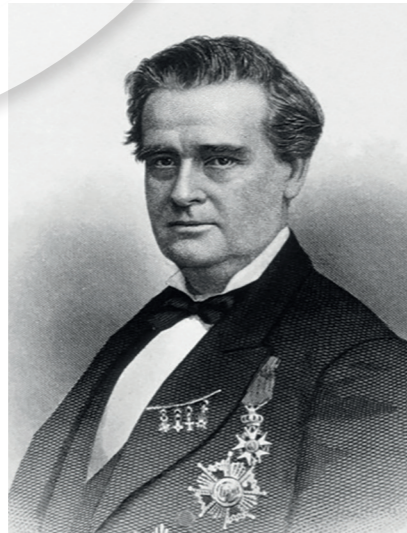


## HARMONIZING MEDICINE AND ENGINEERING: TEAMWORK IN CLINICAL RESEARCH AND IMPLEMENTATION

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**In the world of medicine, technology is assuming an increasingly significant role. The collaboration between technician and clinician in this process is essential. This collaboration can be challenging, but when optimized it will give new opportunities. The different aspects within this collaboration will be further illustrated in order to harmonize medicine and engineering in scientific research and clinical implementation.**



*Portrait of Dr. Sims in the nineteenth century*

attributed to several influential conservative fertility professors who found it challenging to let go of the postcoital test. Conversely, the later implementation of hygiene measures in rural France compared to Paris can be attributed to political decisions. More disconcertingly, cholera's presence in contemporary regions like Malawi underscores the disparity in implementation speeds based on location.

Mark Bauer's treatise on implementation science delves into the nuanced differences between controlled research environments and the unpredictable real world. Transitioning from efficacy (conceptual effectiveness) to proving its effectiveness in varied settings and finally to actual implementation demands an understanding of a multitude of external variables. The crux of implementation science pivots on not just gauging the impact of an innovation but more pertinently, on discerning the multifarious elements influencing its day-to-day adoption.

In this context, Laura Damschroder's 'Consolidated Framework for Implementation Research' (CFIR) stands out as a beacon. The CFIR meticulously demarcates potential factors under five broad domains that can influence implementation:

- + Intervention Characteristics
- + Outer Setting
- + Inner Setting
- + Characteristics of Individuals
- + Process

A case in point is Rebecca Hamm's foray into obstetrics. The introduction of an 'obstetric haemorrhage bundle' bore contrasting results in Pennsylvania and California. The defining difference? California's recourse to the CFIR framework. Apart from the CFIR, other frameworks for implementation have been developed and validated as well. It probably doesn't matter much which framework you use; what's more important is to have a framework in the first place.

### Key Takeaways:

1. The indispensability of a structured framework.
2. The imperative of stakeholder engagement.
3. The weightage of qualitative research.
4. The importance of documentation and knowledge dissemination.
5. Gleaning insights from real-world scenarios.

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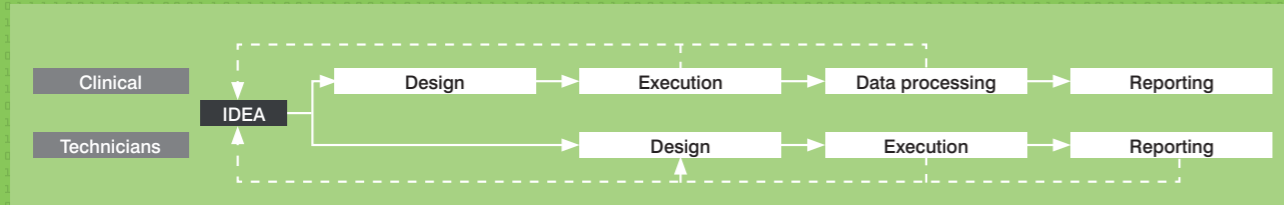


Figure 1. The different pathways of (clinical) research for clinicians and technicians. Alongside the early involvement of technicians in clinical research, we strongly advise technicians and clinicians to meet on a regular basis, both formally and informally. These regular interactions are expected to improve the ease of communication and the sharing of data and knowledge. While these interactions are important for the division of responsibilities and the management of expectations, they could also serve to include technical knowledge in the optimization of the clinical research workflow or to test technical ideas for their clinical implementation. Last of all, informal meetings might result in new research ideas, as they might help to bridge the gap between technical feasibility and clinical desire.

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.

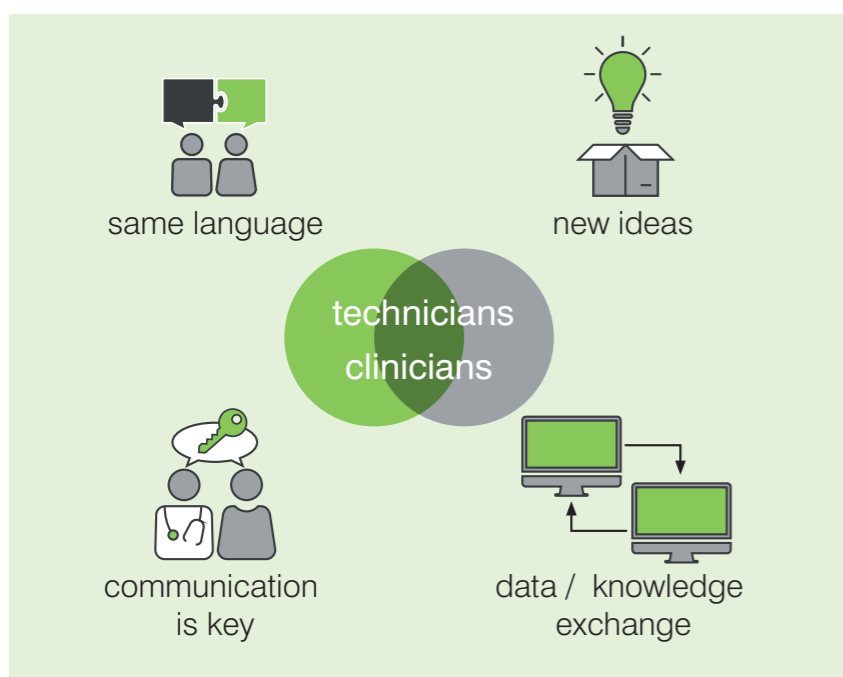


Figure 2. Key features in optimizing teamwork between technicians and clinicians

## RAPID ROUTES TO REALITY: ETHICAL DILEMMAS IN FAST-TRACKING CLINICAL DEVICE IMPLEMENTATION

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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.

The MDR requires a quality management system for manufacturers, the ISO 13485. From this quality management system, documents such as technical documentation necessary for the Investigational Medical Device Dossier (IMDD) for clinical studies are derived.

A Medical Device (MD) is a non-pharmaceutical tool (software, implant, device, reagent, etc.) with the objective of addressing diseases (e.g., diagnosis, monitoring, treatment, etc.). It can also play a role in an injury/impairment or pertain to the investigation, replacement, or modification of anatomy/physiology, or provide information through in-vitro studies or body specimens, such as the coronavirus test.

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