

Medical Data Management – Approach, Concepts, Strategic and Operative Implications




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ABSTRACT

The collection, analysis, and management of clinical data with electronic applications has already widely been used. The digitalization of medical records is expected to bear significant potentials for the increase of clinical efficiency and effectiveness. This has led to numerous legal initiatives by policy makers and healthcare systems in many countries to secure the spatially inclusive and comprehensive establishment of electronic health records in preferably all medical disciplines. The following article describes the principles of electronic medical data management and exemplifies the different approaches, which are followed internationally. Furthermore, it discusses how medical data management systems create value in terms of higher clinical quality or lower treatment and administrative costs. And finally, the strategic and operative implications are deducted and concrete opportunities for action are described how the introduction of electronic health records may be optimally structured.

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I. General Reflections

In September 2018, 2 companies exceeded the limit value of market capitalization that was considered as magic with more than 1 trillion US\$ for the first time. Shortly following one another, the Apple group as well as the online retailer Amazon had a higher value each than the gross domestic product of the Netherlands or the ones of Switzerland and Austria together. Among the most valuable companies worldwide, 2 other data-driven companies are found beside Apple and Amazon: the Google parent group of Alphabet and the social network of Facebook. Investment managers and strategists expect that the performance of the data groups will be stable on a high level for the next years. These expectations are based on the knowledge that data are the “gold” of a global, digitized economy. Data are the glue that keeps the elements of the value-added chain together. Due to the omnipresence of digital technologies, immense data volumes are continuously being created, the management and use of them represent the fundamental conditions for modern value creation.

Increasing storage capacities and nearly unrestrictedly growing processor performance that follows so-called Moore's law [1] described more than 50 years ago, make multidimensional data analyses possible and affordable – due to a technology-related price decline [2]. Large data volumes, commonly called “big data” [3] can be analyzed and evaluated by means of intelligent software [4]. Hereby, it is often the case of recognizing patterns, on one hand to better characterize the data source, i. e. the single user [5, 6], and on the other hand to develop predictive models that allow predicting the (consumption) behavior of the users more precisely [7]. On this basis, for example individual offers may be calculated and positioned by online retailers that allow expecting a user's acquisition with high probability [8]. Furthermore, the technical progress fosters the rapid development of artificial intelligence (AI) applications that have an enormous potential in nearly all areas of life [9].

Digitization has entered all areas of life and modifies the management logic of many sectors in a significant and sustainable way. The so-called digital transformation has an impact on five strategic categories [10]:

- a Customers The power structures between provider and consumer have reversed. The information monopoly is no longer in the manufacturer's hands, but is atomized by the internet. Social networks, forums, and assessment or rating platforms allow distributing mostly invalidated information like viruses. Thus the influence of the individual customer increases significantly. So, the focus of marketing is meanwhile placed on loyalty, shopping experience, and high service quality.
- b Competition On one hand, inexpensive technologies allow the rapid and uncomplicated development of digital products and services so that the number of competitors grows dynamically (“new entries”). On the other hand, the above-mentioned networking effects lead to a concentration of the consumers on few large providers. In all sectors, the field of competition is continuously changing with high dynamism, which requires a high level of reactivity and agility.
- c Data As seen with the above-described examples, data that are generated continuously and everywhere are the basic currency for the value of a company. Even unstructured data may be increasingly used due to modern technologies. Many companies only start understanding and using their “data treasure”.
- d Innovation The high dynamism requires significant acceleration and flexibilization of the management of innovation processes. Successful companies and organizations leave traditional and slow, linear processes and establish experimental, iterative, and nearly chaotic processes in order to find the solution for the correct problem most rapidly. The objective is no longer to find a nearly perfect product that is ready for use, but a minimal prototype that is tested rapidly on the market and continuously optimized (so-called “minimal viable product”, MVP).
- e Value In the analogue world, value creation mechanisms were stable for longer times so that the organizations could refer to them and structure their management in this direction. The success was mostly sustainable because it was based on meeting relatively static needs. In digital times, fluctuating customers' needs and unpredictable market changes require continuous adaptation of the management logic. Hence, permanently new

chances, but also new risks for the company's success develop. Professor David Rogers from the Columbia University summarizes this aspect in one sentence: “Only the paranoid survive” [10].

Also in medicine, information reigns. The clinical medicine lives on generating, collecting, and archiving of information. As empirical science, it is based on as much information as can be retrieved and on analyzing it systematically for the benefit of the patients. The major part of medical interventions uses the communication system of the human body via the sensory system or intervenes in endogenous communication systems such as the immune system, the endocrine system, or the neural system [11]. In all clinical processes, data appear that have to be assessed, stored, and analyzed. Already today, the data volume is very high and increases nearly exponentially. The annually published internet trend report of the consultant company Kleiner Perkins states that in an average medical practice 26 datasets occur per year per patient being treated. In this way, in a typical hospital with 500 beds, each year 50 petabytes of data emerge (1 PB = 10^{15} Bytes = 1 billion MB). The annual growth rate of healthcare data amounts to 48 %. The half-life of medical knowledge amounts meanwhile to less than three years; the number of published studies has been exponentially growing for many years [12]. Hence, the growth of medical data and information is higher than the one of other internet-based data. According to estimations, documented genomic data alone will be more extensive in 2025 than the data of the internet platforms of YouTube, Twitter, and the data of astronomic research together [13]. Driving forces for this development are on one hand the developing technical possibilities, for example digital documentation of radiological or pathological findings or clinical imaging, but on the other hand also the extension of molecular basic knowledge that leads to higher fragmentation and thus higher complexity in the taxonomy of diseases [14]. The more personalized, i. e. individualized, clinical diagnostics and therapy are, the larger will the datasets per patient be. Furthermore, the interdisciplinarity of the disciplines has increased so that more interfaces occur during treatment. And finally, the patients are treated in an increasingly transectoral way, which puts another complexity layer on the clinical pathway. Otorhinolaryngology is one of the clinical disciplines with its fields of otology and audiology where most information is digitally available or can easily be digitized. So it can be expected that the reality of life of otorhinolaryngologists will sooner or later be significantly affected by these modifications [11].

The perceived high dynamism of modifications in medicine is mainly due to the explosion of scientific information and to the necessity to implement this information in the practice of treating patients [15]. In this context, the question must be asked if information technology applied for reasonable management of medical information is only another addition to the long list of innovative technologies that have been domesticated in the course of the time by the clinical requirements of medicine, or if it is actually a disruptive development that will modify the logic of medicine in a fundamental and sustainable way [16]. There are many reasons to believe that the increasing, permanent, and locally completely independent availability of clinical information will lead to a para-

digm shift that the American system biologist and molecular geneticist Leroy Hood calls P4 Medicine. According to him, digitization causes a shift of the clinical focus from a traditional, primarily curative approach to a predictive, preventive, personalized, and participatory logic [17].

