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Medical Software

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From the Editor

Software is about people and technology. Medical software underlines this truism more than any other application domain. Health care is an advanced industry where latest software technologies fuel a fast evolution in a market characterized by high pressure on cost, time, and innovation but also demand strong governance due to the impact on humans and the entire society. In this article, we explain medical software development from an industry perspective. Practical guidance is provided from our projects with Siemens Healthineers. I look forward to hearing from you about this column and the technologies that matter most.—*Christof Ebert*

SOFTWARE-DRIVEN INNOVATION is the call of the day. This is specifically visible in medical technologies where several technology trends meet, such as the convergence of product IT and business IT, stringent safety and governance requirements, and not least a high market pressure to bring new technologies to the market with competitive pricing. These are enough reasons to learn more about current trends and innovation in medical IT and medical software products.

Companies worldwide see innovation as the major challenge both in the short term and for the future. In January 2021, *IEEE Software* published results from an industry survey that gave one clear message: Innovation matters.[1] Figure 1 shows the major trends, both short-term (horizontal) as well as midterm (vertical). Innovation sits right in the upper right corner, indicating the relevance as the major short-term and midterm challenge. Why is it a challenge? The inherent difficulty of innovation is balancing today's agenda, while pursuing drastically new and different things, typically by the same people because they know the markets. Specific challenges such as fast cycle times, severe market pressure to cost reduction, evaluating many new technologies, and the lack of competences explains why so many companies fail on innovation.

A lot can be learned from medical software if we just open our eyes. The medical industry is dealing with advances as we face today in other industries, such as connectivity, the Internet of Things, robot process automation, and autonomous systems. Medical implants connect with cloud services, medical image analysis is a powerhouse of artificial intelligence (AI), and digital twins are increasingly used in medical modeling similar to automotive and industry automation.[2,3] Not least, regulations and homologation are certainly as demanding as in other safety-critical domains such as automotive and aerospace.

Software Development for Medical Products

Digitalization enables a more humane health care.[3] Digital business processes and products facilitate

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new treatments and certainly more efficiency in health care workflows to the benefit of patients. Innovation speed is high in medical software.[4–6] Today, worldwide medical data, and thus knowledge, doubles every 73 days.[5] This creates multiple opportunities to apply digital technologies and a relentless pressure to innovate. Here are some examples of entirely novel software-driven innovations to advance medicine, from which we can learn across industries:

- digital avatar for procedure optimization so that a medical doctor can perform a complicated and critical procedure on the avatar and get familiar with the situation
- pathway companion to use AI for actionable insights for personal care and collect data from electronic medical records, lab tests, genome mix, pathology, and so on, to achieve a better understanding of clinical condition of patient and use this information to improve diagnosis, to better plan therapy, monitor it, and to improve subsequent follow-ups
- evidence-based recommendations and course correction together with comparison with other patients' cohorts to provide clinical context in one single view to get a holistic understanding
- digital twin of organs of patient to explore the intervention, check effectiveness of medication, and, for experimentation, for instance, the digital twin of the heart helps to position the probes for cardiac resynchronization therapy to put the probes properly to restart the heart
- predictive models with aggregated help systems to construct the AI-powered digital twin and thus derive actionable insights and assist decision making.

> Healthcare is an advanced industry where latest software technologies fuel a fast evolution.

The advantages for our society are obvious. AI-Rad Companion, which is an AI-driven radiology workflow solution, identifies abnormal patterns in lungs of COVID-19 patients like lung opacity and lung severity score so that radiologists can, much faster than before, analyze the severity and monitor the progression of abnormalities in patients with symptoms of COVID-19.[3] Tuberculosis can be detected today from chest radiographs with a sensitivity of 97% and a specificity of 100%, using deep neural networks for image analysis and having a radiologist evaluate only equivocal cases.[6]

Obviously, medical software demands highest quality standards. Figure 2 illustrates how medical IT systems are driven by external challenges. With digitalization, medical standards and regulations are getting stricter, especially with cloud and hybrid deployments. Digitalization of medical systems needs connectivity to the outside world, which

