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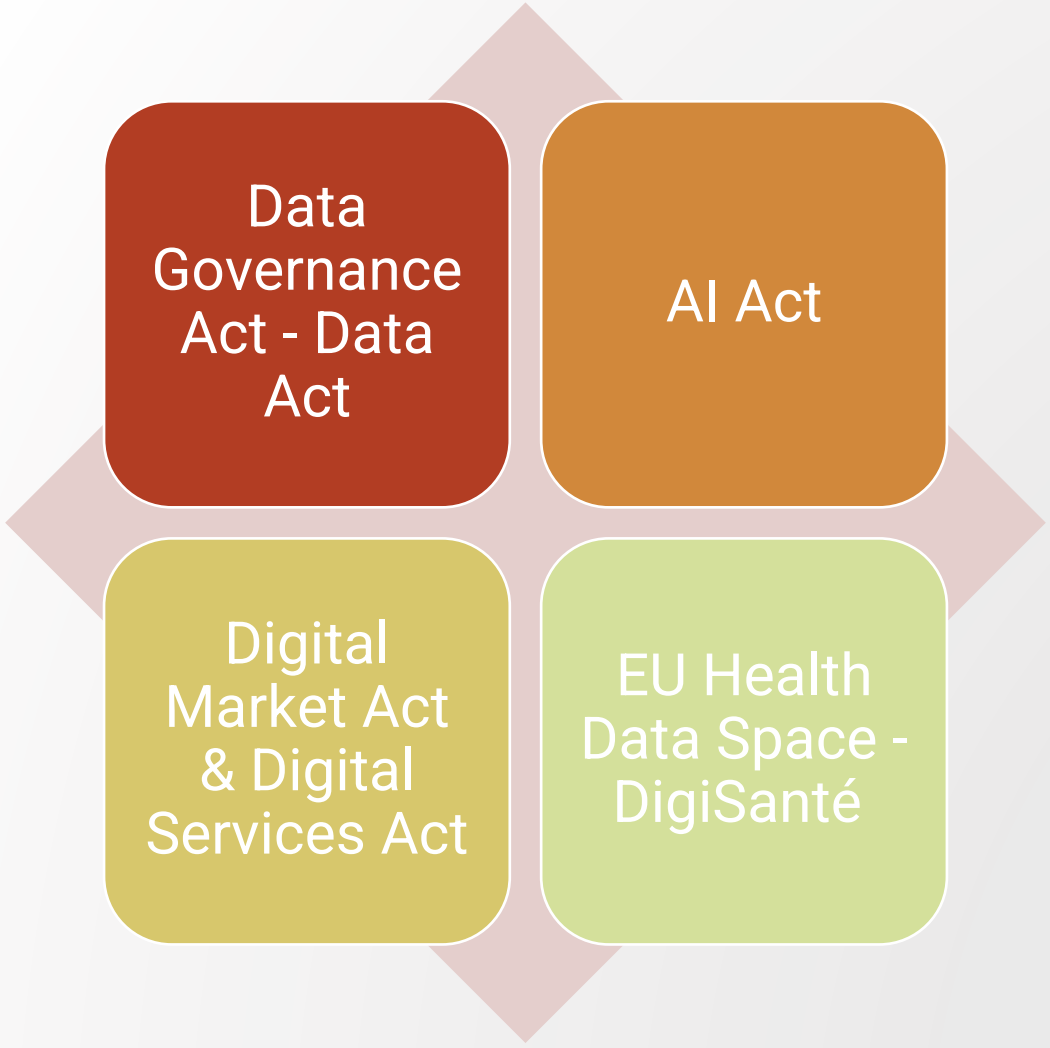
EU privacy & data protection

