FAST TRACK TO CLINICAL INNOVATION
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Introduction

Our health and our healthcare are under pressure. Covid-19 has clearly shown the value of health to people and society at large, but also the capacity and cost limits of our existing healthcare system. The usual short-term reaction to a crisis like Covid-19 is to see to capacity expansion and making funds available. However, a more breakthrough solution is required to cater for a healthy life at an affordable cost. This paper is not about Covid, but rather about sustainable health and care approaches for our future. In short, it is about innovation.

For many years the rising cost of healthcare been subject of global discussion. Although cost in the Netherlands are not among the highest in the world, even though the Netherlands is ranked amongst the highest quality healthcare systems, they are systematically rising and without breakthrough they will soon become unaffordable. Aging population and higher treatment cost are key factors.

At the same time there is rising attention to the outcome of healthcare, particularly the valuation of healthcare in a multi stakeholder approach, with specific interest for patients. The Value Based Healthcare approach introduced by Porter et al. is gaining traction but a structural implementation beyond pilot projects is still a challenge.

The key barriers often cited for hampering structural cost reduction while creating better outcome are:

+ the siloed approach in various healthcare modalities
+ the lack of structural data sharing between specialists, hospitals, across the value chain
+ the focus on developing new interventions rather than optimizing the overall system
+ financing systems that reimburse for treatments

How to create a breakthrough across all these barriers? The Eindhoven MedTech Innovation Centre, e/MTIC, a partnership between science and education, industry and clinics/hospitals drives an end-to-end, multidisciplinary approach in healthcare innovation labelled ‘A Fast Track to Clinical Innovation’. How does it work, what is achieved and what is still to be improved? This paper looks back on the experiences e/MTIC has gained over the past four years since its formal establishment along 6 typical projects.

1 Redefining Health Care Creating Value-Based Competition on Results, Harvard Business School Press, 2006
The Eindhoven MedTech Innovation Centre (e/MTIC) was established on June 14, 2018, formalising the already existing strategic and fruitful collaboration between the Eindhoven University of Technology, Royal Philips and three top-clinical hospitals Catharina Hospital, Máxima Medical Centre and Kempenhaeghe Centre for Sleep and Epilepsy.

The goal of e/MTIC is to provide ‘a fast track to clinical innovation’ where every noun and adjective has a solid meaning. ‘Innovation’ in the sense that it should serve improved patient outcomes and patient experience, lower healthcare costs, and higher healthcare workforce satisfaction, following a Value Based Healthcare approach. ‘Clinical’ in the sense that the innovation should be implemented at scale in the clinical practice. And a ‘fast track’ in the sense that significant reduction in lead time is achieved via standardised ways of working.

Prior to e/MTIC’s establishment over a decade of bilateral and multiparty research collaborations on specific subjects has been conducted. Eindhoven University, has and still serves as a pivotal organisation in this web of research. During this period, growing insight that successful and breakthrough innovation was fuelled by the beneath displayed elements was obtained.

+ Proximity (physically and mentally)
+ Strong executive management commitment
+ Focus on selected domains to avoid dilution and sub-critical mass
+ A cross-domain and cross functional approach
+ An integral value chain perspective (from research to application)
+ Innovative and outcome-based mindset
One could state that partners were well prepared to formally engage, scale and speed up initiatives without creating more overhead and with a mutual interest in the selected topics and activities. The selection and limitation of the scope has also been a key factor in the success of e/MTIC and is until today confined to:

- Cardiovascular diagnostics and care
- Perinatal diagnostics and care
- Sleep diagnostics and care

As stated, those areas are not treated independently, but in a cross domain and multidisciplinary way, leveraging a common infrastructure which is explained in more detail further in this section. Currently the extension with other domains is considered, but no dilution of quality and approach will be allowed.

Today, research and innovation projects are conducted in the three domains by close to 100 PhD students, supported by tens of professors, scientists, clinicians and other professionals, of which several have a cross-organisational appointment. Industrial experts and top clinicians have a part-time professorship at the Eindhoven University and some academics have an advisory role in industry or clinics. This not only contributes to common understanding, the end-to-end approach and speeding up of innovation to clinical implementation. It is also the basis for a solid education program for the next generation of healthcare professionals. More about this in section 2.2.

In each domain, students, professors and professionals form a so-called Daily Management Team (DMT), with full responsibility for their program. Those programs are well defined in roadmaps, that look several years ahead. This not only secures consistency between the various projects and cumulative learning, but also facilitates cross domain alignment, forward planning and concurrent engineering in the value chain (‘fast track to clinical innovation’) and forward planning of talent and resources. Such approach is quite uncommon in academic environments.