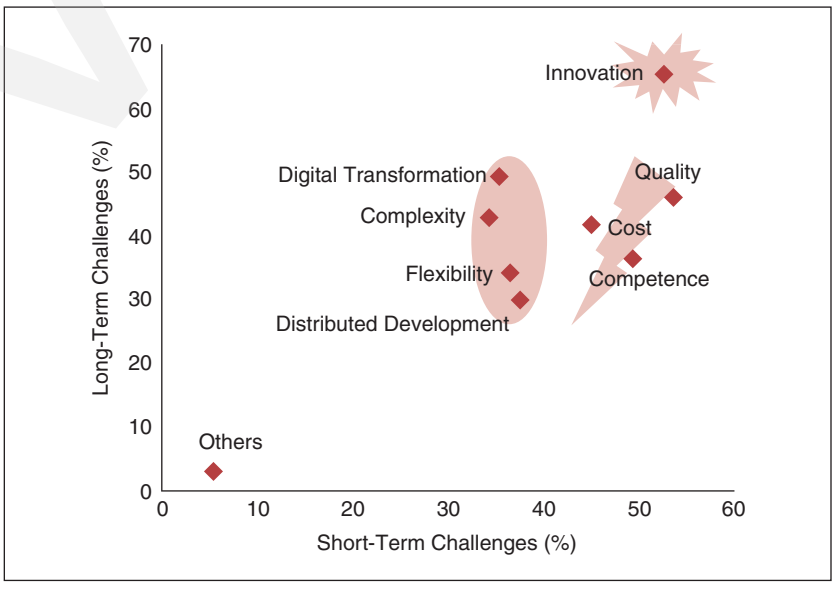

FIGURE 1. Innovation in stormy waters: challenges from an industry survey.

makes them a target for hackers. At the same time, privacy demands are extreme with a high large thrust on edge computing to keep the data on premises. The challenge is to continuously innovate medical software development processes, while adhering to the growing number of applicable standards—and for competitiveness, well balance, efficiency, and effectiveness. (See "Automating Medical Diagnostic Workflows.")

Standards are mandatory for medical software development to foster innovation and governance. Let us look at some relevant domains:

- *Quality Assurance with ISO 13485 (medical devices, quality management systems, requirements for regulatory purposes)*: based on traditional quality management standards and adapted to the medical domain.
- *IEC 62304 (medical device software, software lifecycle processes)*: specifies lifecycle requirements for the development of medical software is building upon the widely used ISO/IEC 12207. It enhances lifecycle management by governance and observability, and mapping to specific medical needs.
- *Medical SPICE for medical product development processes*: Medical SPICE is based on the ISO 33001 (information technology, process assessment, concepts, and terminology) framework for assessments and improvement of software development processes.
- *ISO 14971 (medical devices, application of risk management to medical devices, medical risk management process)*: consists of several steps for the design, development, and production of medical devices.
- *Medical device regulation and in-vitro diagnostic regulation*: increasingly in demand and set forth quite heavy requirements for medical device and in-vitro diagnostic manufacturers that distribute products in the European Union. Similar regulations exist in other markets, such as the Food and Drug Administration in the United States.
- *Usability matters for medical devices*: combining the highest safety demands with lots of direct human interaction by a variety of stakeholders ranging from doctors to nurses, and from administrators to technicians. IEC 62366 (medical devices, application of usability engineering to medical devices) is the primary standard and specifies usability requirements for the development of medical devices. It demands identifying and analyzing use cases of the medical devices as well as negative use cases such as misuse and abuse. This information is required by the medical devices manufactures. While being process-related, the risk assessment and mitigation are covered ISO 14971.
- *Of course, medical software development also demands the more general-purpose standards*: test-management according to ISO/IEC/IEEE 29119 (software and systems engineering, software testing) for software testing. While such standards are generic in examples and vocabulary, they are