Whenever paradigm shifts become obvious or seem at least possible in certain areas of life or sectors, strategic opportunities arise that want to be used commercially. So it is not surprising that also large technology companies such as Google, IBM, Amazon, Microsoft, Facebook, or the German SAP are highly interested in generating and managing medical data. Nonetheless, current results are at best mixed; and some companies had to cope with significant setbacks despite high investments and the important application of knowhow [18–23]. For example Google as well as Microsoft have frozen their initially highly valued digital health activities for several years because they were not successful. Apparently, the well-known principles and structures that are particularly successful in the sector of consumer goods, cannot be linearly or 1:1 transferred to healthcare. In this context, it might not surprise that the healthcare system is far behind compared to all other sectors regarding its level of digitization [24].

Precondition and basis of each type of value creation from data is their exploitation by means of databases that allow the management, evaluation, combination, and further use of data. In the medical healthcare context, the terms of electronic patient record, electronic health record (EHR), or also electronic patient file were established for such database applications. The USA play a pioneering role for these healthcare-specific data systems where in parallel to the introduction of computer technologies in the 1960ies and 1970ies first EHRs had been developed and established [25]. Because of the specific US American healthcare structure, most medical database systems are regionally organized. A nation-wide solution could not be implemented up to now [26]. Since the national implementation of EHRs could not be realized despite the assumed high value creation potentials, the Clinton administration issued the Health Insurance Portability and Accountability Act (HIPAA) that was meant to foster the introduction of electronic health records. Since then, the market dynamism has significantly increased for EHRs. More than 90 % of the US American hospitals and practices have meanwhile introduced some kind of electronic patient records [12, 27]. The global market is currently estimated to 23 billion US\$ (more than 40 % emerge in the USA); and it increases by around 10 % each year [28]. The very dynamic penetration of the American market of the last years may also be associated with the fact that many insurance systems are no longer based on the traditional fee-for-service remuneration. Instead, more and more value-based and pay-for-performance contracts have been concluded that couple the amount of the remuneration to the clinical outcome [29, 30]. The precondition for the operationability of such contracts is the collection, storage, and availability of relevant clinical data that can be verified, i. e. controlled, by the insurer [31–33].

However, the reception of the technology by the users in this globally most developed market is very ambiguous. There is no clear picture that might justify the statement that EHRs always lead to an improved, more efficient, less expensive healthcare that is more suitable for all people involved [34]. Many studies report

about a widespread frustration of the medical and nursing staff [35, 36]. Electronic health records and the associated obligations for documentation are even mentioned as the most important single cause of endemic burnout syndromes of medical staff [37]. They perceive as extremely frustrating that only few implementable intelligence comes back to the treating physician despite the medical time applied for acquiring and entering data [38]. Although there is no discussion regarding the fact that assessing and sharing certain biomedical information is improved by means of EHRs, it is controversial if the interaction with computed systems does not possibly interfere with the psychosocially and emotionally based patient communication [39].

In this context, different hypotheses are mentioned that try to explain the described phenomena. On one hand, clinical treatment is incomparably more complex than any other data-based process of decision making and execution [40, 41]. On the other hand, in clinical healthcare most different protagonists are interacting who sometimes have opposite interests, which contributes to a renitent stabilization of the non-digital status quo [42]. And finally, it is discussed that most traditional computer-based communication and data systems are based on a mathematical, linear model (sender – transmitter – receiver [43]) that contradicts to a more fluid, interpretation-requiring model, which stipulates the necessity of exegesis of possible significances of the information in the Wittgensteinian sense and that is inherent to the medical decision making and the collegial discourse [41–44].

In the following chapters, the authors try to systematize the different aspects of the discussion and to give an overview of the significant operative and strategic implications of medical data assessment and management.

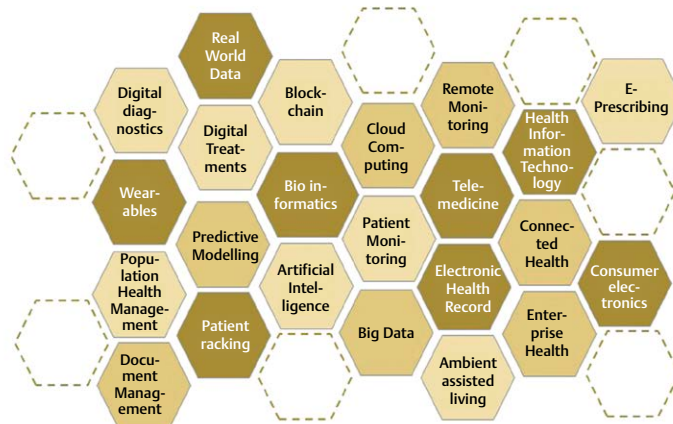
II. Concepts of Medical Data Management

a. Terminology and classification

The dynamism of digitization is so high that within shortest time various thematic “islands” develop. Their taxonomic classification, hence, is not possible or it cannot cope with the pace of the development. The same is true for the legal and regulatory monitoring of digital industry, which bears an enormous potential of conflicts and insecurity especially in a highly sensitive application field such as medicine [11]. Furthermore, the heterogenic and colorful digital application landscape complicates the development of strategic directives in the sense of a digital agenda (► Fig. 1).

A similar diversity of terminologies is also observed in the context of data storage systems. Within those more than 50 years since the introduction of the first prototypes of medical databases, several terms and definitions have been used and then discarded [45]. Initially, it was the question of systematically collecting and archiving clinically scientific literature (MEDLARS and MEDLINE); with the end of the 1960ies and the beginning of the 1970ies, other functionalities came up that had been developed and programmed for clinical decision making, for example based on reminder functions [46]. With the market maturity of databases that were relatively simple to handle and the distribution of personal computers (PC), first systematic reflections were initiated at the beginning of the 1980ies how data and information collected during clinical treat-

Digital health: a fragmented and poorly structured industry segment.



Quelle: SKC-Analyse

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► **Fig. 1** Segment fields of digital health. Digital health: a fragmented and poorly structured industry segment.

ment can be summarized systematically and documented in a multidimensionally evaluable way. Rather early, it became obvious that one of the major challenges for the usability of such systems was that various participants in the process may use the data in different places and at any time simultaneously, sometimes also successively. This is mainly due to the interdisciplinarity of clinical medicine and as essential prerequisite it requires a reasonable application of a multi-user functionality that serves as chronic of the events, as archive, and also as base for decision and documentation of decision making [47].