Quite a few essential steps in bringing innovation to the clinical practice don’t need to wait until research projects are completed and research projects may need prior confirmation on conditional aspects in order to be completed successfully. Examples are asking critical questions on ‘Value Based Healthcare’ aspects in an early research stage and not afterwards, working on implementation financing models under the assumption that research projects will be successful and preparing for (usually time consuming) approbation and regulatory compliance. This is what e/MTIC tries to accomplish via the Taskforce Teams (TT) as explained in the next section.

For the integral management of programs and operations the Steering Team exists, with representatives of all DMT and TT. A supervisory board with executive representation of the e/MTIC partners decides on strategic direction and supervises progress.
2.1. e/MTIC in KPI’s

e/MTIC has found a balance between academic freedom and creativity on the one hand and driving a solid innovation process with key performance indicators (KPIs) on the other hand. KPIs serve primarily for learning and improving things, not to harness creativity and ownership. Some KPIs are owned and measured in the DMTs, some in TTs and they come together on a higher aggregation level in the Steering Team KPIs, at which we also look at progress against the strategic plan, cross-domain leverage and the talent pool across domains.

Typical KPIs include the number and stage of development of PhD candidates, the resources pipeline (financial and talent), number and level of scientific publications, invention disclosures and patent filings, number of clinical studies and participation rate, transfer times and number of landings in business and clinical practice. Moreover educational goals are monitored, such as the number of PhD students that participated in dedicated courses in the e/MTIC program.

With the recent installation of a PhD student council, we also evaluate the feedback of PhD students and graduates in how they perceive the working environment, the dedicated Master program and whether the e/MTIC approach supports them in their next career steps. This is important because e/MTIC wants to make a structural contribution to the healthcare system and, invest in talent that can take it further.

2.2. Taskforce Teams

One of the major steps that was taken with the formal establishment of e/MTIC was the establishment of Taskforce Teams. While research and innovation subjects are unique, there is an increasing common basis that can be leveraged and actually must be leveraged across domains in order to keep efficiency and focus on the core research. It is enabling researchers to find their way and leverage best practices. It is infrastructure, but in a much wider sense than the traditional hardware laboratory environment.

The Taskforce Teams therefore contribute to the ‘fast track to clinical innovation’ by offloading time consuming and diverting processes away from the core research and innovation. The e/MTIC Taskforce Teams are on:

- Education
- Regulatory affairs
- Data – Health Data Platform
- Valorisation and Value Based Healthcare
- PhD support
- Communication
- Funding

The Education Team

This team is institutionalised at the Eindhoven University and provides PhD students with short courses on important aspects of health tech innovation. The courses provide aggregated experience and know-how of collective learning in e/MTIC. Topics include regulatory processes, intellectual property rights, and data management regulations. Those courses not only contribute to smooth execution of individual PhD projects, but very much to education of a new breed of medical engineers, as this knowledge is extremely relevant in clinical and business practice. Feedback from graduates confirms this.

The Regulatory Team

While the Education Team focuses on providing the courses, the Regulatory Team develops the practical insights and knowledge on the subject matter. For example, recent changes in legislation regarding Medical Device Registration (MDR) have created quite some complexity where even a common interpretation of legislation is still under development. Rather than having every PhD candidate find out what applies to his or her project, the Regulatory Team supports them in meeting legislative requirements, but also in finding the right (and fastest) way through all procedures. Other topics include data stewardship, consent, medical and ethical approval flows and good practices.

The Health Data Board

MedTech innovation projects are increasingly data-driven and Artificial Intelligence (AI) is increasingly supporting students and staff in their research, as well as assisting healthcare professionals in diagnostics, triage, monitoring, workflow and treatments. And this is only the beginning of a transformation in healthcare that will be based on data and AI.

Conducting a single data study confined to a single domain is usually not too complex. Often the medical doctor and the PhD student are
entitled to use patient data based on consent within the institution and within the domain. But things become complicated when retrospective data is to be used outside the scope of its original collection, outside the institution and across domains. Maintaining privacy and security and guaranteeing non-traceability requires a strictly professional approach that goes beyond the capability of an individual researcher, who rather focuses on finding the right data, quality and developing insights.

e/MTIC has therefore established a Health Data Board that guides students and professionals in their data management and creates a professional infrastructure to structurally solve the challenges for cross domain and cross organisation data sharing: the e/MTIC Health Data Portal (HDP). It goes beyond the scope of this paper to go into much detail, but the Health Data Board is linking its HDP development activities on a national level with Health-RI 2) and has a strategy to make things scalable and useable for stakeholders beyond the current e/MTIC partners. The Health Data Board not only addresses the technical challenges of secure data management and analytics, but also the legal framework and workflow requirements. The current e/MTIC partners already have a solid experience in data management and access to a

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2 Health-RI is the national initiative to facilitate and stimulate an integrated health data infrastructure accessible for researchers, citizens and care providers. It enables optimal use of health data, samples and images, as needed for a learning healthcare system and to accelerate personalised health.
can be stimulated by a Value Based Healthcare approach. Not straightforward to implement, as the parties that invest are not necessarily the ones that get the highest return on their investment, but overall there is a strong return on investment with increased patient satisfaction. This is why VBH principles are included in the portfolio of the valorisation team and are part of the education program.

