Transfer of Innovations and Research Results Through Standards into Healthcare

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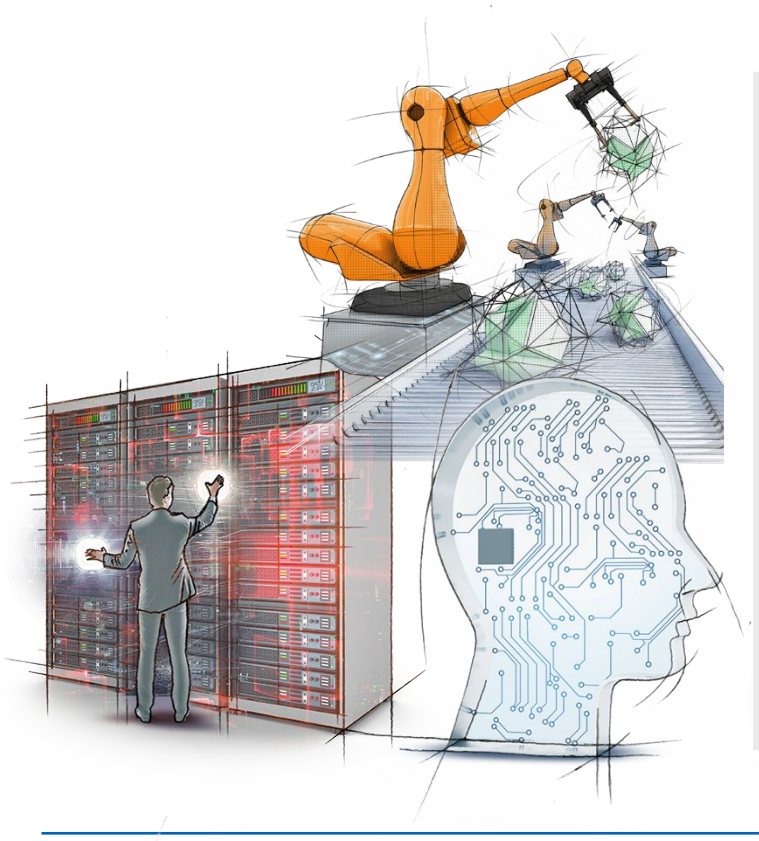
DKE

DKE is the trusted platform for:



- standardization,
- cooperation
- and the interaction of experts

in the areas of:

- electrical engineering
- Electronics
- information technologies

What drives us:

The VISION of standardization – for a livable future for all people

The VISION of standardization

- Taking responsibility for safety and progress in electrical engineering and information technology.
- Developing economic standards and services fully aligned to customers needs.
- Being a worldwide trusted digital based platform for the exchange of knowledge and networking of society, politics and industry.
- Creating a working atmosphere that attracts and develops the best experts of the community.
- Supporting the European market.

Source: sdecoret / stock.adobe.com

What you need to initiate standards (in healthcare)?

- You need a New Work Item Proposal (hopefully on international level). Why international level? Because the healthcare standardization is driven by IEC and ISO for a global market access.
- What for a committee?
- What for publication type?
  International Standard (IS)?
  Technical Specification (TS)?
  Publicy Available Specification (PAS)?
- Level of consensous with regard to acceptance and number of countries.

Source: sdecoret / stock.adobe.com

What is the content of a standard for the NP and how long dos it take to become a standard?

- Product requirements and/or process requirements. Clearly defined
- Specific pass-fail crteria
- Good explanation in the informative Annex to each requirement.
- Time schedule from 12 to 36 month

