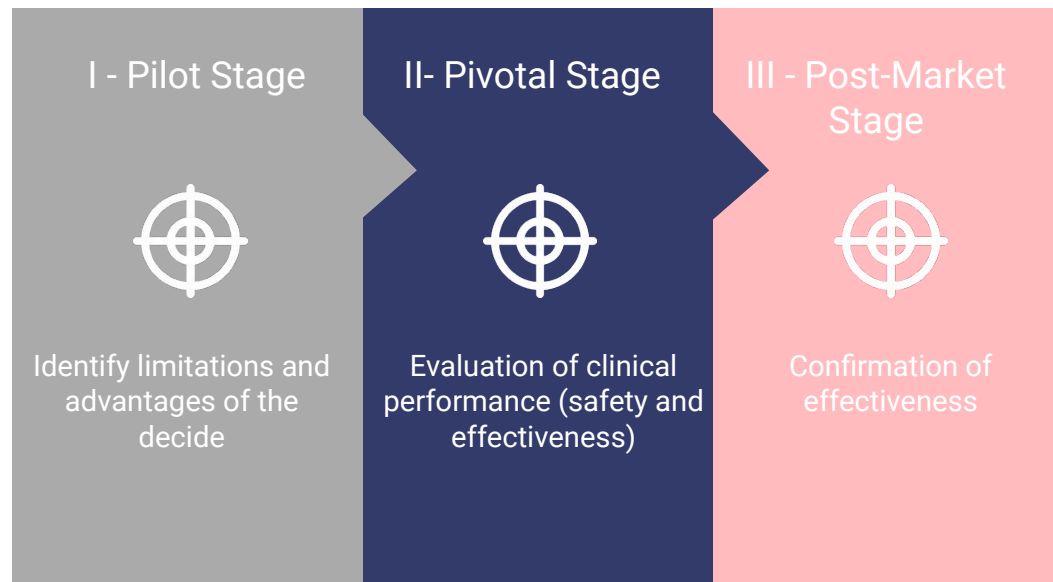
“Clinical Trials are a type of research that studies **new tests and treatments** and **evaluates their effects on human health outcomes**”



Clinical Investigations

“ Clinical investigations are clinical trials using **medical devices**.

They are the segment of clinical research for which an **investigator directly interacts with patients** in either an outpatient or inpatient setting.”



