Frequently mentioned possible barriers in the collaboration between technicians and clinicians are different communication styles (e.g., jargon), various visions and interests, different responsibilities and diverse types of knowledge. When looking at technical innovations, technicians tend to develop complex solutions whereas clinicians desire a more practical solution. Furthermore, there is a lack of awareness among clinicians of what is technically feasible. Due to this knowledge gap, technicians are often not involved in the beginning of a research project. Additionally, clinicians sometimes have a conservative mindset regarding (technical) innovations in clinical care. On the other hand, technicians sometimes come up with solutions that lack clinical insight.

Abovementioned barriers are noticeable in all research stages. The typical pathway of clinical research for a clinician consists of the following components: 1) idea, 2) design, 3) execution, 4) data processing and 5) reporting (Figure 1). The technician’s entry point into research typically comes later, as technicians often conduct their research on clinical data. This often results in conflicts during research due to a mismatch in expectations and responsibilities in data collection. For example, technicians are often unaware of the labour intensity and clinical implications of certain procedures. In the most optimal setting, technicians are involved in the first and second stage of a clinical study.

The difference between technical and clinical research is further illuminated by the possibility of adapting or extending research with new ideas. While technicians can easily design new research questions using the collected data, clinicians often need to set up completely new research due to clinical research regulations.

Our recommendations for the advancement of clinical research implementation can be summarized as follows (Figure 2):

- Communication in each stage of the research project is essential.
- Technicians and clinicians should learn to speak the same language.
- Regular (informal) meetings could contribute to overcoming the knowledge differences between clinicians and technicians.
- Regular (informal) meetings could result in new research ideas.

What do you need in the regulatory domain to implement your product in the clinic? The primary requirement is the Medical Device Regulation (MDR).

In this session, we will study some of the required technical documents and the logic behind them. Additionally, we will also delve into Artificial Intelligence (AI) ethics, which will soon be legislated by the EU.

The MDR is a regulation, directly applicable in all EU countries. It governs patient safety and compliance with it leads to a CE mark, which is valid throughout Europe. This MDR also applies to clinical studies. The former directive was no longer adequate, a fact that became evident through various scandals, such as the breast implant incident.

Changes in the MDR compared to the previous situation include: more clinical evidence is required, as is increased transparency; there’s a greater emphasis on post-surveillance research and a shift in classifications, with many products moving to higher classes. This means there’s a quicker need for a notified body. A notified body evaluates the evidence of whether a medical device is safe and meets the CE mark standards. They have the authority to award the CE mark. Every device now carries a Unique Device Identification (UDI) code. Additionally, the EU has set up Eudamed, the European database in which all medical devices are listed and where all ongoing studies are tracked.

There is a transition period for MDs to shift from the previous situation to comply with the new MDR. Making adjustments to an existing MD under the old legislation is impactful, as it then needs to meet the new MDR standards. This can be rather cumbersome, leading companies to decide against updating certain MDs and even withdrawing products from the market.
market. It’s not only the manufacturer that is subject to the MDR, but also the supply chain partners. The implications of this can be extensive, to the point where certain MDs might no longer be available for patient care. Apart from the MDR, there are other laws, standards, and guidance documents that one may encounter, such as the ICH GCP (Good Clinical Practice), the Dutch law on medical scientific research.

EU Legislation is currently being developed and is aimed at securing fundamental rights and safety. Additionally, it is part of a digital framework including laws on the AI liability framework, safety regulations, the Cybersecurity Act, etc.

For AI, a risk classification has been established with four levels. Within this framework, risk is firstly defined in terms of transparency and information provisions to the users. Secondly, an AI system is considered to be high risk if it is a safety component of products such as medical devices. 

This doesn’t necessarily mean that certain activities or applications are prohibited, but that there are heightened requirements in terms of transparency. Ten standards are going to be established for AI systems:

**HIGH-RISK SYSTEM STANDARDS**

1. Governance and quality of datasets used to build AI systems
2. Transparency and information provisions to the users
3. Human oversight of AI systems
4. Technical robustness and safety
5. Privacy and data governance
6. Diversity, non-discrimination and fairness
7. Environmental and societal well-being
8. Accountability
9. Human rights assessment, democratic values and rule of law
10. Conformity assessment for AI systems

There is also an ethical standard comprising seven ethical principles, often used in research. It adopts a lifecycle approach, meaning that these items must be continually reviewed and addressed.

**ETHICAL STANDARDS IN AI**

1. Human agency and oversight
2. Technical robustness and safety
3. Privacy and data governance
4. Transparency
5. Diversity, non-discrimination and fairness
6. Environmental and societal well-being
7. Accountability

**THE ALTAI PRINCIPLES**

- **1.** Human agency and oversight
- **2.** Technical robustness and safety
- **3.** Privacy and data governance
- **4.** Transparency
- **5.** Diversity, non-discrimination and fairness
- **6.** Environmental and societal well-being
- **7.** Accountability

Probably also: human rights assessment, democratic values and rule of law

For example: No. 1 addresses the role of the human being, e.g., the one who bears responsibility. No. 5 pertains to data collection, emphasizing the importance of avoiding bias, but also regarding discrimination and tackling the complexity of acting on AI’s predictions.

While these principles are set, implementing them requires collaboration from all disciplines to make the right decisions, not just ethicists, for example.

**IMPLEMENTATION SCIENCE: A BEACON OF HOPE FOR LOW/MIDDLE INCOME COUNTRIES’ HEALTHCARE?**

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Low/middle income countries with concurrent low health status of the population stand to benefit more from implementation science in healthcare than high-income countries, given the triad of high need, high potential, and low existing capacity. Nonetheless, studies about implementation science have shown that a technology (or a training course, a protocol, etc.) which works in one setting under certain conditions may not be appropriate in other circumstances. One important aspect to consider is a difference in cultures between the place where a technology was developed and where the technology is intended to be implemented. To understand differences in cultures between countries, the theory of the Culture Map by Meyer can be used. In this theory, national cultures have been mapped on eight scales (Fig 1.). We will highlight three of these scales and give examples of how these differences can lead to challenges, drawing from past experiences in the Netherlands, China and Uganda.

**Communicating**

Meyer differentiates low-context communication from high-context communication. In countries with low-context communication, messages are expressed and understood at face value. Good communication means it is precise, simple and clear, and repetition is appreciated. In contrast, in countries with high-context communication, messages are spoken and read between the lines. They are implied but not plainly expressed and good communication is sophisticated, nuanced, and layered. As a result, people from low-context cultures are appreciated, while often misunder-stand people from high-context cultures.

While these principles are set, implementing them requires collaboration from all disciplines to make the right decisions, not just ethicists, for example.

**Evaluating**

In Meyer’s theory, countries can range from a direct negative feedback style to an indirect one. The direct style means that feedback is provided frankly, bluntly and honestly. Negative messages are not softened by positive ones, absolute descriptors are used e.g., totally inappropriate, completely unprofessional) and criticism may be given to an individual in front of a group. On the other end of the scale,