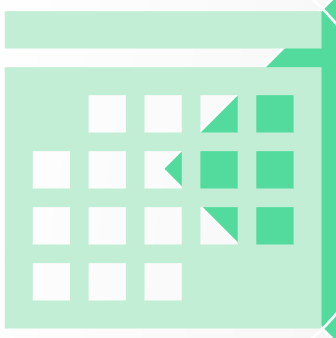
The EU's Digital Health Strategy

Regulation around data



Data Governance Act

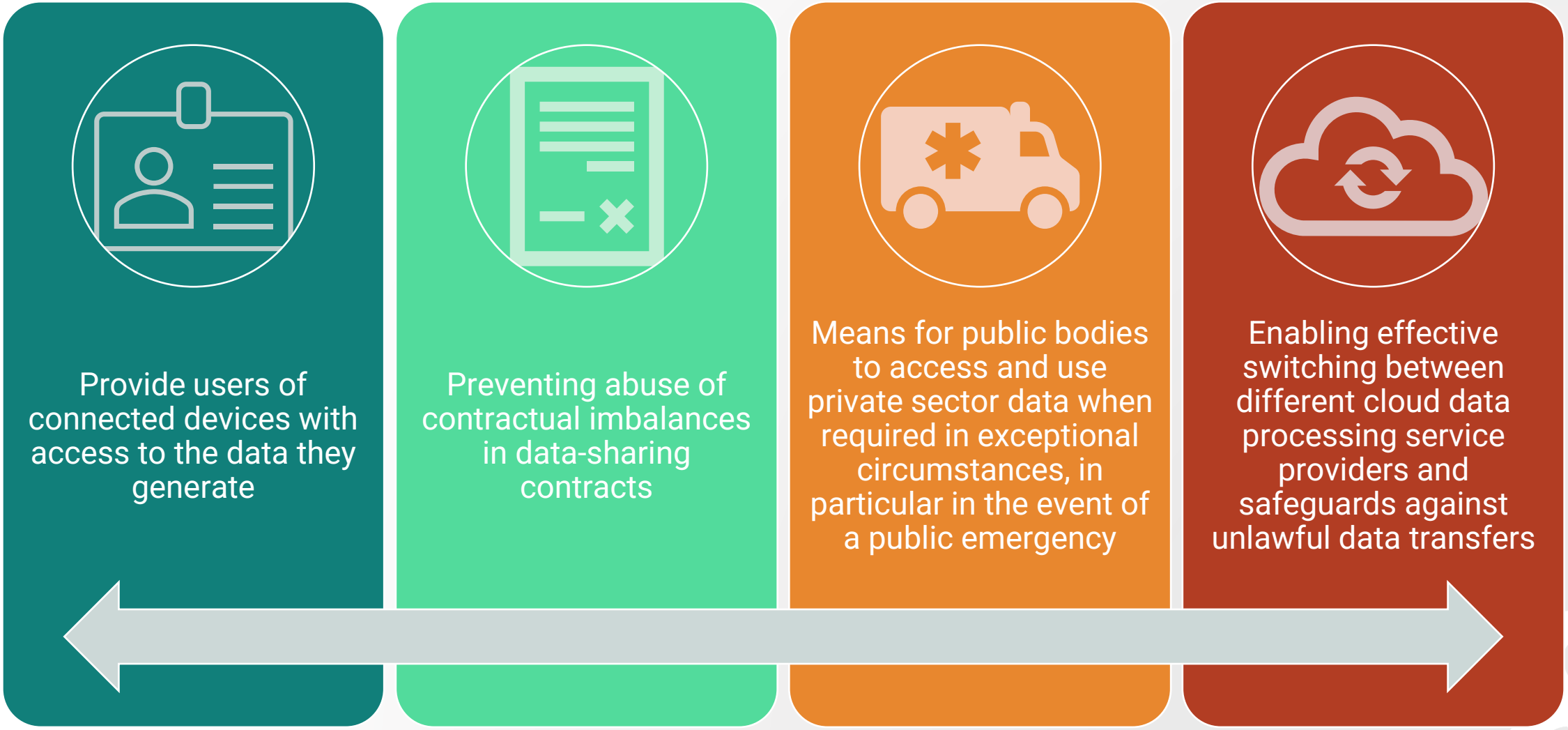
The aim of the initiative is to make more data available and facilitate data exchange between sectors and EU countries in order to harness the potential of data for the benefit of European citizens and businesses



