Do Physicians Have a Duty to Support Secondary Use of Clinical Data in Biomedical Research? An Inquiry into the Professional Ethics of Physicians.

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Abstract: Secondary use of clinical data in research or learning activities (*SeConts*) has the potential to improve patient care and biomedical knowledge. Given this potential, the ethical question arises whether physicians have a professional duty to support *SeConts*. To investigate this question, we analyze prominent international declarations on physicians' professional ethics to determine whether they include duties that can be considered as good reasons for a physicians' professional duty to support *SeConts*. Next, we examine these documents to identify professional duties that might conflict with a potential duty of physicians to support *SeConts*.

Secondary use of clinical data in data-gathering, non-interventional research or learning activities (*SeConts*)[1] is widely considered to have the potential to expand biomedical knowledge and improve patient care. Several initiatives strive to take advantage of this potential by building infrastructure and governance frameworks to make clinical data available for *SeConts*.[2] Physicians play a key role in implementing *SeConts*: They are the ones in a special relationship with the patients whose data shall be used. They (alongside other medical staff) also generate and document clinical data during patient care. Given the great potential to foster scientific progress and improve future diagnostics and care it would seem obvious that physicians should support the sharing of their patients' data for *SeConts*. However, such sharing might conflict with physicians' professional duties towards their patients, e.g., the sharing of clinical data for *SeConts* could infringe on the physicians' duties of medical confidentiality and to respect their patients' informational rights. Additionally, sharing data for *SeConts* might also raise practice-related concerns by physicians, e.g., concerns about additional workload when physicians already have limited time to spend with their patients. Therefore, the ethical question arises whether physicians have the professional duty to support the sharing of their patients' data for *SeConts*. In short: do physicians have a professional duty to support *SeConts?*

To further clarify the paper's research question, it might be helpful to briefly determine the limits of its scope: (1) We focus on the *physicians'* role and do not address the responsibilities of other professionals such as nurses who (to some extent) may also be involved in the generation and documentation of clinical data. (2) We focus on *clinical* data and thereby exclude other types of health data (see the pertaining clarifications

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in the background section). (3) Our focus on the sharing of clinical data does *not* include moral questions that arise at other points of the cycle of clinical data usage as, for instance, by the ideal of a Learning Health Care Systems. We thus do not address ethical questions regarding translation from learning activities or research to care or questions of intellectual property, profit sharing and of pharmaceutical products and medical tools that companies might develop by using clinical data. *SeConts* might also lead to the development of products or tools such as clinical decision aids based on artificial intelligence. However, the ethical issues associated with the use of such instruments and products, as well as the responsibilities of physicians applying them to medical care, also fall outside the scope of this paper.

To answer our research question, we proceed as follows: *First*, we provide a quick overview of the current state of the relevant bioethical literature. *Second*, we clarify the concept, implementation, and potentials of *SeConts*. *Third*, we explain our normative basis and methodological approach. *Fourth*, in the analysis section, we examine the professional duties of physicians that constitute good reasons for a physicians' professional duty to support *SeConts* and, *fifth*, professional duties that potentially conflict with such a duty. We draw the preliminary conclusion that professional ethics argues for a physicians' professional duty to support *SeConts*. *Sixth*, we evaluate practice-related concerns that might challenge this conclusion and argue that, if certain measures are taken to implement *SeConts*, physicians have a professional duty to support *SeConts*. *Seventh*, we subsequently present these measures.

State of Bioethical Research

In a survey of cancer patients and physicians, 68% of physicians confirmed that they had such a professional obligation[3], and 91% of patients expected physicians to share their patients' data for *SeConts*.[4] There is debate around the duty of *patients* to participate in (interventional) biomedical research in general[5] and specifically whether *patients* should share their data for *SeConts*.[6] However, thus far there has been little discussion on the *physicians'* duties in the context of *SeConts* or their duties to contribute to research in general. One possible explanation for this shortfall may be that bioethics in the past has strongly emphasized the need for a clear distinction between treatment and research and thus has rather highlighted the ethical challenges associated with physicians carrying out research. It is only in the debate on the ideal of a Learning Health Care System (LHCS) and its implementation, in which some argue in favor of abandoning the research-treatment-distinction[7], that we find initial attempts to define a duty of physicians (and other actors) to share data.[8] Faden et al. argue that "every practitioner … [has to] accept a responsibility to feed information into the system that increases our knowledge".[9] Van der Graaf et al.[10] postulate, with reference to London[11], that physicians have a duty to support the development of an LHCS. The ideal of the LHCS, to which the argument of Faden et al., London, and van der Graaf et al. is closely linked, is based upon a fully comprehensive and systematic implementation of *SeConts* and is thus a rather far reaching and ambitious vision. In this article, we adopt a different and broader perspective. For one, we focus on *SeConts*, which can be seen as an initial step towards creating a