In the last years, various terms that finally describe very similar functionalities have been introduced and discussed in the sense of a taxonomy. The term of “computer-based patient record (CPR)” has been widespread. It elucidates that the patient and the respective treatment and care processes represent a significant data source [48]. Around the turn of the millennium, the term of CPR was mostly replaced by “Electronic Health Record (EHR)”. Meanwhile, this term is standard in the international context. Synonymously, the terms of “Electronic Medical Record (EMR)” or – more rarely – “Patient Health Record (PHR)” are used while PHR differs in that it is filled out and managed by the patient while the other two, EHR and EMR, are managed by the care provider or also the health insurance. CPOE (Computerized Physician-Order Entry) are systems or functionalities that allow the treating staff to induce and document prescriptions or orders. Finally, CDSS are Computerized Decision Support Systems, i. e. software linked to EHRs that support medical decisions by means of “intelligent” algorithms [49, 50]. This subdiscipline of medical data management is currently booming due to the further development of artificial intelligence although a general rating is currently rather difficult (see below).

In Germany, an own terminology is used that is not always unambiguous. The term of electronic patient file (elektronische Patientenakte, ePA) is widest-spread, which has already been coded in the Social Security Code (Sozialgesetzbuch, §291a). In this context, legislature has extended the physical element of the electronic health card that had originally been conceived as data medium and intended to simplify the clinical as well as administrative data-flow between care providers and cost bearers, by the concept of a web-based solution. This seemed to be obligatory because the common development project of the self-governing parties (“gematik”) remained without result and finally had to be considered as failed according to the original purpose. As of 2021, the ePA should be available for all medically insured people in Germany and applied cross-sector with all care providers including all health insurances [51]. The definite conception, however, is still unclear, i. e. it is not known who is responsible for the administration of data storage and management and how systematic administration has to be performed. The cost bearers have started several initiatives. At the time of writing this paper, three different approaches had been presented and in parts already implemented in clinical routine. On one hand, this was the decentrally organized AOK model that provides data in a decentral organization, i. e. on the computer systems of the care providers (medical practices and hospitals). On the other hand, there is the central model of the Techniker Krankenkasse in cooperation with the private health insurers of Signal Iduna and Generali where healthcare data are stored and managed on IBM servers. Finally, there is the system of the private provider called Vivy that is mainly financed by the Allianz health insurance and that has been joined by different statutory and private health insurances and where the data are also stored centrally. All these systems have in common that the patients keep control of

► **Table 1** Functionalities of EHRs according to the Institute of Medicine [16].

Core functions	Additional functions
Data management of healthcare information	Electronic communication and connectivity
Outcome management	Patient support
Electronic assessment of prescriptions	Administrative support
Decision support	Reporting and healthcare management of populations

their data and decide who is allowed to access which data at what time [52]. However, currently it is still completely unclear if and how the different systems may communicate and exchange data in order to ensure interface-free communication that represents the basis for a smooth, reasonable, and valuable use of healthcare data. The two other terms that are used in Germany are electronic health care file (elektronische Gesundheitsakte, eGA, according to §68 of the Social Security Code) and electronic patient record (elektronisches Patientenfach, ePF, according to §291a of the Social Security Code). Most probably, they will be replaced because based on the current stage of decision, these terms will be withdrawn.

In the following, mainly the term of Electronic Health Record (EHR) will be used because it is internationally established and the associated functionalities also correspond to the German version of ePA.

In the past, the US American Institute of Medicine has worked on a classification of the wide and fluid field of health information technology (HIT) [16]. According to this definition, an EHR has to assume eight functionalities (► **Table 1**).

It means that an electronic patient record generally has to be able to collect patient data and to store them, to provide this information to care providers or treating staff if required, to allow the treating physicians inserting instructions and prescriptions and documenting them (CPOE), and to provide physicians and caring staff with decision support regarding treatment alternatives of individual patients (CDSS). This definition shows that the support and facilitation of the clinical activity of physicians and caring staff are in the focus of the functionality [53]. The support of the administrative processes including accounting is considered as necessary, but not indispensable additional function. From the German point of view, this perspective anchored in the entire international publications is remarkable because in Germany the support of administrative processes and expectations of cost reductions in healthcare are considered as central function of electronic data management. In contrast, the English-speaking countries agree in their opinion that the main purpose of HIT is to optimize the three components of a physician's time: the time spent with the patient, the time spent for documentation, and the time used for continuous medical education [54]. A physician-related EHR as well as a patient-related PHR should be designed and conceived in that way that they may be implemented into the professional or private environment without any problem. Only when this precondition is fulfilled, electronic patient records will be successful [52].

Currently, the global market for EHRs is estimated to 23 billion US \$ and since many years it is increasing with a constant growth rate of more than 5 % [53]. There are various segments that are based on different approaches. So the difference can be made between web- or cloud-based systems and systems with own servers, with regard to the central purpose of the system (e. g. practice management, patient management, transferal management, or network management) or according to the configuration of the user (hospital, practice, care homes, acute care etc.). All systems have in common that they are based on the simple GIGO principle that must not be underestimated: garbage in, garbage out. This means that an electronic data management and analysis system can only be so good as the poorest quality of the entered data. Even the smartest algorithm can only provide poor, unclear, invalid, or even false analyses if the entered data are incomplete or incorrect [56]. As a consequence, already the collection and entry of data in an EHR determine the result that can be generated from the use of the system at a later time. Thus the focus has to be placed on the data collection process, and it is not surprising that the efforts for newly introduced and established EHR systems increase at the beginning of data processing, for example when creating a new dataset. However, many people involved perceive this situation as contra-intuitive and often this is one of the crucial origins for the failure of the system and for the users' disillusionment and deception [57].

b. Value creation logic

In Germany, healthcare provision is generally performed based on quality and efficiency rules anchored in the social law. This effectiveness or efficiency paradigm is also applied in the argumentation regarding the benefit of electronic health records. On one hand, there is the statement that the quality of healthcare provision might be increased based on organized and reasonably evaluated data; on the other hand, the costs might be reduced so that the system benefits from savings. As mentioned above, the quality of the data is a relevant precondition for being able to keep promises. Furthermore, also the quality and the intelligence of the applied algorithms, the technical processing quality, and the quality of results and reports significantly influence the benefit of EHRs.