The PhD Team
The PhD students are the heart of e/MTIC. This initiation of the e/MTIC PhD team was triggered by one of the e/MTIC KPIs to keep 20% of all e/MTIC students and PhD candidates within the e/MTIC ecosystem after they finished their research project. A survey conducted with the >100 e/MTIC PhDs showed e/MTIC could improve on PhD support and communication. With different activities such as poster events, mailings, courses, introduction webinars and other specific programs, the exchange of information between the e/MTIC steering team and amongst the PhDs themselves has improved.

The Communication Team
Creating an e/MTIC community is important for cross learning but also in positioning our approach to the outside world and particularly in corona times it is important to bring stakeholders together. Not only the approx. 100 PhD students and staff members, but also external stakeholders in our partner organisations (hospitals, university, business) and the healthcare ecosystem in the Netherlands. The communication team supports dissemination of results, an internal and external newsletter but also online webinars (and post-corona events) where researchers share their experience with colleagues. Communication is a core process in establishing an innovative ecosystem.

The Funding Team
While the Daily Management Teams, introduced in the previous section, focus on private and public funding of the roadmap on their application domain, the Funding Team of e/MTIC takes a more holistic approach on general funding opportunities, their constraints and boundary conditions and match with e/MTIC strategies. One of the guiding principles is that we don’t want to extend the scope of e/MTIC (by adding new domains) without realising at least the same basis in human and financial resources, i.e. without dilution of the basis. Since PhD projects have a scope of 4 years, it is important to look ahead and make sure that either new candidates and/or new subjects are identified in advance so that continuity is obtained. The Funding Team also serves as a preparation team for strategic direction.
In this section we look at the results of the e/MTIC approach along six different cases. We not only look at the cases as such, but also how they were able to leverage the Taskforce Teams, identifying positive effects as well as room for improvements.

One of the difficulties in measuring ‘fast track to clinical innovation’ is that one does not execute parallel approaches, one leveraging e/MTIC and the other going traditional on the same subject. This would imply a waste of resources. So how do you measure end-to-end speed improvement? The approach e/MTIC follows is to use leading indicators rather than lagging indicators. The latter take a long time and may only give a fair comparison as an average on multiple projects. Leading indicators give indications on parts of the innovation chain and provide faster feedback, that can be compared with more traditional approaches and can be predictive for the final outcome.
3.1 TRICA study

Roadmap and goal
The TRICA (TRansItional CAre) study has been part of the peri-operative roadmap managed in the cardiovascular DMT. Its goal was to investigate the possibility to dismiss patients, recovering from bariatric and abdominal surgery, earlier and have them recover at home under remote supervision. TRICA used data from wearables for post-operative monitoring of recovery and potential complications. It is one of the world’s first studies of its kind that started in 2018, including 350 bariatric and major abdominal surgery patients.

The Philips Healthdot, a wearable sensor for patients at home, measuring breathing rate, heartbeat, activity and posture has been developed in close collaboration with the Catharina Hospital. TRICA study was a 350 patient validation study, incorporating infrastructure, devices and analytics, that was setup, executed and concluded within 1 year. The commercial launch has followed less than 18 months later, in the midst of the Corona pandemic.

Over 35 professionals have been collaborating on this subject in the e/MTIC ecosystem, including Philips technical teams, multiple clinical experts from the Catharina hospital and TU/e PhDs. This study has led to the market introduction of the Philips Healthdot in 2021, only 2,5 years after the start of TRICA.

Approach
The study has deployed wearable sensing devices (the Healthdot and smart watches) to continuously collect data such as respiration rate, pulse rate and other relevant data to monitor the recovery of surgery patients at home while being able to detect complications earlier.
The study preparation started in September 2018 with all stakeholders in the value chain represented and many disciplines such as clinicians, researchers, healthcare economists, technicians and data scientists. This team addressed technical aspects, clinical aspects, data management, METC approval and many more subjects considered important not only for the study itself, but also for a ‘fast track’ to clinical innovation. The study officially started in May 2019 and lasted one year. During the study period, frequent team meetings took place to monitor the study process, resolve issues and establish a rapid and monitored inclusion.