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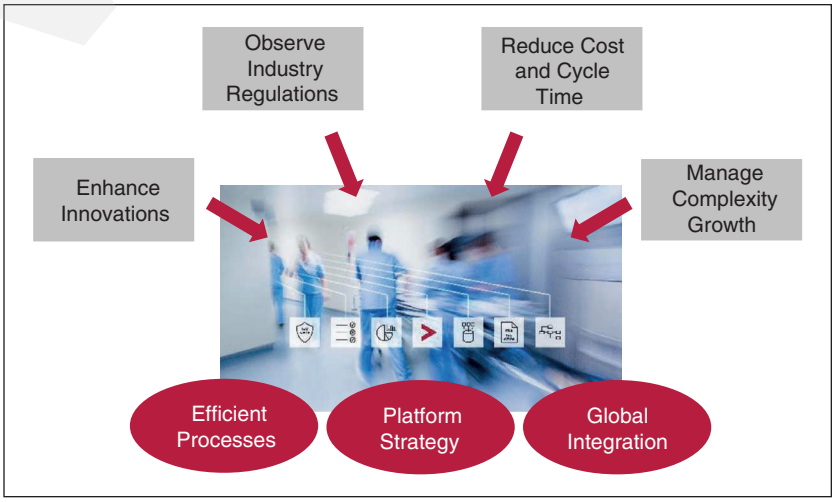

FIGURE 2. Business and technical challenges in developing medical products.

AUTOMATING MEDICAL DIAGNOSTIC WORKFLOWS

The push for innovation in health care is accelerating constantly and accordingly the demands placed on medical technology are growing. In this case study from consulting with a global medical market leader, we will show how to improve efficiency of medical software development, while adhering to strict governance rules. As medical software systems must be technologically innovative and exhibit safety without any compromise, global markets require an ever-shorter cycle time with simultaneous efficiency pressure. The answer to this is increased productivity through lean and efficient development processes. To shorten lengthy development and approval processes, many companies change their development approaches toward iterative and concurrent engineering approaches. However, without systematic requirements engineering the probability is high that a project fails. For example, if quality requirements are misunderstood, problems will arise with usability, security, and performance. Doctors and nurses are decision makers in favor of or against a product. If the product portfolio management is decoupled from development, the functions will not match the market requirements. Requirement changes arrive too late and cause unnecessary nonconformance costs. Since clinical workflows are difficult to model due to their high combinatorial complexity and a relatively low standardization with their ad-hoc character, medical requirements engineering must exhibit specific techniques for medical and health care needs.

Let us show such advances by means of a case study with development of an imaging platform for medical technology. A distributed IT system was developed that is specifically adapted according to the respective hospital needs and environments. It included more than 5,000 requirements and had several hundred developers at different locations worldwide. Lean development was combined with requirements engineering (RE) to specify customer-oriented requirements and progressively refine. The need for a clear feature orientation was achieved with product line engineering.

Our starting point for the improvement was an analysis of the current state of practice. It has been found that it no longer scaled in various places, particularly in four points:

1. The structure of the work products in development had insufficient relation to the product properties, as demanded in the market, communicated, and used, and thus did not allow assessment of the market benefits and specific optimizations, for example for effective product marketing.
2. The organically grown architecture was complex because it had evolved independent of product characteristics and feature relationships.
3. The established V-model development processes were useful for the gradual clearly specified development structure, especially from the approval perspective; however, it was not flexible enough for future changes.
4. The necessary handling of amendments based on traceability was complex and caused severe manual overhead.

Based on these observations, the lifecycle has been carefully adapted. Unlike typical increment structures, which are derived from the requirements based on dependencies, our focus was a direct reference to the requirements development. The implemented approach "Feature-Oriented Requirements Engineering," based on the principles of Lean RE, had the following properties:

- Feature model, which is maintained for internal dependencies (e.g., variant management, testing, and documentation) and external relationships (e.g., marketing, product management), is at the heart of all engineering artifacts. All requirements are modeled first at the previous feature model and evaluated before they are specified in detail and taken into the product.
- Value-oriented evaluation of all features to preserve the economic perspective of Lean development from the requirement elicitation to the feature prioritization to delivery. The marginal value of new and updated functions must be always transparent.
- Graphical modeling of workflows to support the user and usage of every requirement, and to quickly uncover dependencies as well as errors. The user benefit must be tangible based on workflows in the language of the user, because only on such a basis is market-oriented product development and positioning possible.