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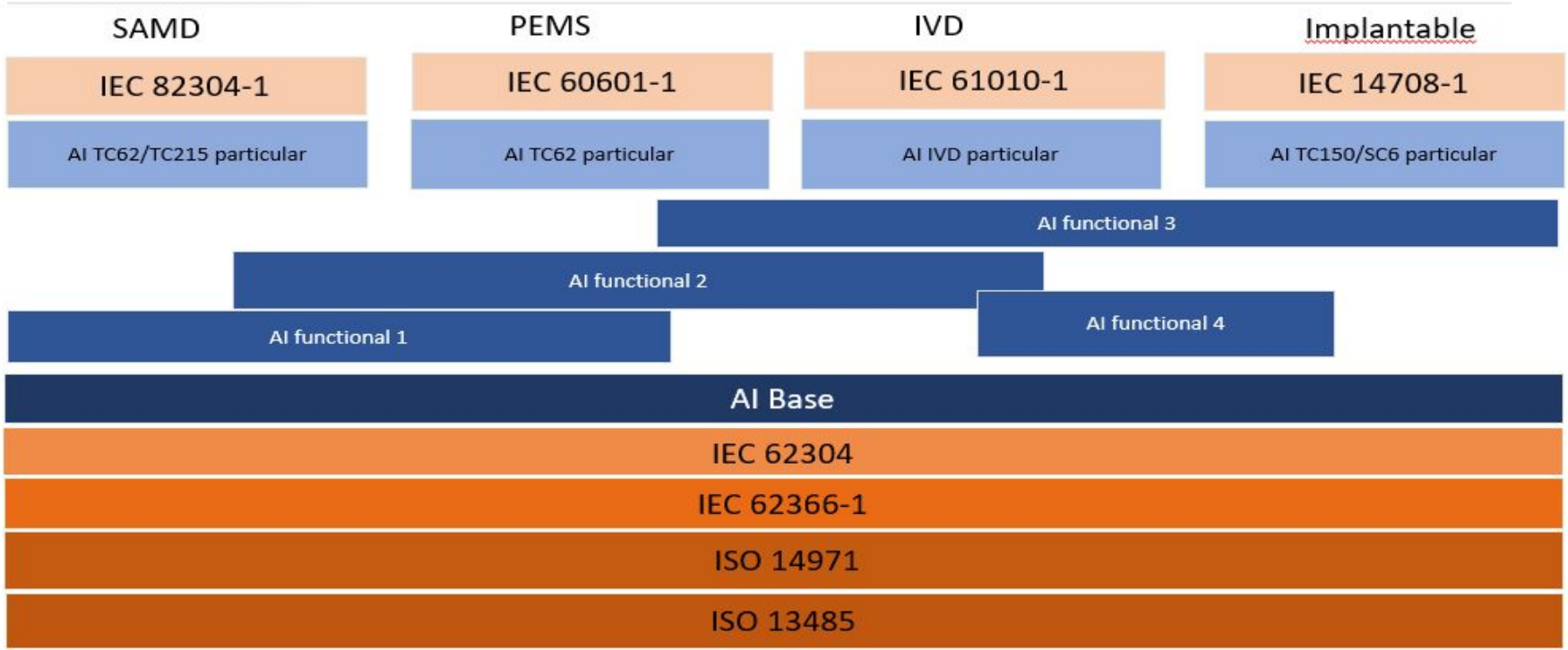
An example on „artificial intelligence“ – for emerging technologies – how to fit in the system framework for healthcare

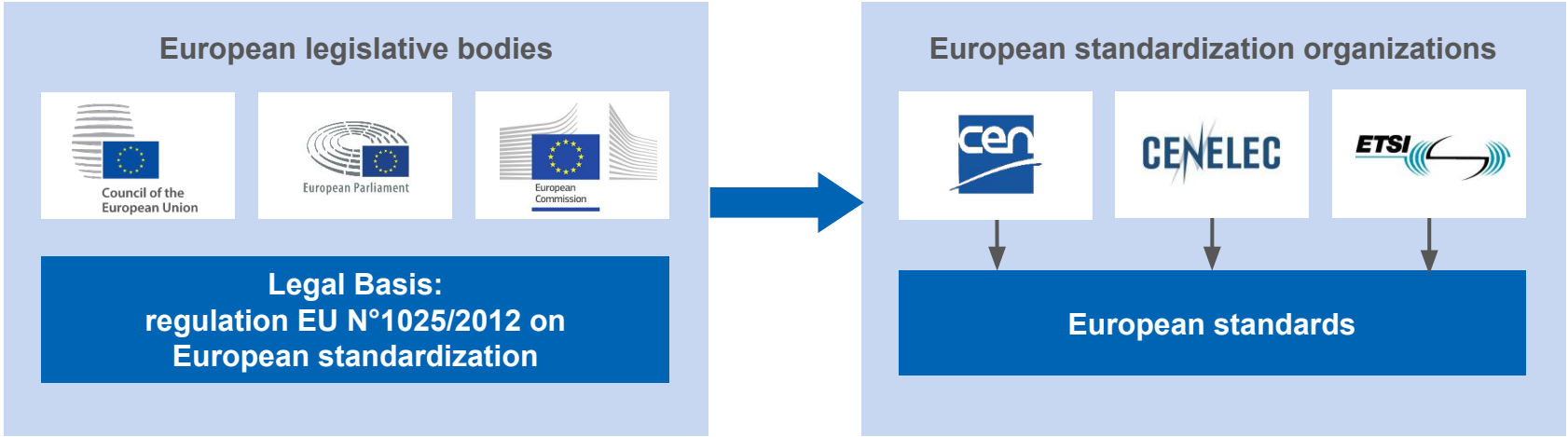


Other borderlines/challenges in healthcare

- Regulatory framework in different areas in the world.
- US the FDA is responsible - acknowledged by recognized standards.
- EU Medical Device Regulation by Harmonized and Listed standards.
- Other areas…. Hopefully the IMDRF (International Medical Device Regulator Forum) will provide help.
- Standards will have a more.added value, if these will be accepted by the regulators in regions around the world.