From June 2019, the TRICA data analysis team held weekly multidisciplinary meetings with 10 experts from Catharina Hospital, TU/e and Philips. These meetings facilitated fast decision making on the re-use of established methods, use of clinical and contextual information for diagnoses and developing a common language, ensuring an increase of accuracy, speed and impact.

**Results**

The analysis was finalized by the end of 2020. Already in February 2021, Philips received CE marking of the Healthdot sensor. The certification was prioritized because of its relevance to the COVID-19 pandemic. The first clinical implementation was at the Antonius Zorggroep in Sneek, The Netherlands, exactly for the purpose of home monitoring of COVID-19 patients. Through broad deployment of the Healthdot following the TRICA study, Philips supports the transition of care from the hospital to the home. The patient’s vital signs (breathing rate, heartbeat, activity and posture) are measured every 5 minutes, for 14 days in a row. The Philips IntelliVue Guardian or Engage platforms allow health care professionals to monitor their patients inside and outside the hospital. The patient can thus continue to recover at home under supervision of medical professionals in the regional care network, and caregivers can intervene if the vital signals would give rise to do so.

“With the Healthdot sensor we can monitor patients recover at home. Patients need to undergo less physical measurements at the bedside, reducing nurses’ workload. Through the Healthdot, patients at home and caregivers alike feel reassured, because we can continue to follow the patient’s health condition in their home situation. Remote monitoring allows us to more quickly intervene in case of problems.”

Dr. Arthur Bouwman, Anaesthesiologist, Catharina Hospital

- A practical eMTIC case - TRICA Study (tue.nl)
- Healthdot sensor voor monitoring op afstand van patiënten - nieuws | Healthdot sensor for remote patient monitoring - News | Philips
While the Healthdot in its current form is the balance between low-threshold measurement, convenience for the patient and relevant information monitoring, the incorporation of other vital parameters into Healthdot is still a serious goal. In addition, Arthur and his e/MTIC team are working on text mining of nurse notes with promising results. This new feature should recognize characteristic words in the reports of the nurses in order to ‘read’ their concern about the patient more easily.

Arthur concludes: “e/MTIC catalyses knowledge, ambition, and means to launch healthcare into an effective, efficient, and patient-oriented future. Technology is no longer the limiting factor, but legal and organizational issues are. These are addressed in e/MTIC, a creative, professional playing field in which I, as a healthcare professional, can warm up young TU/e researchers for the clinical world. That makes my day.”

Prof. dr. Arthur Bouwman, newly appointed professor at the TU/e and Anesthesiologist at the Catharina Hospital indicates the potential impact of the use of Healthdot: “the implementation of the Healthdot could lead to a staggering result of saving the hospital 56% of hospitalization nights.” Although this is very promising, he also mentions that 50% of the target population that was asked to wear the Healthdot refused. An important signal that made him realize that much remains to be done on the quest to standardize this working method.

Foundation for clinical decision
In a traditional care environment, a nurse has to visit a patient approximately three to four times a day to measure and monitor heartbeat, physical activity, breathing, blood pressure, saturation, and consciousness. Apart from the number of visits, which is quite intense for both the patient and the nurse, also ‘nurse worry’ about the patient that comes along with these visits contributes as a factor to clinical decisions. Therefore, the peri-operative roadmap features several new objectives.
3.2 SOMNIA database for sleep medicine

Roadmap and goal
A good night’s sleep is of the utmost importance and sleeping disorders have a huge impact on people’s well-being. 10% of our population suffers from one or more forms of sleeping disorder and that number needs to come down.

Sleep medicine has serious limits in terms of measuring and monitoring. New technologies to monitor sleep and sleep disorders over long periods of time in a home setting are urgently needed. However, suitable non-obtrusive sensing technologies are basically a surrogate for gold standard measurements. To achieve adequate performance, algorithms need to be developed and validated, but this requires large datasets in patients of all ages with a variety of sleep pathologies, which combine gold standard polysomnography directly with innovative sensing technologies.

Polysomnography (PSG) is the primary tool for sleep monitoring and the diagnosis of sleep disorders. Recent advances in signal analysis make it possible to reveal more information from this rich data source.

Approach
The SOMNIA (Sleep and Obstructive Sleep Apnoea Monitoring with Non-Invasive Applications) project has created a database combining clinical PSG with advanced unobtrusive sleep monitoring modalities in a large cohort of patients with various sleep disorders. The SOMNIA database facilitates the validation and assessment of the diagnostic value of the new techniques, as well as the development of additional indices and biomarkers derived from new and/or traditional sleep monitoring methods.