The quality of healthcare provision may be increased via different value mechanisms [58]. It is assumed that more and more systematically processed data improve diagnostics as well as targeted therapies. The expected flood of data due to the development of personalized medicine has already been mentioned above. Some studies could confirm that EHRs contribute to a higher adherence of therapists to evidence-based guidelines [16, 50, 59]. The precondition is that the system disposes of current evidences and provides them as decision making tool in the respective therapy situation. Additionally, data processed in this way facilitate the recognition of patterns, in particular regarding the interindividual comparison and the identification of trends within certain populations [60] which may be beneficial in the context of rare diseases or untypical clinical situations.

The patients' participation in the clinical decision making process (shared decision making) and their active contribution to the management of the disease increases healthcare provision and may be realized by means of electronic health records [61]. The interactivity of the files and thus also sharing of information and docu-

ments is the necessary precondition. Perspectively, it has to be taken into account that the data sources controlled by the patients as well as those generated in the professional, clinical environment from most different source are configured interoperably. This is not ensured in the context of devices produced by consumer goods industries, e. g. wearables such as fitness watches or personal electronic assistants (Alexa and others) because a common data standard does not exist.

The study data regarding the hypothesis that EHRs improve the communication, collaboration, and coordination in clinical healthcare provision are not clear [50]. Apparently, the investigated healthcare situations are so heterogenic in their respective setup, their complexity, and the target definition that the often cited value proposition (the intersectoral and interdisciplinary cooperation quasi automatically improve with introduction of electronic health records) has to be critically discussed [62, 63].

Avoiding therapy faults, in particular when prescribing or administering drugs, is considered as another important value factor for the benefit of electronic health records. For example, integrated expert systems may indicate interactions, intolerances, or specific contraindications and thus avoid incorrect treatment [16, 50, 64]. Interestingly, there are also studies that seem to confirm the contrary, i. e. that therapeutic errors may increase because of EHRs [65–67]. This means that also here the study and evidence situation is not clear and depends on the specific circumstances. The above-mentioned GIGO principle is explicitly indicated in this context. Complete and well-structured electronic health records where the quality of data entry is ensured based on behavior controlled elements, may reduce the risk of data and information loss and the susceptibility to manipulation of clinical documentation [50]. The usual scenario of findings or radiological imaging that cannot be found does not arise in cases of central, complete, and available data storage. This is certainly one of the strongest arguments for the development and implementation of electronic health records.

With the obligatory introduction of a hospital discharge management according to § 35 SGB V, another aspect of value creation has gained in importance due to the electronic health records. The idea is that the provision and availability of patient- and therapy-relevant data might lead to a significant reduction of information interruptions between the inpatient and outpatient sectors. These interruptions are considered as origin of a significant percentage of avoidable re-admissions in hospitals. Different studies could show for example that 20 % of re-admissions are due to drugs and could have been avoided in more than two third of the cases if therapy management had not been interrupted or changed [68, 69]. Also in cases of stroke, information breaks lead to suboptimal healthcare in the acute situation as well as in the context of post-acute therapy and rehabilitation [70–72]. Numerous investigations confirm that a better, i. e. more seamless and complete information, communication, and thus collaboration between the outpatient and inpatient sectors based on electronic information systems may lead to a significant reduction of the so-called “revolving door effect” (inpatient admission – discharge – inpatient re-admission) and thus to a clearly higher quality of healthcare provision [73–81].

In addition to the quality, electronic health records shall also increase the efficiency. The efficiency gains shall be based on a reduction of the use of resources (time, capital, staff). Provided that the

database carrier (server, cloud, internet) is technically available, a reduction of the search and access times is mostly recognized compared to analogue systems [50, 82]. The hypothesis associated with the factor of time saving is that the time saved due to EHR can be used reasonably for direct patient healthcare. In addition, cost reductions are postulated in various areas, e. g. by more efficient prescription of drugs, more efficient use of radiological devices, by avoiding double examinations or unnecessary tests, by reducing billing mistakes, or successful handling of liability claims [83–86]. The efficiency gains achieved by process improvements, e. g. by providing a central dataset that does not need to be redundant in different contexts along the healthcare process, might contribute to a reduction of the staff and thus the staff-related costs that represent the largest expenses in a hospital [67, 87–90]. The effect of EHRs on this cost item is generally considered as argument for the reciprocal financing of the considerable development, implementation, and operational costs of an electronic health record system. Only few data are published about the expenses. An American trial from 2011 estimates 19 million US \$ for an acute hospital with 280 beds [64]. Since the healthcare landscape is highly complex and extraordinarily heterogenic, probably no reliable benchmarks may be developed. Instead, the individual constellations must be considered regarding the efforts to be calculated. So it may be stated that the undisputedly high potential for efficiency and effectivity increase in healthcare provision that electronic health records have, cannot be realized immediately, directly and without fulfilling certain preconditions [67].

c. Stakeholders and business models

For the estimation and the assessment of the success, i. e. for the realization of the promised value of electronic health records and the implementation in business models, the perspective of the respective user is crucial: Cui bono? (Cicero; To whose benefit?). Since different groups with highly various requirements are included in a complex and collaborative healthcare system, target conflicts cannot be excluded; they rather belong to normal daily life. The aspects that seem desirable and beneficial for health insurances, may be discussed critically and even considered as useless from the physicians’ point of view (“One person’s failure may be another’s success” [91]).

If the focus on the patients is meant to be the paradigm of a modern healthcare provision, data storage and management have to be assessed from the patients’ perspective and at least indirectly contribute to the benefit for the patients, either by increasing the effectiveness or the efficiency. It is generally acknowledged and also internationally intended and confirmed by legislation that medical data “belong” to the patients so that they might access them unlimitedly and they alone can decide who might retrieve them when, how, and under which conditions. All data storage and processing systems are subject to this imperative. De facto, however, no consolidated data are available, but the respective sources dispose of fragmented or nearly atomized data details. The cost bearers dispose of so-called social data that consist of administrative elements and performance data documenting healthcare provision, i. e. performed or initiated services of the healthcare providers and thus the induced expenses in the sense of billing data. The healthcare providers dispose of anamnestic and clinical data of the

patients that are documented and administrated individually in a non-standardized form. From the healthcare researchers' point of view, healthcare providers dispose of primary data, while the cost bearers possess or administrate secondary data. Thus, certain delays occur until the data are available. It takes about 2–3 months until medication orders reach the health insurances and may be evaluated.

The interest in and the support of conceiving and implementing electronic health records is very different regarding the various parties and interest groups and is mainly oriented at the “job to be done”, i. e. the requirements that an EHR would have to meet and which benefit may be expected [92]. Physicians and health care providers might use database systems to support clinical decision making in order to increase the service quality. Also other clinical registries should serve to achieve this objective by allowing to analyze longitudinal courses and to identify cause-effect correlations in clinical routine [93]. However, the current focus of healthcare providers regarding generation, documentation, and evaluation of data is mainly placed on fulfilling documentation obligations and on complete performance recording that is the basis for billing to the cost bearers. Most electronically recorded clinical data are assessed for the purpose of administrative controlling and not primarily to improve healthcare provision.