Challenges and considerations of DHTs in clinical trials



Challenges of Digital Health Technologies in Clinical Trials

DATA QUANTITY

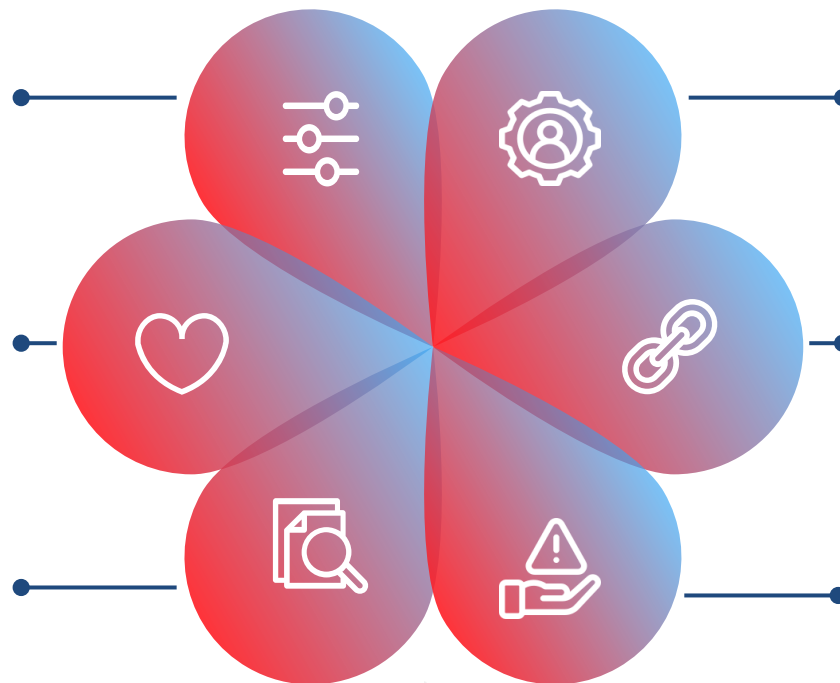
Amount of incoming data

INFORMATION FLOW

Constant flow of information

DATA ANALYSIS

Ensure data's relevance to safety, wellbeing and efficacy



RESPONSIBILITIES

Fulfilment of responsibilities

SAFETY

Safety alerts design

RISKS

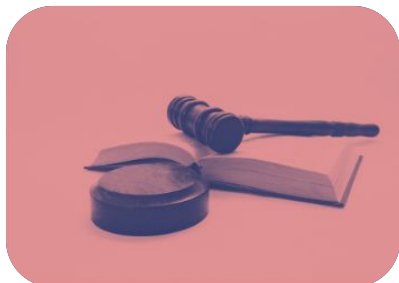
Mitigation of the different risks

Digital Health Technologies considerations

Regulatory

- Compliance with local and international regulations
- Standards
- Medical devices requirements

Digital Health Center for Excellence - FDA



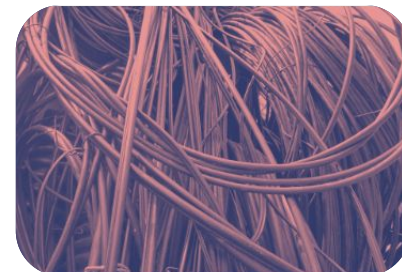
Ethical

- Informed consent (privacy)
- Equity and accessibility (digital divide)
- Data ownership
- Data usage
- Authentication
- Bias



Technological

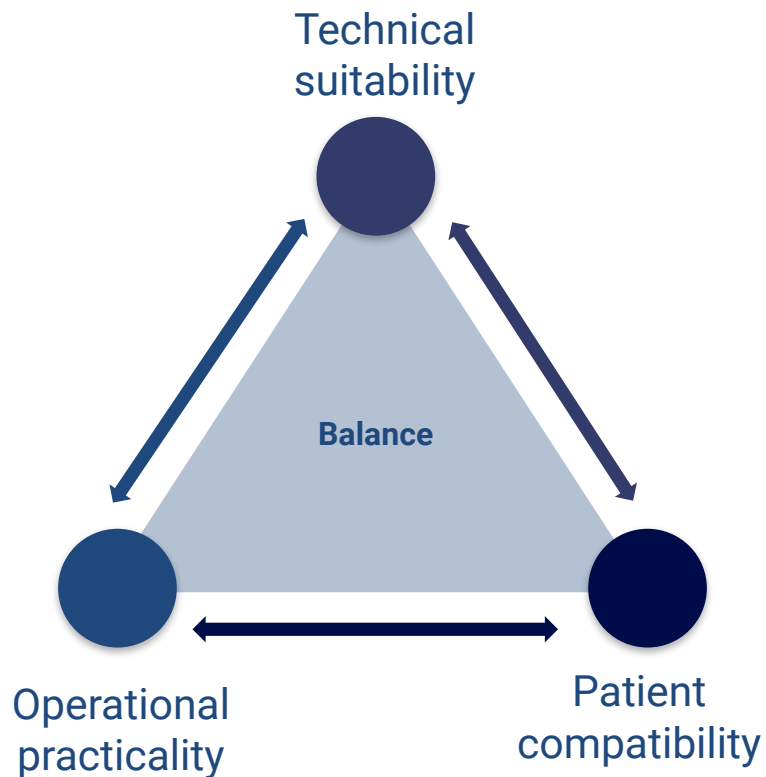
- Infrastructure
- Fit-for purpose DHTs
- Interoperability
- Data integrity and quality
- Data exchange
- Cybersecurity risks



DHT selection process



Factors to consider when selecting a DHT



Clinical trial population



Disease



Participant's age



Ability to use technology



Language



Technical and performance specifications of DHT



Design and operation of DHT

How to best proceed



Expand trial team

- Technical
- Regulatory
- Clinical
- Operations
- Patient expertise



Start with pilot studies

- Protocol adherence
- Uninterrupted data capture & transmission
- Establish healthcare provider
- Patient acceptability
- Usability



Evaluate data collection

- Timing
- Volume

Steps to evaluate a DHT

1.

Verification: confirmation by examination and provision of objective evidence that the parameter which DHT measures is done accurately & precisely (e.g. temperature)



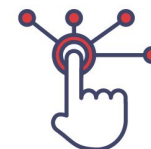
2.

Validation: confirmation by examination and provision of objective evidence that the selected DHT assesses the Clinical event or characteristic in proposed participant population (e.g. heart rate)



3.