(Continued)

AUTOMATING MEDICAL DIAGNOSTIC WORKFLOWS *(CONTINUED)*

- Architecture-based modeling provides a clear link between the external view (why: business benefits; what: requirements, features) and the internal perspective (how: architecture, modules, code, test cases) and thus achieve consistency without overheads. The existing architectural model has been adapted to provide the link at any time from the feature model, and to model and maintain variabilities.
- Agile development with a direct link to project management to achieve earned-value progress along the incremental steps.

A profound cost-benefit analysis that we conducted in the underlying medical case study showed that this novel feature-oriented agile engineering approach can save about 15% to 20% of an annual R&D budget. The benefits are distributed as follows across project cost: product definition (25%), project planning (23%), architecture (7%), and improved verification and reviews (45%).

readily applicable in the medical domain. The same holds for other general-purpose standards in the software domain, such as IEC 61508 for functional safety of electronic components or the currently fast-growing standards on cybersecurity such as ISO 27001, which provides a framework for organizations to establish, implement, operate, monitor, review, maintain, and continually improve their information security management system.

Cybersecurity of medical systems is a good showcase because it is critical with its direct impact on patient safety. Development must comply with the applicable regulations including the strict guidelines on how data are handled, as we can currently see in many medical projects.[7] Secure development lifecycles are defined and followed to ensure all software is designed for security. Security is embedded at all stages. It is no longer an extra feature but a cofeature. It is not a desire but a must. A secure development lifecycle typically includes threat modeling, secure architecture and design, secure coding with static code analysis, secure testing with vulnerability scanning, and penetration testing. Usually, static application security testing and dynamic application testing are automated to integrate security with agile development and DevOps practices.

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AI for Medical Products

Today, AI is already being widely used in medical products and health care workflows.[2,6] For instance, diagnostic imaging workflows are accelerated with AI. With more diagnostics, both in vivo and in vitro, more data are generated, thus there also is more need for AI to analyze. For example, AI algorithms enable automated detection of anatomical structures, intelligent image registration, and

reformatting. These kinds of efficiency gains will become increasingly important given the growing demand for diagnostic imaging and the need to lower costs. Introducing AI to an established diagnostics process is a lengthy and data-intensive process in which software developers and clinical experts closely collaborate. Figure 3 shows the workflow from initial diagnostics toward hospital-scale AI systems.

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The promise of AI in medical imaging not only provides higher automation, efficiency, and standardization, but also a wide use of data science beyond the limits of human cognition. This will support better, and more personalized, diagnostics and therapies. Current prototypes investigate AI-based image analyses with specific measurements, i.e., so-called imaging biomarkers, for instance in cardiac imaging. AI also allows (semi)automated drafting of necessary medical reports with AI-based landmark detection and image registration. Radiological data sets can not only be analyzed graphically by AI, but they can also be annotated textually. Radiology thus is fast expanding with a data science discipline called *radiomics*.

A practical use case is medical image acquisition, processing, and interpretation. Siemens Healthineers, for example, has developed a pattern recognition algorithm (Automatic Landmarking and Parsing of Human Anatomy, ALPHA) for its 3D diagnostic software "syngo.via," which automatically detects anatomical structures, independently numbers the vertebrae and ribs, and aids in precisely overlaying different examination methods and modes or even different modalities. This considerably helps simplify workflows in diagnostic imaging.

With advanced software technologies, medical applications are cheaper and at the same time more effective. AI algorithms currently establish themselves as virtual "second readers" in a wide variety of disciplines. For example, they would call a doctor's attention to specific disease patterns and pathological changes to suggest necessary further differential diagnostic methods. This facilitates a more humane health care and reduces case cost, for instance by enabling minimally invasive procedures and reducing diagnostic errors.