In this article, we adopt a different and broader perspective. For one, we focus on *SeConts*, which can be seen as an initial step towards creating a LHCS, yet it also already exists, can be carried out, and is also currently being implemented independently and separate from any radical transformation of the current health care system into a LHCS. Furthermore, as to our normative approach, we do not rely on or aim to create a new and specific medical ethics that might suit the innovative and somehow revolutionary ideal of the LHCS. Instead, we address physicians' responsibility to support *SeConts* from a more traditional and consensus-oriented perspective, relying on physicians' professional ethics and declarations that can account as consensus and self-binding expressions on their professional ethos by the international medical community.

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Background

Before beginning the ethical analysis, it is necessary to shed light on the concept, implementation, and potentials of *SeConts*. We understand *SeConts* as *activities that solely reuse clinical data generated for the sake of health care to carry out research and learning activities that aim to improve biomedical science or services*.[12] By *clinical data* used in *SeConts* we mean data collected for and during diagnostics and treatment of patients like laboratory reports, diagnostic information, medication plans, therapeutical outcomes etc. as well as data collected for accounting purposes or patient management. Clinical data do not include data generated primarily for research purposes (research data). Regarding the various kinds of health data and health-related data commonly referred to as "patient-generated data," e.g., data generated by smartphone applications or health devices, our understanding of the term clinical data encompasses only a specific subtype with the following features: (1) the respective application or device is clinically validated (independently tested and approved by the authorities), (2) the data generation is initiated by the physician as part of diagnostics and treatment, and (3) the data are also stored in the patient record. The reasons for recognizing solely this specific subcategory of patient-generated data as part of clinical data and consequently as relevant for the paper's question and scope are twofold: First, only in this subcategory of data the standard of quality control is comparable to that of clinal data. Second, it is solely with respect to this category of data that physicians are clearly involved and have responsibilities in the generation and use of the data, which is a prerequisite for being relevant to the paper's ethical question concerning *physicians'* duties. One rather specific question regarding the understanding of clinical data relates to the role of clinical decision aids using artificial intelligence (AI). In a (future) scenario with AI based decision aids as approved tools of diagnosis and treatment (standard care), the "recommendations" by the decision aids, i.e., the data they generate to support diagnostic and treatment decisions, are part of care and thus to be considered as clinical data.

SeConts encompasses a wide range of possible *research* and *learning activities* that aim to improve biomedical science or services. Based upon our understanding of *research* as activities to generate generalizable knowledge to be published in scientific journals, *SeConts* encompasses various forms of research activities (studies) such as health services research[13] or comparative effectiveness research.[14] Drawing on our understanding of *learning activities* as activities that aim to directly control or improve care, *SeConts* also encompasses a variety of learning activities such as quality measurement and quality improvement activities in hospitals[15] or public health surveillance[16] to inform public health measures. Clinical data are also important for research and development of bioinformatics tools and for research in medical informatics, in particular for training and development of AI based software such as decision aids for the health care sector. These kinds of uses of clinical data for informatics research and development activities are part of *SeConts*.

Our ethical analyses take into consideration four scenarios in which *SeConts* can be conducted: each scenario has specific ethical implications for physicians' roles and workload as well as for patients' informational self-determination and privacy.