Apart from the relevance of creating this rich database for sleep research, the use of it in a multidisciplinary context and for analytics beyond sleep has created a breakthrough for many e/MTIC studies.

Led by Kempenhaeghe Sleep and Epilepsy Center, e/MTIC has built a dataset with the sleep patterns of over 2,000 insomnia patients. This dataset is an enormous help to improve diagnostics and effectiveness of sleep products. The solution hinges on a close collaboration between Sleep Medicine Center Kempenhaeghe, Eindhoven University of Technology and Philips Research. The clinical care team, including doctors, nurses and sleep technicians is engaged to enable data collection. With all partners we developed streamlined data sharing procedures and an open framework to allow relatively quick introduction of new devices. All these were basically the result of a co-creation approach between trusted partners.

Figure 5: Unobtrusive sleep monitoring applying new sensor technologies, AI algorithms and validated through the SOMNIA program
Prof. dr. Sebastiaan Overeem, somnologist at Kempenhaeghe explains: “Somnia is a flexible, scalable and yet highly standardized data collection program. It is a vital part of our research and meanwhile fully integrated in our routine. An efficient source for collecting, analysing and disseminating datasets for multiple use. A unique and intelligent library where data of over 2000 registrations is gathered and evaluated. It is this technology that bridges the gap between collecting relevant data on a large scale and its effectiveness for the daily practice of patients and doctors. The uniqueness shelters in actual incorporation of new technology: AI and algorithms. It is this technology that marks the path from early idea to better and more efficient healthcare.”

Results
The database has been used in many projects already and has led to over 20 published scientific papers. One project concerns the accurate determination of the stages of a person’s sleep. e/MTIC researcher Pedro Fonseca and co-workers have been able to develop an automatic sleep staging algorithm using heart rate variability, body movements, and recurrent neural networks. This ap-
This approach has been validated in a sleep disordered population through the SOMNIA project. New sensor technology, infrared observation cameras and future smart apnea monitoring devices are among the tools developed in the e/MTIC ecosystem that will bring the principles of value-based healthcare from bench to bedside. The way of working of both data collection, sharing and analysis serves as an example to several other e/MTIC projects. In the future, the Health Data Portal will support SOMNIA studies without data having to leave the hospital.

Sebastiaan: “Sleep medicine is a young and complex science. Therefore, I am even more proud that we are lifting our profession from the safe, warm e/MTIC bath into the future. As a distributor of valuable data, as a stimulus for tomorrow’s care talent and as an accelerator of care in general.”
Figure 6: Columns 1 and 2 show lung ultrasounds without and with annotated COVID-19 biomarkers (orange: moderate, red: severe). Columns 3 and 4 respectively show the semantic segmentations and contours of COVID-19 markers by means of deep learning analysis. Image: TU Eindhoven.
3.3 AI for Ultrasound imaging

Roadmap and goal
The WHO estimates that two-thirds of the world’s population lack access to any form of medical imaging. This is even worse for high-quality imaging, such as MRI: about 90% of the world does not have access. Global access to high-quality imaging is a challenge, and MRI is not likely equipped to fill that gap due to its high costs, poor scalability, and low portability.

Ultrasound has strong potential to provide this access. The problem is that ultrasound image quality is low, much worse than MRI. Expanding to less-skilled users, with devices that are smaller and cheaper, and the increasing prevalence of obesity, all further deteriorate image quality. Consequently, any paradigm-shifting advancement that enables ultrasound with excellent image quality will have a big impact on the field of medical imaging. In e/MTIC applications are explored in the cardiovascular and perinatal domains.

Ruud van Sloun, Assistant professor Machine Learning for signal processing at TU/e, introduces how the e/MTIC team intends to improve ultrasound imaging.

"Because it is a self-learning algorithm it will become smarter with every new diagnosis, and thus generate even more accurate images"
Ruud van Sloun

Approach
Ruud van Sloun, Assistant professor Machine Learning for signal processing at TU/e, introduces how the e/MTIC team intends to improve ultrasound imaging.

"Now imaging techniques perform the same trick for every patient, time and time again. A probe sends soundwaves and builds an image out of the obtained data. I strongly believe that we can improve imaging drastically by making the system 'closed loop'. Closed loop processing obtains data by sound waves and decides in real time how to use that information to get new, more accurate information. The system itself decides what to measure to maximize data on, for example, a pathology."

This closed-loop system is a process of perception, interpretation and action. "We are manipulating specific characteristics of the sound waves, changing the way the system measures. Machine learning models predict properties of the object to perfect the image. In a controlled test set up we try to validate the concept, the added value and most importantly the inefficiency of current system architectures."
At the core of the research is artificial intelligence to make a system so smart it can perform things people do not have the bandwidth for. “It is my fascination with technology, to observe the human brain mechanism and translating the outcome to mathematics, algorithms and eventually create efficient, valuable solutions for people to benefit from.