Entered into force on 23 June 2022 and will apply from September 2023 after a grace period of 15 months

https://digital-strategy.ec.europa.eu/de/policies/data-governance-act

Data Act



https://ec.europa.eu/commission/presscorner/detail/de/ip_22_1113

AI accelerates medical research

AI leads to the development of new treatments and cures for various diseases

AI analyzes large and complex datasets, identifying patterns and insights that may not be visible to humans alone

AI aids in the development of new treatments and therapies by quickly identifying potential drug candidates and predicting their efficacy and safety

AI can streamline clinical trials by identifying suitable patient populations, monitoring patient safety, and improving data collection and analysis efficiency

EU AI ACT

The text might still be subject to minor adjustments at the technical level. It is expected to go to a plenary vote in mid-June

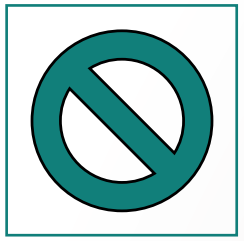
Many criticisms have been raised

Many amendments have been proposed to the Parliament

The regulatory landscape is very complex (many divergences between EU regulations)

EU countries are already struggling to comply with the GDPR

AI Act regulates 3 types of AI systems



Prohibited AI systems

Art. 5

High-risk AI systems

Art. 6 and Annex III

AI systems that require transparency

Art. 52

Newly inserted: General purpose Art. 4a - 4c

Digital Market Act & Digital Services Act

DMA

The Digital Markets Act contains rules for gatekeeper online platforms

Gatekeeper

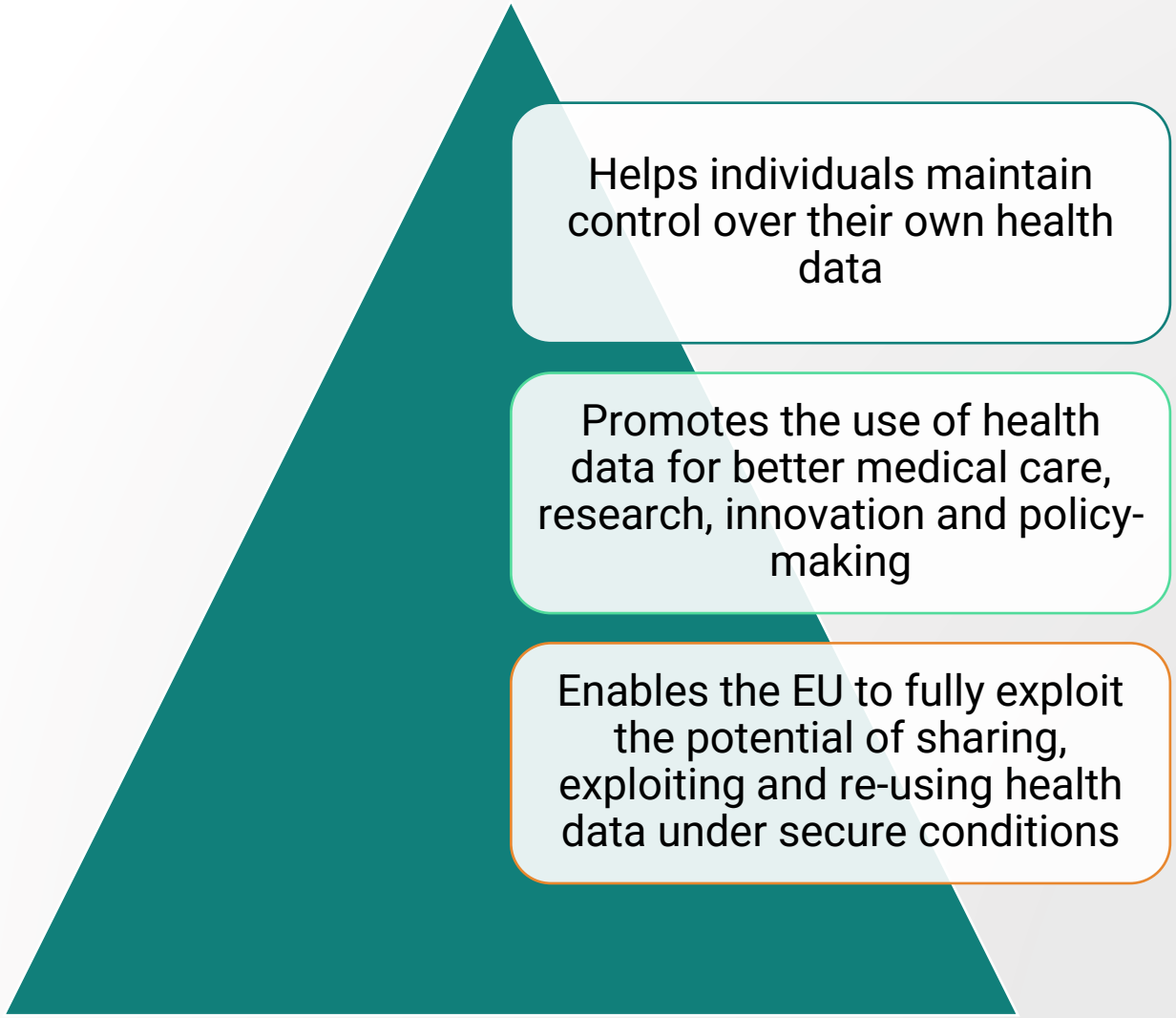
Gatekeeper platforms are digital platforms with a systemic role in the internal market that act as bottlenecks between businesses and consumers for key digital services