The cost bearers implement electronically documented data in healthcare service management, for example structured disease management programs (DMP), or in integrated healthcare provision models according to § 140 of the social security law (SGB V) and use them for compliance measurement of quality-oriented processes. But also the cost bearers place their focus of data management on assumed efficiency increase. The transmitted performance data of the cost bearers lead to financial flows that have to be controlled closely. Based on a morbidity-oriented risk structure compensation, the health insurances are interested in reporting datasets as complete as possible, where morbidity and performance data are included, to the healthcare fund. Interestingly, in this aspect the interests of service providers and cost bearers are equal, even if their economic interests are usually rather diametrical. The more morbid a treated patient or an insured person is, i. e. the more diseases are coded and documented in the respective dataset, the higher is the remuneration for the service/healthcare provider and the higher is the reimbursement to the cost bearers from the healthcare fund. It is obvious that this model can be easily manipulated. The cost bearers furthermore use the transmitted datasets for budget planning, for management of the insured subjects and sales issues as well as for identification of accounting fraud. Some healthcare insurances have established risk management competences that process the service data in predictive models and calculate them actuarially compared to private healthcare insurances. This allows implementing strategic options for actions with regard to developing risks (e. g. important growth of treatment costs in oncology, increase of sickness benefits for insured subjects with the diagnosis of depression).

Pharmaceutical industry and medical technology are also interested in electronic clinical data. In the future, the pharmaceutical industry will more and more depend on generating data from the real situation of healthcare provision (“real world evidence”) because the approval institutions and the HTA agencies (HTA: Health

Technology Assessment) that are responsible for pricing and remuneration start making only preliminary or temporary decisions regarding the market access. Prolongation of the market authorization or the period of validity of a certain remuneration then depends on the evidence of the product's clinical performance in the real healthcare service situation, i. e. finally on a confirmation of the usefulness or additional benefit in real life (beyond artificial clinical tests). Due to this reason, it is essential for pharmaceutical companies to acquire clinical data from the EHRs and to evaluate them in the sense of a phase-IV trial. Since the access to these data that are either administrated by the healthcare providers or the cost bearers, is only possibly in a very cumbersome way, some companies pursue the way of establishing registries allowing them to assess study data from treated and untreated patients. Another option is the implementation of internet-based patient platforms where patients voluntarily publish or exchange their data. This variant, however, can merely be quality-assured so that the generated evidence is rather weak or must be questioned overall. Medical product companies have expanded their business models for some time in that way that they appear as system providers mainly in hospitals. The devices equipped with software and own computers should first be implemented in existing hospital information systems. Meanwhile, the objective of many, especially large medtech companies, is to work as system provider and to provide also controlling, evaluation, and documentation software beside the device hardware. Electronic health records are a central aspect of the strategic agenda of medtech industries [94]. It seems to be problematic that most providers have developed proprietary software for controlling of the devices that are not interoperable in the above-mentioned sense.

Until now, software companies and so-called system houses had mainly focused on hospital information systems for the management of administrative processes. Since these providers are already “on site”, i. e. close to clinical routine, the extension of existing systems and structures seems to be a logical consequence to complete electronic healthcare records that correspond to the mentioned expectations. For example, the software company SAP has created a separate division of “Health” that pursues the objective of becoming the gold standard of clinical documentation. Currently, however, the impression arises that the complexity and the particularities of clinical service provision and the resulting requirements to data storage and management are mostly underestimated. The data dimensions along a clinical treatment pathway are so voluminous that good business chances exist also for specialized niche players who focus on isolated tasks. In the USA, for example, so-called Pharmacy Benefit Managers (PBM) have established themselves whose objective is exclusively to monitor drug consumption in healthcare provision and to optimize it with regard to expenses, but also evidence-based guidelines. As intermediaries, they mediate between healthcare providers and cost bearers and strive for balancing the different interests. For this purpose, they retrieve specific information from EHRs and analyze it based on own evaluation algorithms and benchmarks. In some models, further data providers and claim groups are involved beside the usual parties. For example, biobanks may enter genetic data; and even consumption data of supermarket chains may be considered as relevant

sources, e. g. when the shopping behavior of subjects suffering from diabetes shall be assessed [95].

Agencies, organizations, and institutions of public healthcare provision that deal with population-based questions, are also highly interested in data from electronic health records. The current healthcare reporting is strongly delayed, very rough, and only descriptive so that the usability for answering strategic issues is very low. Legislature and the organs of indirect public administrations must be highly interested in generating current and authentic healthcare data in order to be able to react adequately from the political perspective. This background is also seen in legislative initiatives that request or order rapid implementation of universally applicable electronic health records. Currently, patients and insured subjects use their health data mainly for documentation and archive them as paper documents. Privately insured patients sometimes use these data for accounting their healthcare expenses with the cost bearers. Via devices of consumer electronics such as wearables or smart watches, however, continuously biological and behavioral data (heart rate, sleeping behavior, movement, nutrition, oxygenation, tracking etc.) are generated and in most cases also archived, which may have a clinical impact. However, these data are regularly stored at the manufacturers' premises and managed there in an intransparent way. In this way, quasi en passant electronic health records and user profiles are created that are not intended for the autonomous and exclusive access of the patient. Another type of systematic database-based use of clinical data is social networking and patient platforms where patients share their data and make them available for other members of the network. These datasets are suitable to perform analyses of the entire patient population. In particular in the USA, platforms such as www.patientslikeme.com play an increasingly important role because the data provided by the patients, e. g. sickness diaries, allow substantial analyses [16]. So the American approval institution FDA (Food and Drug Administration) has concluded a contract with [patientslikeme.com](http://www.patientslikeme.com) on pharmacovigilance since the patients' postings shared on this platform reveal possible side and interaction effects of drugs significantly earlier so that they are identified earlier than it occurs via the traditional way of medical reports.

It is obvious that the assessment, storage, and management of very personal clinical data causes legal and ethical problems. Their discussion, however, will not be included in this article because of the limited scope of the manuscript. But it can be stated that the legal dimensions of data protection and data safety are discussed intensively; nonetheless, solutions still have to be found. It cannot be expected that the administration of justice and jurisdiction keep the pace with the technical dynamism. However, it would be helpful if certain standards could be stipulated and fixed [11]. Also from an ethical point of view, many open questions still exist that can be answered probably only based on a social consensus [96]. The respective discussions, however, only start very slowly and such as the legal reflections they are delayed with regard to the technical development.