Novel AI-driven software solutions allow personalized diagnostics and treatment. Through interoperable

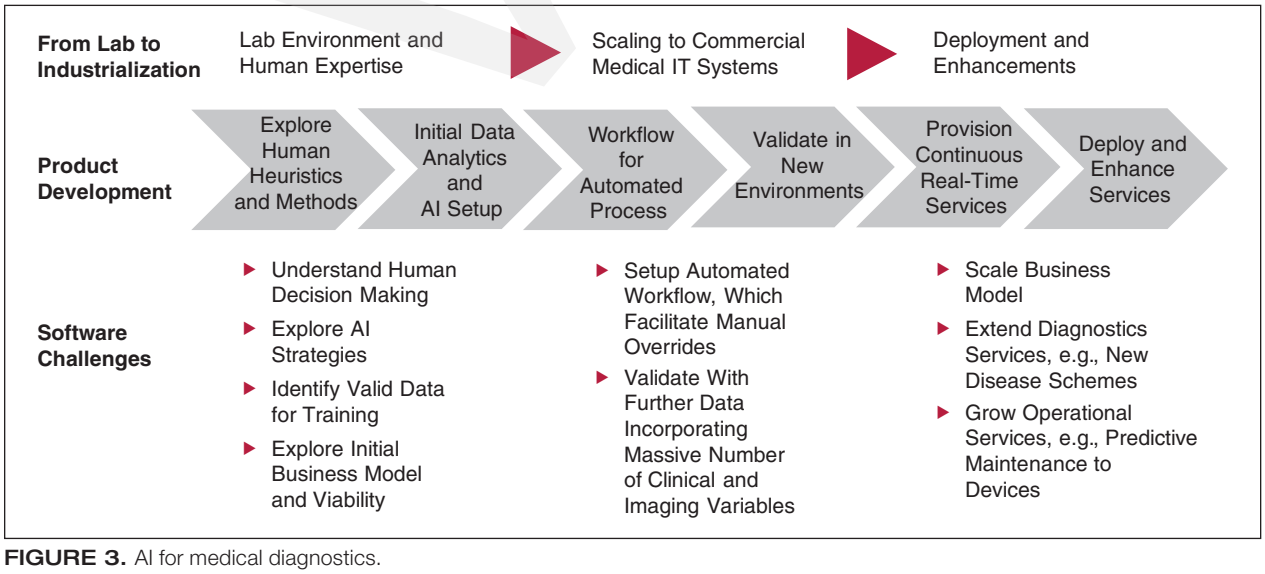

FIGURE 3. AI for medical diagnostics.

information systems, clinical patient data can be linked with imaging algorithms to pursue individualized scanning strategies. In addition, AI applications would likely enable more precise diagnoses and more meaningful risk scores by gathering large quantities of information. As a large multicenter study recently showed, the long-term risk of mortality of patients with suspected cardiovascular diseases can be estimated with much greater precision if manifold clinical and computerized tomography angiogram parameters are integrated into a personalized prognosis model using machine learning procedures.[6] Such AI-based approaches could, in the future, better identify high-risk patients and also help prevent unnecessary treatments, thus involving diagnostic radiology more closely in outcome-oriented clinical decisions.

Outlook: Toward a More Humane Health Care

Software is about people and technology. No application domain exhibits this more than medical software. Innovative technology will not replace the role of physicians, but it will provide them with highly accurate tools to detect disease, mitigate risk in a user-centric way, and optimize patient-specific treatment and further tests and surgeries. While machines will not replace doctors, automated workflows that are AI-based will ease doctors' work by reducing error risks while at the same time facilitating focus on the patient rather than on lengthy reporting, which today eats far too much personal clinical time.

Today, the smartphone is a benchmark for any software-driven innovation. Indeed, there is a lot we can learn from smartphones, such as platform strategies and extraordinary user experience. But medical devices are more challenging. They demand functional safety and very high reliability. While normal IT systems periodically crash, medical devices at most are allowed to fail operationally, not to endanger humans. While smartphones and consumer goods are thrown away after few years, medical hardware platforms are expected to run for decades. They are updated and maintained long after end of production, while most IT suppliers stop support a few years after declaring end of life.