1. In the *anonymous data scenario*, solely anonymous data of patients are shared for *SeConts*. Anonymous data include anonymized data, i.e., data from which all (potentially, directly or indirectly) identifying information has been removed, as well as data that never had any identifying information. If it can be assumed that the data is anonymous, patients' consent is not legally or ethically required for use in *SeConts*. However, informing the patients or the public in very general terms about the fact that their anonymous data are used for research might be ethically desirable. Nonetheless, anonymous data are of limited scientific utility. To be considered anonymous, the data must have very low granularity – and low granularity is of little value for research.
2. In the *code to data scenario*, de-identified but non-anonymous data are analyzed in the local data center of the respective data collecting hospital

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using algorithms (code) sent by the external researcher. Only aggregated and thus anonymous results of this analysis leave the local data center.[17] In this scenario, we assume, no consent is needed.[18]
3. In the *consent scenario* patients are informed and asked to consent to the storage, sharing, and subsequent use of their de-identified but non-anonymous data. This approach relies on an informed consent or a broad consent, or, alternatively, on a dynamic consent[19] or meta consent[20], which, however, have been rather debated in the literature than applied to practice on a larger scale so far.
4. In the *opt-out scenario*, de-identified but non-anonymous clinical data are collected, shared, and used in *SeConts* by default. In this scenario, there is no individual patient information and consent process. Patients only receive general information on *SeConts* (e.g., in the form of information material distributed in the hospital or by public information campaigns) and can opt out of the use of their data.

We assume that *SeConts* has the potential to generate knowledge that can improve medical care and thus benefit future patients, the health care system, and thus society.[21] The assumption of *SeConts* improving care for future patients is not without controversy: Authors like Ploug argue that *SeConts*, like many biomedical research projects, may not produce relevant findings or, if it does, those findings may not be translated into improvements in care.[22] Admittedly, it is a fact that many biomedical research projects fail to produce knowledge of clinical utility.[23] However, we believe that the likelihood of *SeConts* to benefit the health care system is higher than it is with other types of biomedical research, such as basic research, for several reasons: *SeConts* includes many different study types;[24] a lot of them are very application oriented and thus likely to improve health care more quickly than basic research. In addition, the data can be used an unlimited number of times in different studies in many different areas of biomedical research, further increasing the likelihood that the data will one day contribute to better health care. Of course, realizing the potential benefits requires significant investments in IT infrastructure and faces numerous technical and organizational challenges, such as harmonization, standardization, and interoperability. However, in general terms many initiatives or national health care systems have invested or are investing in necessary infrastructures and have encouraged or initiated endeavors to manage the technical and organizational challenges. Furthermore, it should be kept in mind that the quality of the results generated in *SeConts* depends on the quality of the data used. In the worst case, the use of biased data may perpetuate, amplify, and solidify social biases and existing injustice. There are practical challenges in *SeConts* related to the quality of clinical data used in *SeConts* that require careful methodological handling, critical awareness, and transparent communication.[25]

Methods

After clarifying the concept, implementation, and potentials of *SeConts*, we will now introduce the normative basis and method of our investigation. We frame our ethical analysis as an inquiry into the physicians' professional ethics. By physicians' professional ethics we mean a system of values and norms that is widely recognized by physicians and their associations as entailing central values and norms that determine standards of ethical behavior for the medical profession. Physicians' professional ethics is a (complex) phenomenon of social reality in which physicians and their associations "profess", i.e., declare through official and self-binding acts of communication, that they *recognize* determined values, norms, and associated rights and duties as those according to which they *should* behave. It does not mean that physicians really (always) adhere to them.

The question is how we can identify and investigate physicians' professional ethics. In a basic step, we take official declarations issued by medical associations regarding physicians' professional ethical duties as an identifiable, representative, and reliable expression of such ethics. By this approach we follow the understanding of their ethics and its expression displayed by the World Medical Association: "Over the centuries the medical profession has developed its own standards of behaviour for its members, which are expressed in codes of ethics and related policy documents."[26] As there are many codes of ethics and similar declarations on a national level, we focus on prominent declarations of international medical organizations such as the World Medical Association (WMA) and the Charter on Medical Professionalism, developed by the Medical Professionalism Project. To still broaden our account of physicians' professional ethics, beyond the codes and declarations we also draw on positions on physicians' professional ethics expressed in the bioethical literature.