Results
The research is leading to higher-quality ultrasound images from fewer measurements, which should ultimately lead to more effective and more efficient diagnostics with ultrasound. In the coming years we will continue this research line with follow-up e/MTIC projects focused on AI for ultrasound in obstetrics and cardiology. For this research e/MTIC truly accelerates the path from early technology to clinical innovation and widespread use. Next to the access to relevant datasets required for large-scale deep learning, the ability to innovate on Philips platforms, and business support is making all the difference.
It is the quintessence of e/MTIC says Ruud: “The hospital partners provide user needs and data, Philips contributes its relevant market and product expertise, and the university provides inspired research capabilities. Together we provide a comfortable red carpet for solutions to reach the hands of the doctor and the health of patients.”

Ultrasound diagnostics has shown a remarkable progress over time. Initially requiring highly specialized equipment, not only for the transducer/receiver but also for the signal processing, a breakthrough was achieved when the transducer/receiver became a ‘USB pluggable’ device connected to a standard computer. This created a much wider access for people to imaging. Now, with the use of AI algorithms, images become much more meaningful and can be tuned to the application.
The clinical studies were performed in Máxima Medical Center. The ALARM team was chosen in such a way that clinical, technical and business expertise were available. 2 PhD students and 2 postdocs performed the studies and analyses, always supervised by a team with all three stakeholders involved. Lab and office spaces at all partner locations facilitate progress meetings and the testing of ideas before using them in a clinical study. As part of the study, a new data collection system has been installed and a large dataset of vital signs is collected. Subsets of this large datasets are annotated for machine learning experiments.

Results
The workflow optimization study has led to a significant 30% reduction of critical alarms in current clinical practice while patients were kept longer in their physiological target range for 35% of the time, thus improving patient safety. This had a direct clinical impact and increased value. The optimisation method is published and can be used in all ICU settings to optimize alarm pressure in a safe way.

The machine learning models are still in a development phase but developed in such a way that exploiting them in a patient monitoring environment, without complex connections to the EMR, is feasible.

The unobtrusive thermal camera system and algorithms to detect respiration from the videos has not only been shown clinically feasible in a proof-of-concept study but has also led to several patent applications.

Peter highlights the relevance of early detection and prediction: "For me, the true nature of value-based healthcare lies in early prediction of pathological processes like infection, a huge problem with these patients."
Gaining a few hours can mean the world: adequate reaction time, quicker treatment and less damage for the child, which in turn means better chances for a future grown-up.”

Carola indicates the importance of the e/MTIC partnership in this case: “Earlier detection of apnea, an extremely important indicator in the NICU, was made possible thanks to the profound expertise of Philips and TU/e. Now they are even able to measure baby movement from measurements of the blanket and respiration flow. After the recent completion of the ALARM project, this way of unobtrusive sensing is the next project selected from the roadmap.”

Learnings from the e/MTIC approach
The e/MTIC approach, involving hospital, industry and university, ensures that all aspects of health technology developments can be addressed. The expertise in the team is high, the way of working and the relaxed atmosphere creates a friendly environment for the PhD students to work in, allowing them to grow.

In addition, for machine learning large datasets are needed. In an Intensive Care setting, informed consent cannot always be obtained upfront. But with guidance of data (security) officers and legal advice from the regulator team, it was possible to adequately anonymize or, in some cases, decode the signals for further processing within all GDPR rules.

The best results are obtained if focus is kept and expertise further developed. Improvements can still be found in strengthening research lines, better alignment of partner roadmaps and increased sharing of information and expertise across the many e/MTIC projects, further contributing to the fast track to clinical innovation.
3.5. Accelerating digital innovations: from Bench to Bedside in 6 months

Roadmap and goal
Implementing AI and data science into clinical applications is a challenge. Literature indicates four important impediments that hamper a smooth translation from bench to bedside: organization and commitment, non-multidisciplinary teams, data management and interoperability, scalability to sustainable and responsible digital solutions.

At first glance the path Ymke de Jong (Data & AI Partnerships Lead at Philips) and her team chose to accelerate digital innovation is simple. And that’s a good thing. A 6-months cycle, 4 phases and a lot of collaborative expertise. Relevant for all e/MTIC roadmaps and many projects that intend to develop data-driven solutions. When you take a closer look, her research is nevertheless quite a challenge.