DSA

Some of these services are also regulated in the Digital Services Act, but for different reasons and with different types of provisions

https://digital-strategy.ec.europa.eu/de/policies/digital-services-act-package

EU Health Data Space



https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_de

DigiSanté

DigiSanté is the EDI's programme to promote digital transformation in healthcare

It is being developed on behalf of the Federal Council and will be developed jointly by the BAG and the BFS by the end of 2023

Implementation will take place from 2025

https://www.bag.admin.ch/bag/de/home/strategie-und-politik/nationale-gesundheitsstrategien/digisante.html

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Swiss data protection

What’s in store for me, what do I have to do?

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Agenda

Medical apps with user data - When does user data become so-called health data and how should it be handled?

Use of data from clinical trials and post-market surveillance measures according to MedDO / EU MDR - What should be considered when using the data in the technical documentation?

An example of the distinction between electronic patient records and medical devices.

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What are health data?

Art. 4 No. 15 GDPR defines health data as personal data relating to the physical or mental health of a natural person, including the provision of health care services, and revealing information about his or her state of health.

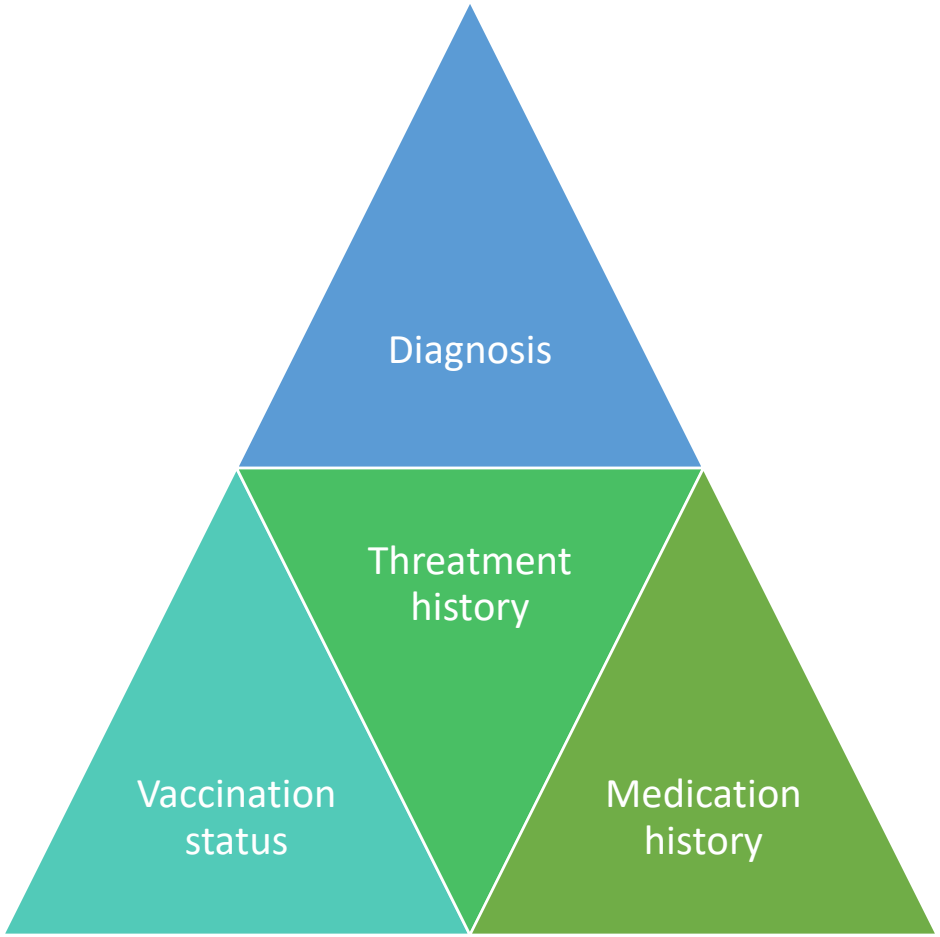
Personal health data also includes information about the natural person that is collected in the course of registration for as well as the provision of healthcare services as defined in Directive 2011/24/EU. This is numbers, symbols or identifiers assigned to uniquely identify the natural person for health purposes.