The different stakeholders have very different perspectives on electronic data storage. The enormous potentials for the increased quality of healthcare provision, i. e. for an improvement of medical care, and for increased efficiency can only be put into effect when most different data from various data sources are summarized in a

patient-centered way [97]. In this context, actually equal interests of all parties involved should be expected. This precondition also determines if – as often stated – medicine faces disruptive changes and a real change of paradigms must be expected. Possibly, this decision is made with competition which in any case has to be preferred to a political top-down directive [98]. For market players on the side of the healthcare providers (hospitals, practices) and on the side of the cost bearers (statutory and private health insurances) the strategic imperative is that own data must be understood and rated and options should be developed that allow improving the own quality of healthcare provision and increasing the efficiency to the benefit of the patients.

d. Technical aspects

The technical elements that are important from the users' point of view depend on the required functionalities, i. e. the "job to be done" (see above). Since medicine, i. e. diseases and their treatments, is a continuous process (24/7), the crucial technical precondition of electronic health records is the high presence or availability and thus possibly low or no "down times". This aspect requires redundant and mirrored systems so that maintenance times can be bridged. Herewith associated is the request to technology that data loss must not occur because the complete continuity of information is essential for medical decision making. Since the data volume is very high, as described above, and will exponentially increase in the future, respective EHR systems have to provide unlimited or rapidly and highly scalable storage capacities. The analysis of the immense data quantities further requires highest processor performances so that rapid conclusions may be drawn, at best even in real-time. A central aspect is data safety, i. e. the question of how data can be protected against unauthorized access, theft, and misuse. This also includes protection against falsification so that manipulations are not possible or become at least transparent. In this context, the potential of the block chain technology is discussed. It means that the worldwide distribution of an uncountable number of copies of the datasets makes unauthorized manipulation impossible [99, 100].

The central technical aspect regarding data storage and management is the interoperability that is considered as first priority also on many governmental agendas [101]. Since the relevant clinical and administrative datasets appear at various points of the healthcare provision pathway and are assessed and documented by most different systems, it must be ensured that a transferability from one system to another may occur without any data loss and that the convergence is made compatible. This aim is pursued by the Health Level 7 standard (HL-7) that allows the exchange of data between organizations in healthcare systems and their IT systems. In Germany, HL-7 is nearly exclusively used in hospitals and not applied for data exchange between the clinical and outpatient sector in healthcare. This is partially due to the fact that a multitude of data exchange formats had been developed regarding the software used in practices where xDT are the formats with the highest distribution. Fast Healthcare Interoperability Resources (FHIR) is the next generation of HL-7 standards that is currently internationally implemented [34, 102]. Not only has the technical interoperability by means of specifications had to be ensured for optimal use, but also the semantic interoperability [100]. This means that dif-

ferent data that are generally not only generated by the device, but written down and documented in the patients' records as (free) text modules created by humans, have to be understood and interpreted by others who access those data. Of course this is more complicated because every discipline has its own terminology and idioms, synonyms are not used as such by different disciplines, and professional language is different from lay and common speech regarding structure and contents. Multilingualism, i. e. the use of German and English terms makes understanding even more complicated.

The Healthcare Information and Management Systems Society (HIMSS) has developed an Electronic Medical Record Adoption Model (EMRAM) that seems to be suitable for assessing the progress of the introduction of electronic health records. In this model, seven steps are defined, along which an organization up to complete implementation of a completely paperless electronic health record and the associated treatment pathways should develop (► Fig. 2).

As of today, only two German hospitals have reached level 6. On level 6, no German hospital is found and in total there are only 4 European hospitals (two in The Netherlands, and one each in Portugal and Turkey). For the USA where EHRs are implemented in many more hospitals, the prediction is made that the majority of institutions will not reach level 7 before 2035 [105]. It is clear that the value propositions of artificial intelligence and machine learning in healthcare can only be fulfilled when it is technically possible to connect these algorithms with electronic health records [34].

Another technical aspect that has to be taken into account for further development of EHRs is the possibility of collaborative cooperation without being in the same place. In software development and project management, it is realized via different collabo-

ration tools such as Microsoft Teams, Sharepoint, Slack, or Trello. These platforms allow working simultaneously on documents by several persons and they include a structured storage and calendar system as well as different communication ways via chat, e-mail, phone calls, or video. These functions are based on an authorization system defining who is authorized to assess, implement, comment or work on, or modify which data. Furthermore, these systems make certain hierarchic decisions so that conflicts or contradictory entries are shown or solved. The technical development outside the field of medicine in this regard has progressed enormously and it will be important in the future that the solutions developed in this way are integrated in the data storage and management system. The major technical challenge that determines the success and the failure of EHRs at the same time, is the development of a user-friendly interface on the basis of cohesive user experiences [54]. The most important success factor that leads to the broad distribution and application of software tools and apps is simplicity, accessibility, and intuitiveness of the user surface, which is impressively proven for example by Google. Only if it is successful to describe the high clinical complexity in an easily understandable data structure, electronic health or patient records will be broadly accepted by the users.

e. Limitations and evidence

Fulfilling the technical requirements and the level of how "good the job is done" by the EHR, determine the benefit of the system and thus its success. The trials published on this topic draw an unclear picture that is very heterogenic [25, 106, 107]. In many constellations, the frustration of the users prevails [108] and in a large burn-out study, the introduction of electronic patient records is considered as its leading cause among the medical staff [37]. It is a com-

The EMR adoption model: stepwise approach for achieving the optimal EMR environment.



Stage	Cumulative preconditions
Stage 7	Complete EMR integrating all clinical aspects (e.g. outpatient data, intensive care unit, emergency unit) and replacing all (medical) paper-based records. Application of standards for data exchange regarding integrated healthcare. The data warehouse is the basis for clinical and business-related analyses.
Stage 6	Physician documentation is supported by intelligent clinical decision making tools (based on discrete data elements) AND presence of an IT-supported closed medication process (closed loop medication).
Stage 5	Complete Radiology Picture Archiving and Communication System (e.g. PACS) replaces all film-based imaging.
Stage 4	Electronic prescription with clinical decision support (based on a rules engine) in at least one clinical unit and for medication.
Stage 3	IT supported clinical documentation as well as utilization of electronic order entries by physicians or nursing staff; this also includes the documentation of medication (eMAR; electronic medication administration record).
Stage 2	Electronic medical record (or CDR; clinical data repository) allows the summary and harmonization of data from different sources in the entire hospital.
Stage 1	Information systems for the core diagnostic and clinical departments (laboratory, radiology, pharmacy) are implemented or data from external service providers may be electronically processed.
Stage 0	Information systems for the core diagnostic and clinical departments (laboratory, radiology, pharmacy) are not installed. Data from external service providers cannot be electronically processed.