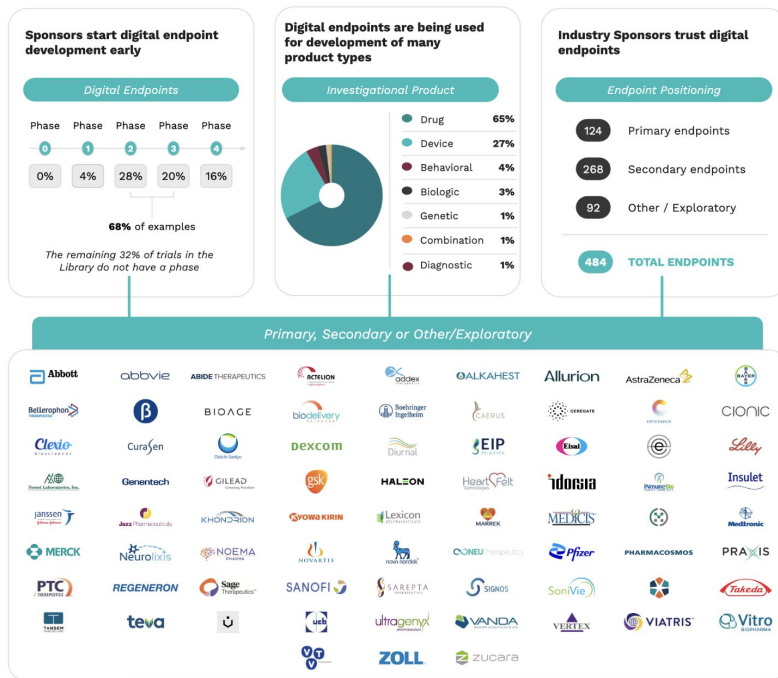
Usability: evaluation to identify and address any potential use errors or difficulties that trial participants or other intended users may experience when using a DHT (data captured should be analysed and documented with special attention to consistency of measurements, reliability and meeting regulatory standards)



Digital Endpoints

DHTs use **new ways to measure clinical characteristics or events** which were previously measured in clinical settings (e.g. blood pressure) which can lead to new insights into participants function or health.

As of 25 July 2024, **76 Sponsors** have collected **484 digital endpoints**



Library of Digital Endpoints

Digital Health Measurement Collaborative Community (DATAcc) by Digital Medicine Society (DiMe)

What is it?

A library focused on industry-sponsored studies of new medical products or application

What sources does it leverage?

1. [Clinicaltrials.gov](https://clinicaltrials.gov)
2. Community reviews eligibility of crowdsources submissions