AI poses even higher demands on medical software. For instance, when there are adaptive algorithms in medical products such as implants, their behaviors must be specified, approved, and homologized. Underlying AI rules must be transparent and, upon self-learning, it must be ensured that rules that are still valid and would not be overwritten. While big IT giants have centrally governed replicated operational systems that facilitate rollback, medical implants must be autonomous in their usage and updates of software. In short, while we enjoy a smartphone-like user experience, we don't want to face its downsides, such as frequent crashes and nondeterministic behaviors.

The future of health care brings fundamental changes, where we see several strategies to accomplish the medical software innovation:

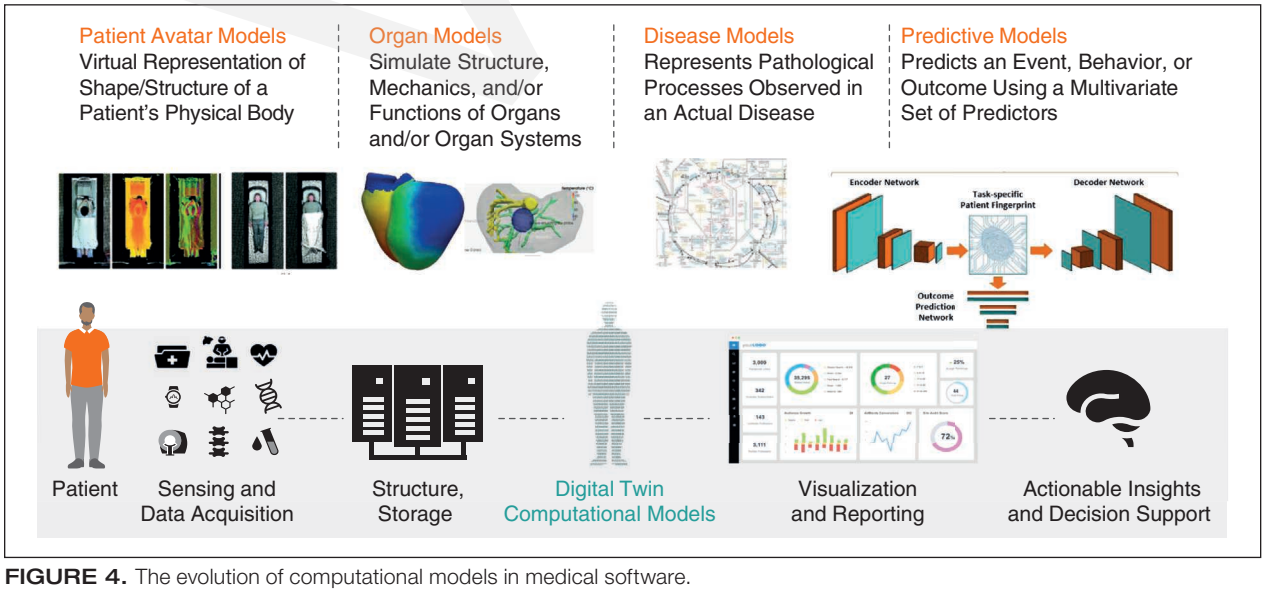

FIGURE 4. The evolution of computational models in medical software.

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- automating clinical workflows
- improving quality and precision of health care
- easing the delivery of medical treatment

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- perfecting the user experience of both patients and medical staff.

Figure 4 shows an example of software-driven modeling and how technology innovations advance medical treatment. Developing software for smart health care must not be misunderstood as merely to build software that attempts to shift decision making from people to computers and advance automation. The goal is to facilitate a more humane health care. Software must enhance and facilitate people's ability to interact in smart-health-care processes in increasingly complex and heterogeneous environments and with increasingly complex and fast-appearing constraints, as we have learned during the COVID-19 pandemic.

Medical technology advances on a fast track, and the major downside toward more humane health care is what science fiction author William Gibson once pictured: "The future has arrived—it's just not evenly distributed yet." Let us strive toward advancing not only the technology but also getting it to the people.

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