Information derived from the examination or testing of a body part or bodily substance, including from genetic data and biological samples, is also included, as well as information about, for example, diseases, disabilities, risks of disease, pre-existing conditions, clinical treatments, or the physiological or biomedical condition of the data subject, regardless of the source of the data, whether it comes from a physician or other health professional, a hospital, a medical device, or an in vitro diagnostic device.

Taking into account the case law of the ECJ on the Data Protection Directive, the concept of health data is to be interpreted broadly, also under the application of the GDPR, so that it refers to all information relating to the health of a person from all aspects, both physical and mental. This also includes information that a person has injured his or her foot and is on partial sick leave.

Medical apps - When does user data become so-called health data and how should it be handled?

Examples



Health data in health apps

– Where are the data? – Why is this relevant?

Awareness of which products store data.

Where are the data? On smartphone or cloud or both?

How to remove the data?

How to make the data safe againts unauthorized access?

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Use of data from clinical trials and post-market surveillance measures

What should be considered when using the data in the technical documentation?

In the focus: Processes / SOP`s - Employee training - Privacy policy

What are the **processes and documents** regarding workflows for

- Clinical trials
- Clinical evaluation
- PMCF
- PMS

?

Anonymization of data is a key point.

What are the data collected, stored and used for and why?

What is the legal basis and interest?

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An example of the distinction between electronic patient records and medical devices.

– What is the difference?

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An example of the distinction between electronic patient records and medical devices.