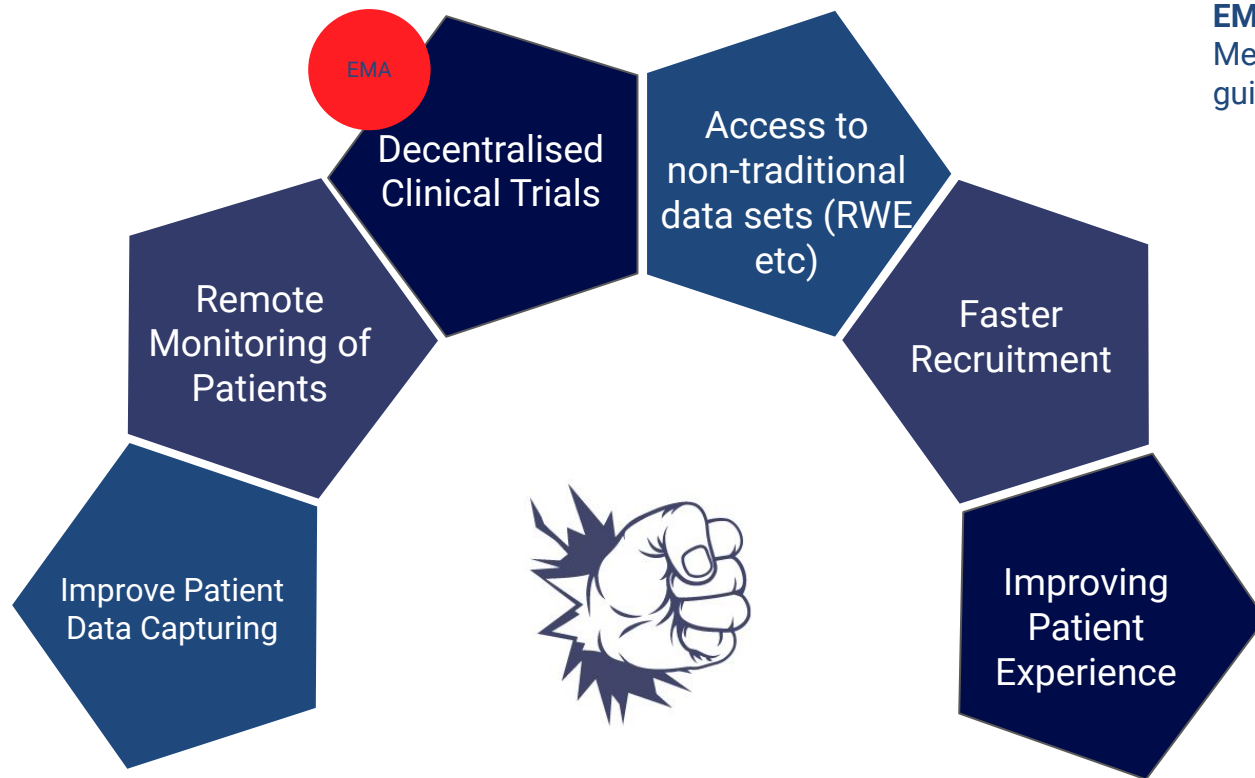
Eligibility criterias

On public clinical trial registry, industry-funded, assess regulated intervention, included specific endpoints captured by sensor-based DHT

Impact of DHTs in clinical trials



Impact of DHT in Clinical Trials



EMA: European Medicines Agency guidelines

Comparison between traditional and DHT clinical trials

DHTs Clinical Trials

Continuous data capture

Clinical trial accessible from home

Broad reach

Faster clinical trials

Decentralised clinical trials



Traditional Clinical Trials

Sporadic data capture

Travel to clinical sites

Local reach

Burden for HCPs

Centralised clinical trials

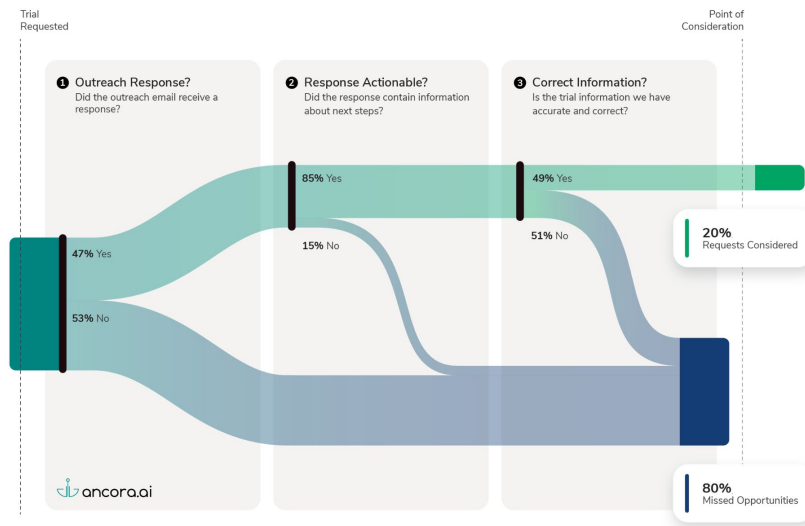
Use cases



Use case: Patient Recruitment

Clinical Trial Recruitment Barriers Prior to Consideration

Ancora.ai Patient Trial Requests
September 2021–June 2024



Challenge: Patient recruitment is main cause of delays in clinical trials leading to 30% of trial failure¹

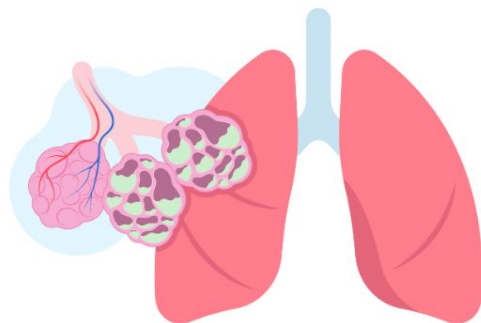
Pilot study between Tufts Center for the Study of Drug Development and ancora.ai on cancer patients

Results Identification of the pain points in the recruitment process of patients
With ancora.ai can significantly increase identification of suitable candidates for a trial



ancora.ai helps patients find personalised trials options in an easy, fast and free way leveraging AI technology

Use case: Patient engagement



Chronic obstructive pulmonary disease (COPD) is a progressive, chronic, inflammatory lung disease characterized by persistent airflow limitation.