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► Fig. 2 EMRAM for development of an optimized EMR environment [104]. The EMR adoption model: stepwise approach for achieving the optimal EMR environment.

mon phenomenon that during and shortly after introduction of EHRs the productivity of medical activity decreases by 10–20% [16] and the time percentage of the medical routine is shifted from the direct time of interaction with the patients to the exposure to EHRs so that overall nearly 50% of the physician's time resources are consumed by managing electronic health records [109]. The reason may be that many electronic data systems have an own and thus other workflow than the clinical process flow that had been trained in clinical routine [110]. Indeed, it can be seen in the practice that the clinical workflow has to be adapted so that the information system works properly. Finally, the cart is here put before the horse. The consequence that can be seen is that the users' compliance is very poor and that the systems are applied only minimalistically [82].

Also for EHRs, spam occurs because the system itself cannot differentiate between valuable and useless information (GIGO). So reports are found about "decision support overload" that may lead to "alert fatigue" together with alarmism that is inherent to several programs by no longer reacting on permanent indications and invitations to act [36, 40]. In this context, it is not surprising that also trials have been published where an endangerment of the patient safety was confirmed in the first year after introduction of a comprehensive clinical data system [111]. It seems to be particularly problematic for the patient safety that computer-based decision support systems misguide their users to "phantom objectivity" [50]. Since the computer recommends a certain activity option that is based on highly sophisticated analysis algorithms, it is probably reasonable to follow them already from a medico-legal point of view. So in an organization-wide electronic database system, false algorithms bear the risk of repeated systematic wrong decisions [91]. The best antidote or the most effective prevention against such risk for the patients is an intensive exchange between physician and patient [112]. Of course, this takes time which is very limited and – as described above – is further reduced by the introduction of electronic patient records. Thus, physicians are led into a resource-related dilemma that is rather difficult to resolve [113]. It must be stated, however, that the experience with EHRs is not clear and that the studies in this context are very heterogenic. The quality of the published studies varies and because of the heterogeneity in the single settings no satisfactory modelling may be performed [82, 114].

With the introduction of electronic patient records, in particular when decision support systems are functionally linked, also liability questions arise that are mostly not understood or at least not answered up to now [115]. The fact that artificial intelligence programs and their basic pattern recognition algorithms are not infallible, but can even be outwitted and captured by hackers is a circumstance that is currently intensively discussed by experts [116]. Overall, it has to be questioned if the extension of the analytic functionality of EHR systems does not at the same time lead to increased weak points that may be accessed by hackers. This does not only bear risks regarding data manipulation, but also with regard to retrieving most private data and the retrograde identification of actually anonymized or pseudonymized data sources (i. e. individual patients) [117]. It does not surprise that the patients' lack of confidence increases because of such reports and studies and that their readiness to introduce personal data into electronic records decreases [118].

The introduction of electronic health records, either in hospitals or in general practices or also in health insurance, is a complex and error-prone project. All reports about poor experiences, deceived expectations, and contraproductive effects have in common that too few resources (time, money, staff) were invested for communication [16, 119]. The conceptual and practical knowledge to handle complex and powerful data storage and management programs is not very sophisticated in healthcare professions [120]. Hence, there is the risk of dividing two categories: a digital elite that is able to apply and use the new technology and a digital precarity that does not know how to use the applications and rejects or even boycotts them. This phenomenon is also seen in other areas with planned digital transformation. Up to now, there is a significant deficit of best practice guidelines how an EHR system may be best developed and implemented so that many projects have to quasi reinvent the wheel again and again and venture terra incognita [121]. By nature, this procedure is associated with enormous risks for the culture of an organization dedicated to success.

Of course, the mentioned obstacles call for regulatory politics that meanwhile also in Germany try to accelerate the nation-wide introduction of electronic patient records. In centralized one-payer systems such as the British National Health Service, this is easier than in fragmented market-oriented systems such as the United States, Switzerland, or Norway [122]. In Germany, the development is incumbent upon self-administration systems, i. e. representation of the service providers and cost bearers, that try in an extremely long negotiation process to achieve a balance of the interests in a common approach. Nonetheless, legislature has announced to modify the legal conditions in that way that Germany being internationally not competitive at all has to implement a nation-wide EHR system within very short time.

III. Success Factors, Strategic and Operative Implications

It is undisputed that the electronic data storage and management bears a high potential of quality and efficiency and that it is inevitable already due to the technical developments. However, the question must be asked how the described risks can be minimized, the systemic obstacles can be overcome, and the success perspectives can be maximized. From the literature and based on practical experience, some success factors may be identified. The conception and implementation of electronic health records is a strategic management task that has to be anchored on the highest management level and requires its utmost and undivided attention. In a clinical setting, the focus of all efforts is the interaction between medical staff and patients. So it is the clinical or the healthcare perspective that is most relevant and not the administrative process [123]. The welcome the creation of central information technological expertise on the management level is, for example by nominating a chief information officer (CIO), these activities are often related with the uncomfortable way of delegating technical issues. Finally this leads to the fact that the core competence of knowing about the central value creation process is not used as structuring element of the CIO functions or is available for them. Each development should start with the assessment and understanding of optimized clinical processes in the sense of healthcare provision

and in this context represent data sources, characteristics of data, data flow, i. e. also data receivers, and the planned utilization of the data. The high interaction and interface density of the clinical situation increases the complexity in this context. Since biological systems per se are characterized by volatility, uncertainty, complexity, and ambiguity (VUCA), classic linear development processes are inappropriate for the task. Instead, an iterative and agile procedure is recommended which develops prototypes in short time and tests them in the real situation regarding their applicability. If the prototype does not contribute to solving the problem in the real situation, it has to be discarded and a new prototype has to be developed. Hereby it is important to follow the customer journey that defines which is the “job to be done”. This definition that takes into account the so-called “pain points” is the most important strategic task for which sufficient resources have to be available to work on it. The core questions that should be answered are:

- Which problem has to be solved?
- Which question has to be answered?
- Which elements that have led to success have to be preserved?
- How can the success be measured?
- Which risks can be foreseen and how can they be addressed?
- Which skills are necessary and how may they be built up?
- How can we involve all contributing parties and show them the importance of success?
- Which incentives can be offered?
- Which modifications within in the organization are necessary and which ones are we ready to perform?