Approach
To tackle the problems of bringing data science from research to the clinic, a methodology has been set up to accelerate a process of digital innovation in a specific area of healthcare. This is done by working in teams consisting of clinical and technical experts, with expertise in data science & AI, medicine, IT and business. The ‘Bench to bedside methodology’, developed between Catharina Hospital (CZE), Philips and TU/e, has three design criteria:

1. Co-create; have one case from CZE with Philips support and one case from Philips with CZE support;
2. Quick feed-back; have 6 months innovation cycles;
3. Increase adoption by sharing; share learnings to all parties involved by innovation sessions and demos/presentations.

Every ‘6-months innovation cycle’ covers four phases: identification of clinical requirements, identification of technical requirements, building the proof-of-concept (PoC), and testing the PoC. After each innovation cycle we discuss if and how to continue to make steps to the bedside.

Since January 2020 different projects started with 10 experts with weekly working sessions on-site (Catharina Hospital and High Tech Campus Eindhoven) and later on digitally due to Covid-19. Since then, our team grew and every 6 months new deliverables have been created, tested, and validated. Topics we have been working on include:

1. Capacity management improvement using AI methodologies
2. Nursing notes analytics to extract nurse worry
3. Nursing notes analytics to prevent in-hospital falls
4. Patient similarity cardiac ischemia decision support

Insights to our approach can be illustrated from these use cases. For example, nurse worry was already referred to in the TRICA section: nurses spend a lot of time with patients which helps them develop a good judgement about the patient’s condition. One aspect of that judgement is called nurse worry, which is subjective information on how well patients are doing. We hypothesized that nurse worry could be extracted from their daily notes and might have predictive power on certain aspects of deterioration of the patient. Subsequently, we have applied and compared different AI/NLP (Natural Language Processing) techniques to extract nurse worry from the textual content of nursing notes and evaluated that worry in the context of augmenting Early Warning Scores (EWS).

In the case of Capacity Management improvements using AI methodologies: Given the capacity challenges hospitals are facing, efficient use of OR, ICU and ward resources will be vital to provide the timely care that patients need. The increased demand for care, partially delayed due to the COVID-19 pandemic, requires optimization of the planning and use of resources. We have investigated AI-driven approaches that provide true, actionable insights based on available data. Machine learning technologies based on specific individual patient characteristics allowed for the creation of customized models to optimize OR, ICU and ward utilization. These predictive models, implemented in an adaptive user interface, will support surgery planners by creating an optimized surgery schedule. Such schedule is essential for an effective
use of capacity management, leading to improved patient and staff satisfaction.

Results

Next to these Proof-of-Concepts themselves, Ymke summarizes the results of the methodology pilot: "In a short period of time, we achieved more together than we were able to do on our own. Working together on algorithm development within the hospital systems shows the challenges on data management directly at the source. Incorporating these challenges at the beginning of the project, will prevent time-intensive migrations and frustration in a later phase. By starting from a relevant clinical need and continuously involving clinicians during the creation of a new tool, the likelihood for acceptance is expected to be much bigger. All participants appreciated the contributions of each team member. Their different knowledge and background led to a quicker mutual understanding and increased creativity. Learn from each other’s knowledge and therefore being able to make fast and important steps."

Learnings from the e/MTIC approach

The e/MTIC ecosystem supports bringing data & AI solutions from the bench to the bedside on 2 levels. e/MTIC brings together the ‘golden triangle’ of partners to accelerate clinical innovation. One of the pitfalls of digital innovation is the lack of a multi-disciplinary approach throughout the innovation process, where a multidisciplinary approach is a pre-condition to start a project within e/MTIC. In addition, the e/MTIC framework agreement helps to quickly start a new project, without the need to negotiate on collaboration agreement for every new project. This allows our experts to focus on their core capabilities.

We believe digital innovation in healthcare can be further accelerated if privacy terms on data sharing are clarified, which is difficult given the rapidly changing regulatory environment in Europe. In addition, digital innovation in healthcare is not only a technical field, but also requires understanding of business models and re-imbursement. Especially digital solutions ask for innovation of the financial model from idea to deployment to achieve a lasting impact in healthcare.

Ymke reflects: "It is not enough to build smart algorithms, to develop intelligent machine learning processes or to build an ingenious data management program. If you cannot implement your solution in a healthcare environment it is skilful but a waste of energy. Therefore, the presence of all involved partners is so extremely important. By starting from a relevant clinical need and continuously involving clinicians during the creation of a new tool, acceptance proceeds more quickly and more solidly. You develop, work and grow together. You appreciate your fellow team member and the difference in background and expertise will bring more creativity and better, quicker results. That is the way I like to contribute to accelerate innovation in healthcare."
3.6. The Health Data Portal

Roadmap and goal
Only six months after the establishment of e/MTIC, Antonie van Noort (senior project manager at Philips Research) and his multidisciplinary team of IT experts, legal officers, privacy and security specialists, system architects, and a scrum master took off. Their target: Facilitate access for researchers to clinical data sets in a safe and scalable way to accelerate and improve research results.