Challenge: Patients with Chronic obstructive pulmonary disease (COPD) have difficulties detecting exacerbations and making informed decisions about the level of medical need.

Traditional solution patients use paper or online app checklists to self-manage their symptoms

DHT: Iterex is a predictive model that uses a customisable interactive Patient Decision Support app, with cloud-based access to HCPs that serves as an at-home triage option for management of COPD



Iterex Therapeutics is an app offering tools for at-home chronic health management.

Future impact of DHT on clinical trials



Future of DHTs in Clinical Trials

- ➡ Digital Health Technologies with sensors revolutionise the way we collect data
- ➡ Transform patient engagement
- ➡ Shift toward gathering holistic data
- ➡ Design trials which impact patient's quality of life
- ➡ Use of blockchain (data integrity and transparency)
- ➡ Clinical trials information system in Europe 

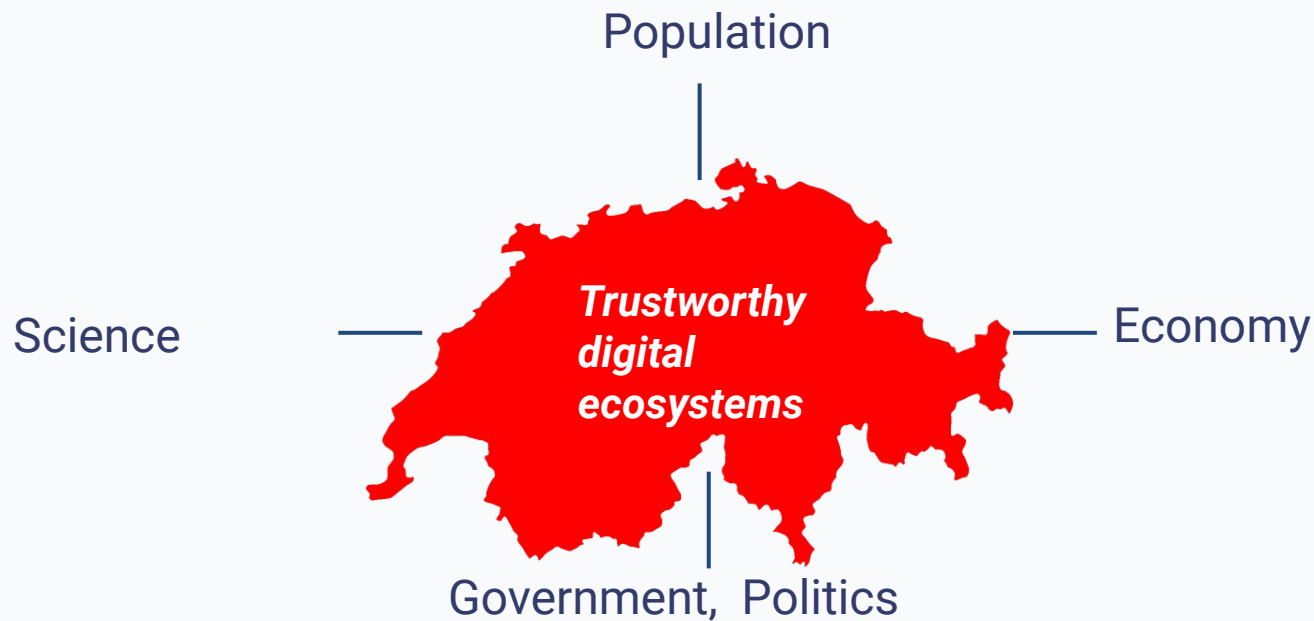


Best approach: Combination of digital approaches with traditional activities requiring for in-person visit to study site