– What is the difference? The Definition is the difference

(1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— **diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,**

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— **providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body**, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

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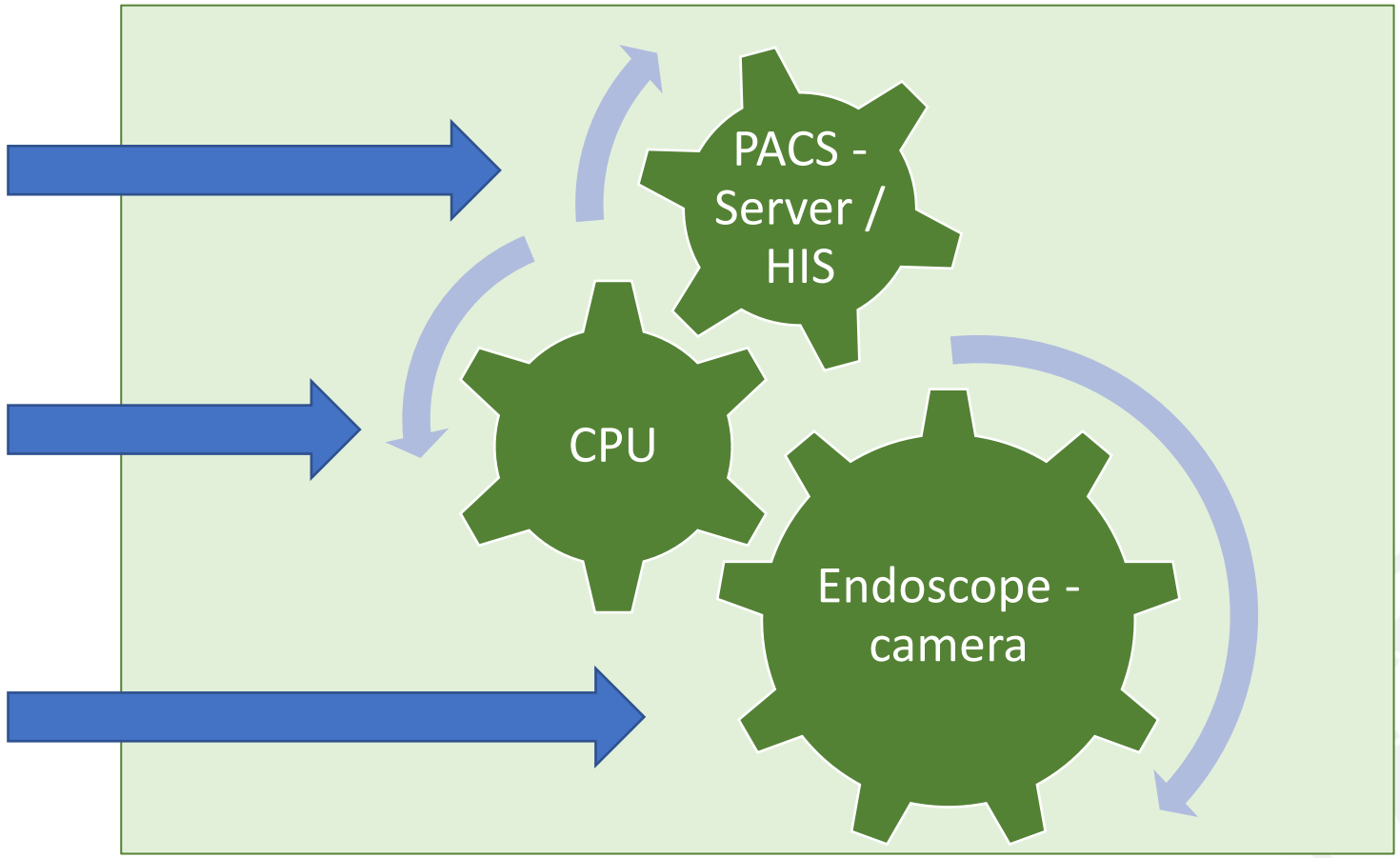
An example of the distinction between electronic patient records and medical devices.

– What is the medical device and what the patient record?

Patient record
is not a medical device, if outside the medical device and defined as patient record system

Medical device
with memory for images and preparation of transfer to PACS

Medical device



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01

Your Regulatory
Compliance is our job!

02

We are engineers and scientists from medical technology and related fields with many years of experience.

03

You can receive support from us in all matters relating to the conformity of medical devices in Switzerland, EU / EEA and other countries.

Prof. Dr. Frank Stein

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Questions & Answers

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