Overall, the introduction of EHRs leads to a cultural change that makes many actors leave their comfort zone and for this reason it is considered as difficult and risky.

In order to place the focus of the efforts on the patients' perspective, it is reasonable to involve the patients early in the sense of a co-creation process and to understand their preferences [124–126]. Hereby, anonymous market research studies have only limited value, whereas their direct implementation in the initial conception and testing of the prototypes is recommended. The consideration of multiple data sources includes the rather unstructured data that the patients may contribute for example by means of diaries [90]. Useful electronic patient records also dispose of this functionality so that rather anecdotic narrations, which seem to be more and more important, are assessed as well and evaluated [127]. As mentioned above, the simplicity, i. e. the accessibility to the data system is a relevant condition for its use and a significant factor for the respective user's satisfaction [34, 54, 112, 128–130]. Finally, it is about developing an internal system, consisting of patient, clinical staff, and technology, that then may enter into an external connection for example with the cost bearer or other service providers [54]. Already 50 years ago, in a completely analogue world, the proposal was made how clinical data may be reasonably structured in order to optimize the quality of the healthcare process and at the same time to generalize the knowledge and experience from an individual case as basic learning experience [131]. Finally, digitization did not change these principles. Beside all already discussed regulatory requirements, the question must be asked which incentives may be offered to promote the success of

EHRs. In this context, financial incentives seem to play a major role [132–134]. However, it is doubtful if so-called workarounds, i. e. the application of technology reduced to the absolute minimum, may really be avoided by the “hygiene factor” of money [135, 136]. In general, financial incentives do not lead to sustainable cultural changes which would be necessary, as explained above, to implement the effectivity and efficiency potentials of electronic patient records. All parties involved in the organization process would have to work on developing and implementing new skills that up to now did not belong to the classic competence profile of healthcare activities. Knowhow regarding conception and application technology as well as methods from design thinking and system analysis turn out to be core competences of the future, digitally modified medicine and should be regularly included in the education and training catalogue of healthcare professions [35, 38]. It is obvious that sufficient time has to be available [137, 138].

Many clinical units have made the experience with initiating and implementing quality management projects that dealing with the core processes is cumbersome, sometimes uncomfortable, but finally useful because it leads to finding different approaches for improvement. Regarding the introduction of EHRs, it is moreover the matter of radically questioning current processes, modifying them if needed, or even completely re-structuring them. As in all digital transformation processes, the slogan that “digitalizing a shitty process gives you a shitty digital process” is also true in this context. So it is essential to put the patient-centered workflow in the focus of the reflections and to integrate data storage and management [39, 139, 140]. Hereby it may be suitable to build development teams together with software developers and system architects being close to clinical practice [141]. In this way, not only customer journey (see above), but also data journeys may be understood, in which possible system discontinuities may be identified early and conceptionally taken into consideration [142]. So what is needed to overcome the highest digital effectivity and efficiency barrier of EHR systems, i. e. the cultural inertia [143]? Various influencing and success factors have been mentioned and certainly all of them have their relevance in such a complex environment like healthcare provision [139]. However, the most important factor that has been confirmed by numerous studies and case reports, is the undivided attention of the highest management level and the unlimited commitment of the top management [144, 145]. As in many critical change projects of large collaborative organizations, a continuous intensive communication must have highest priority. Multipliers on each hierarchic level and in all organizational units or responsibilities are indispensable elements helping to transport the change momentum into the organization in a powerful and sustainable way [146, 147]. Since electronic patient records are conceived as interdisciplinary database, the project of conception and implementation has to include all disciplines [148]. As medicine, healthcare provision, thus the professional environment, but also the patient, his reality of life and his expectations, and overall even society changes with high dynamism, consequently the change process that has started with implementing an EHR system, will have to be conceived adaptively and not in a timely limited way [50]. Sociological and organization-psychological investigations of the performance of internet-based social networks emphasize that an iterative and permanently adapting, quasi experimental proce-

ture containing at the same time rigid evaluation and selection processes is the key to success [149, 150]. The competence of solving problems that is inherent in all active parties in medicine and healthcare provision and the associated cognitive and emotional skills are actually outstanding conditions to accomplish a suitable development and implementation of EHR systems and to implement a high benefit for all involved subjects [151]. Frustration tolerance is an important virtue in this context because it is the matter of learning systems [36, 40]. And finally it is recommended to develop a certain sensitivity to possibly arising market distortive effects [152]. The required high efforts regarding capital, manpower, and time are beneficial for large entities and might foster oligopoly. Such concentration processes may be observed in search engines, internet traders, and social networks.

IV. Conclusion

Electronic data storage and management systems in medicine will become the standard of clinical documentation in the next years. Clinical as well as administrative data will be summarized in electronic patient records or electronic health records (EHR). The data are retrieved in healthcare provision, accounting processes of the healthcare providers with the cost bearers as well as the patients themselves who may include measurement values and also narratives into the database. By means of further technologies such as artificial intelligence or machine learning, it will be more and more successful to suitably structure and evaluate the immense data volumes and to develop reasonable decision support systems for all parties involved. Already in the context of data assessment, it becomes obvious if the value proposition of increased quality of healthcare provision and/or an increased efficiency can be fulfilled because an incomplete or incorrect dataset cannot lead to a sound result of analysis. Since fully functional electronic database systems have the potential to sustainably modify clinical medicine and traditional healthcare provision logics, the construction and implementation of EHRs has to be a top priority on the strategic agenda of the medical decision makers, i. e. practices, hospitals, associations, and scientific societies. As of the start, each project needs a strategic perspective describing exactly which the "job to be done" is. The focus should be placed on the direct and also indirect benefit of the patient. Based on the clinical core process, i. e. the interaction between healthcare professionals and patients, the mechanism of value creation can be described and the existing data treasure can be identified. The development and implementation of valuable and beneficial data storage systems requires an enormous amount of resources, i. e. time, money, and manpower. New skills, for example agile working methods or design thinking know-how have to be developed; old virtues such as discipline, commitment, and reliability have to be promoted. The risks that are associated with the changes of the processes and the basic ways of thinking should be addressed thoroughly and countered. Those are for example a positivistic and uncritical faith in the infallibility of computer-based algorithms, the renunciation to work on the direct and personal exposition by using electronic communication instead of face-to-face interactions with patients or colleagues, and finally the voluntary or forced (because there seems to be no tech-

nical alternative) renunciation to holistic assessment of clinical data and unstructured information in favor of simplified, checklist-based information rudiments. In summary, medical database systems may contribute significantly to an improved healthcare provision and thus represent a relevant competitive factor in the future.

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