Source: sdecoret / stock.adobe.com

European standardization system in the European single market



Thank you
for your attention!

We are building the e-dialistic future.
Please join us.

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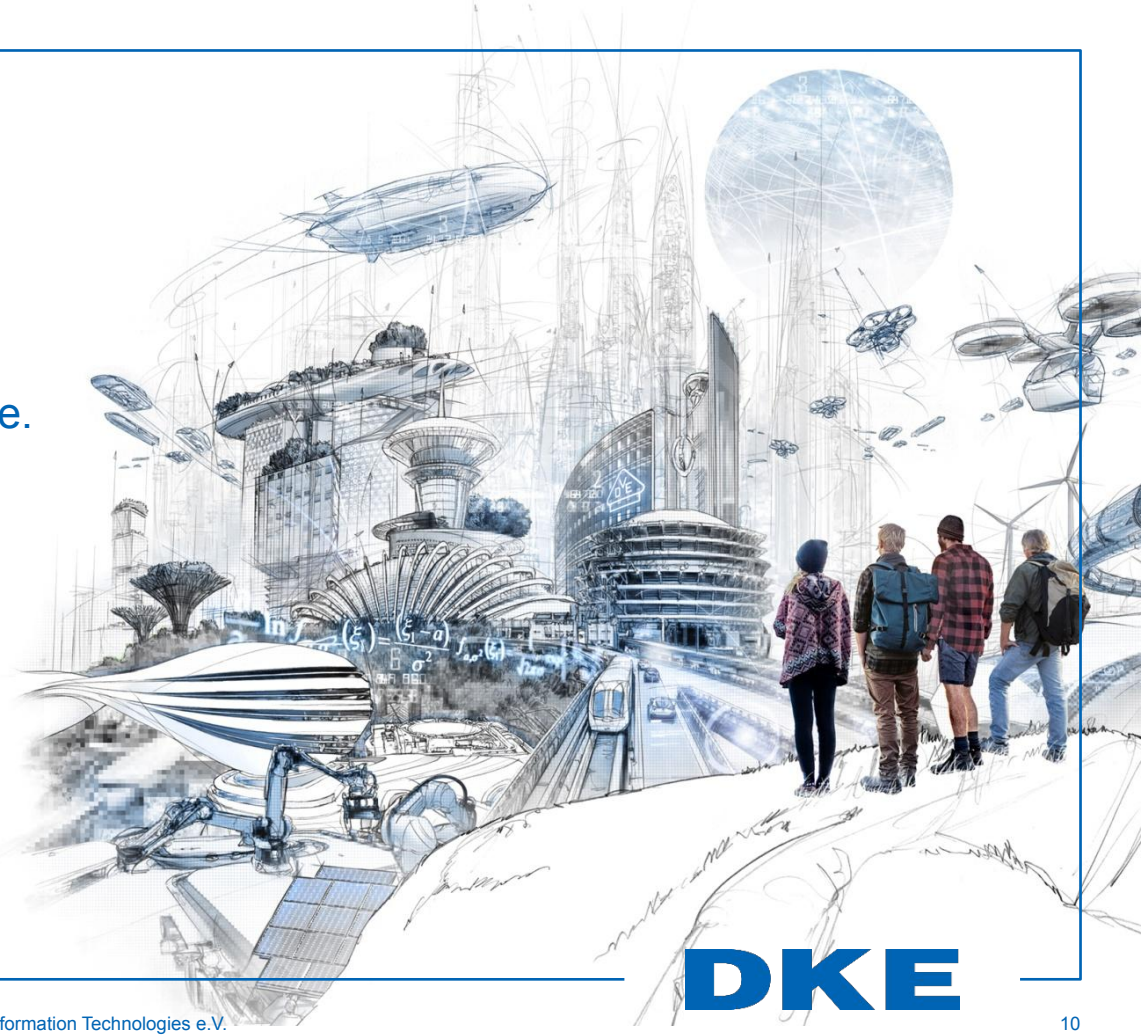

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