Historically, data exchange for scientific research has been very cumbersome and has often been carried out in an insecure way. The increasing security and privacy requirements and upcoming regulations triggered the idea of developing a secure, privacy-conscious, scalable, FAIR and multi-centre data portal: the Health Data Portal (HDP).

HDP is a scalable collaboration platform that builds on existing initiatives to provide an infrastructure for sharing medical data from multiple institutions safely and allow researchers to collaborate on those data. It further allows medical data from different types of healthcare institutions to be shared securely and anonymously between hospitals, universities and industry.

Large datasets will enable scientists to discover and develop new hypotheses about human health and enable new applications in cross-disciplinary research or machine learning to contribute to the AI revolution in healthcare. HDP supports researchers to gain knowledge about more general diseases often treated in non-academic hospitals. Datasets that become available can be used to improve or develop medical devices. Therefore, HDP has the potential to become a platform that can lead to faster life sciences and health innovation.

Approach
The biggest challenge in the HDP project has been to get all requirements clear and all stakeholders aligned and work together in the same direction. The HDP team has formulated extensive requirements and specifications: what do we want and how do we achieve what we want? No less than 27 similar initiatives in the Netherlands have been examined to see what is out there already, discovering some useful modules and their owners. Amongst those owners are Philips with the "Clinical Data Lake" (CDL), the "andDREa" Digital Research Environment, an initiative of a.o. Radboudumc, and "ZorgTTP" for pseudonymizing data. Today, these parties are contributing as partners to realize HDP. Together they are optimizing and connecting the modules through a step-by-step process to achieve a mature solution for a significantly better research data infrastructure in e/MTIC and beyond.

Results
Antonie: “We are about to launch the first version within e/MTIC so that researchers can get accustomed to the portal. The first pilot will be a single-centre study in close collaboration
with anDREa and CDL. Organisationally, we aim to establish an independent HDP foundation that will provide data sharing services not only e/MTIC but to many other stakeholders in the Healthcare research ecosystem. We do this in collaboration with the national Health-RI initiative.”

What makes HDP unique is that it supports federated data sharing (and therefore the application of the FAIR standard) as well as providing a solution to share and process data which is not (yet) suitable for a federated approach. In addition, it offers a powerful data infrastructure which the average data user does not have.

A bright future for the Health Data Portal
The portal will be launched like a three-stage rocket, with increasing functionality and applicability in each stage. The first stage is a test of the portal concerning the three main clinical domains within e/MTIC.

The second stage involves multi-centre studies that will also cover other healthcare domains such as oncology. The pseudonymization expertise of ZorgTTP required for healthcare privacy, will be vital at this stage.

After that, the third stage requires the involvement of other hospitals and research institutes outside e/MTIC, further expanding scope and scale of the datasets. This fits very well in the Health-RI initiative, supported by the National Growth Fund, which creates a collaborating network of nodes across the Netherlands to build a national Health Research Infrastructure.

Antonie concludes: “I am proud of the collaboration between the e/MTIC partners, the creative and successful market quest for partners and portal modules, and my diverse team of specialists. Contributing to the acceleration of innovation through the Health Data Portal is a great way to spend the day.”
The established healthcare systems are under pressure, not only in the Netherlands but in many countries in the world. Aging society with associated chronic diseases, increasing cost and complexity, increasing workload for fewer healthcare professionals and still a large fraction of the world population that has no or insufficient access to care, pose major challenges. While the primary goal of e/MTIC is to make a strong contribution to solutions and the health and well-being of people via innovations in MedTech, it is the conviction of e/MTIC that this cannot be accomplished by individual research projects only. A much more integral approach to innovation is required, involving many disciplines in an early stage, providing structural support for common challenges and teamwork across the value chain establishing ‘a fast track to clinical innovation’.

In the past few years, e/MTIC has created a strong innovation ecosystem in which science and education, top-clinical institutions and industry work together seamlessly in a value-based healthcare approach. Close to hundred PhD students are supported by tens of healthcare professionals, professors and senior scientist, as well as by task forces that take care of common challenges in e.g. regulatory affairs, accumulated learning and education, valorisation, funding opportunities, and data management. This defines the e/MTIC ecosystem, rather than a set of siloed projects. We have presented the practical implementation and experience along 6 projects, not only creating valuable innovation but also contributing to and exploiting common knowledge and breeding a new generation of scientist and clinical professionals that will cope with healthcare challenges of the future. With a mindset to learn and improve, as there is still work to do.
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