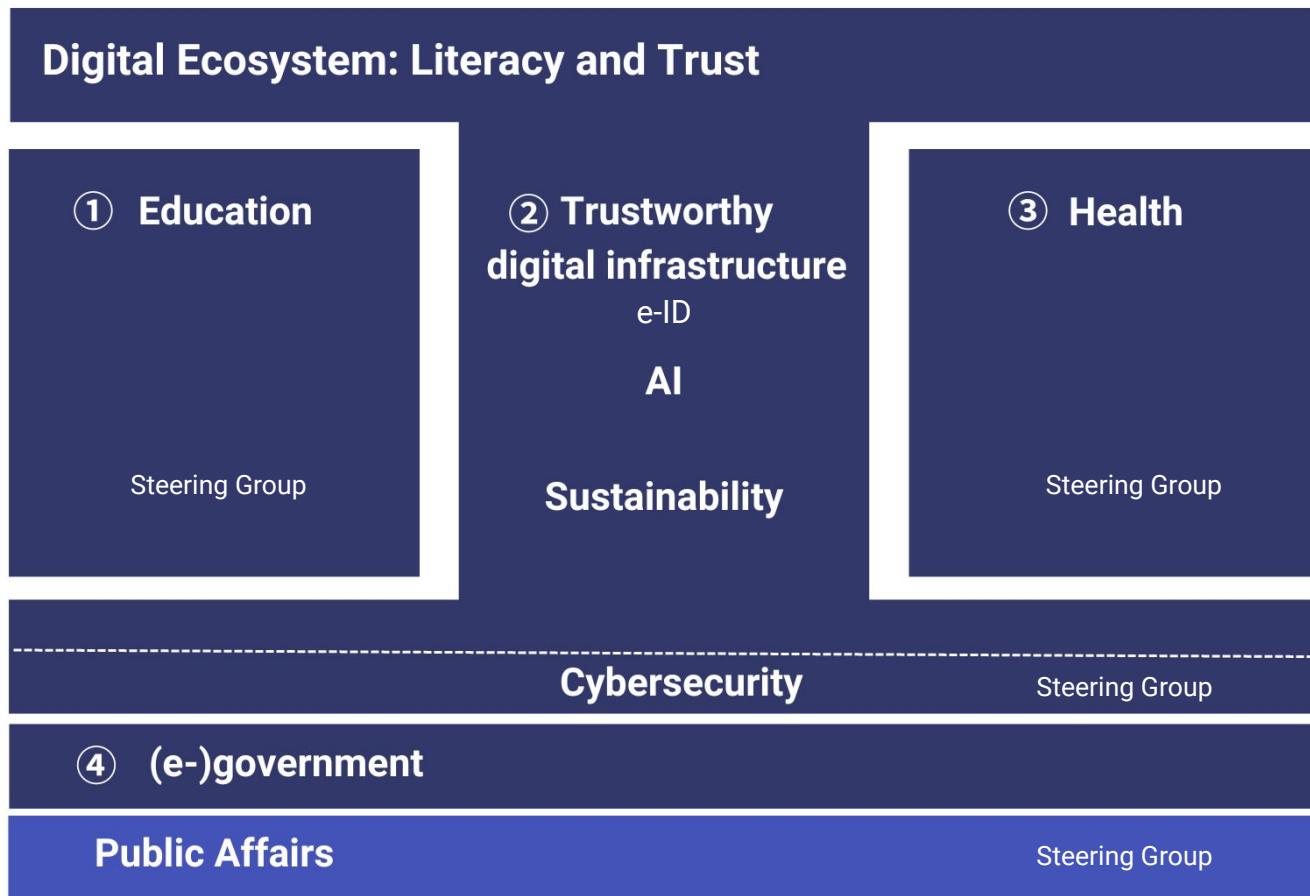
digitalswitzerland



Our mission is to transform Switzerland into a leading digital nation



Focus



Digital Health

We want to **digitalise** the entire healthcare system in Switzerland and make it **patient-centric**

Digital Health Steering Committee

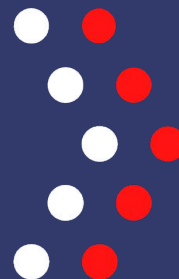
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 Susanne Weissbäcker EY-Parthenon	 Alexandros Giannakis Accenture	 Thomas Gross BINT & ofac	 Pius Zängerle curafutura
 Mathias Becher FOPH	 Toni La Rosa ELCA	 Matthias Glück Post	 Ivo Schmid IBM
 Garif Yalak Cisco	 Andri Färber AD Swiss	 Anna Lisa Martin-Niedecken ZHdK	

Stakeholder Group

- Medical/Hospital industry
- Insurance industry
- Pharmaceutical industry
- Patient
- Government
- Technical providers

We want to **bridge** the **existing gaps** to ensure a **coherent efficient healthcare network** in Switzerland as a **neutral** player **orchestrating all stakeholders** of the ecosystem

Thank you!



For more information visit

<https://digitalswitzerland.com/>

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