Our analytical approach to the codes and documents is a normative one — and not, for instance, a sociological or historical one. We take and recognize the codes and documents as what they have been

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intended to be by their authors: normative statements. We do not aim to critically evaluate from an independent and external ethical viewpoint whether the contents of the declarations and codes are ethically justified or not. We are rather interested in them as an expression of physicians' current ethical self-understanding and accept and recognize them as such. We search for professional duties within the codes or declarations that apply to our specific question. As we will see, the duties that appear to be relevant are often formulated in a very abstract manner and, of course, were not originally intended as a response to our specific question. To determine their concrete relevance, we determine whether and to what extent our specific question can be subsumed under the scope of each of the potentially relevant professional duties. We assess their normative meaning concerning our question, i.e., we determine whether it speaks for or against a physicians' duty to support *SeConts*. In assessing the relevance of single duties contained in the codes or declarations, we also refer to the bioethical literature on physicians' professional duties.

In our normative analysis of the codes and declarations we proceed in two steps that address the following questions: (1) Do the documents encompass duties or responsibilities that can be considered as good reasons for a physicians' professional duty to support *SeConts*? As we will discuss in more detail later, one challenge when analyzing the relevance of a single general duty that seems to underpin a physician's professional duty to support *SeConts* is that general duties are rather undefined. The normative analysis therefore needs to show why physicians should fulfill the general duty by means of supporting *SeConts*. (2) What rights and duties can be found in the documents that might restrict or contradict a potential duty to support *SeConts?* From the normative analysis of professional ethics codes, we will conclude that in terms of principle, physicians' professional ethics speaks in favor of a physicians' professional duty to support *SeConts* if some conditions are met. However, this preliminary conclusion can be challenged by practice-related concerns that stem from backgrounds or contexts other than professional ethics. We thus (3) take into consideration and assess further arguments and concerns from the empirical literature, addressing the question: Would a duty to support *SeConts* be reasonable for physicians and thus relevant in practice? The overall goal of this third step is to shed light on and critically evaluate all potential concerns that could be used to object that the conclusion gained from the professional ethics documents may be true in theory but does not hold in practice. In a final step (4), we assess and evaluate the preliminary conclusion in favor of a physicians' duty to support *SeConts* in light of the potentially conflicting concerns and interests mentioned in step 3 and conclude that physicians have a professional duty to support *SeConts* if certain measures are taken, which we present in the following section.

One might object that basing our normative approach upon physicians' professional ethics is in some sense normatively limited and that a moral issue such as ours should be analyzed and evaluated from a more general and independent normative standpoint like principlism or from a utilitarian or Kantian normative stance. One might further object that, by drawing on the physicians' professional ethics, at the end of our investigation we will not have a real ethical answer to our question but rather merely a response that depends on what de facto is recognized as physicians' professional ethics.

There are several responses to these objections that also give us the opportunity to further clarify the chosen basic normative approach of this article: (1) Medical professional ethics, which we understand to be reliably expressed in official declarations and codes issued by physicians, is not a normatively contingent matter but the result of more than 2,000 years of ethical deliberation, practice, and reflection. It largely reflects our common moral intuitions on physicians' role and responsibilities. (2) The moral question at the center of this paper, as well as other moral questions concerning physicians, cannot appropriately be addressed without taking physicians professional ethics into consideration. Even those who might call for a broader and a "more genuinely ethical" approach and evaluation of our question will need to consider the response from physicians' professional ethics as a socially and normatively important source and authority in medical ethics and practice. (3) Drawing on physicians' professional ethics has huge advantages in terms of relevance, applicability, and implementation: physicians' professional ethics consists in broadly recognized rights and duties of the medical community, reflects a broad social consensus and is, thus, widely accepted by physicians, other stakeholders, and society. The implications we draw from applying physicians' professional ethics to our research question therefore have the potential to receive widespread attention and consideration among physicians and beyond. (4) We do not limit our work to merely reconstructing documents on physicians' professional ethics but also incorporate further arguments and concerns from the bioethical and empirical literature.

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Analysis

Professional Duties that Might Imply Physicians' Professional Duty to Support SeConts

As a starting point in our analysis, we assume that physicians have a key role in *SeConts* and that *SeConts* can hardly be realized without them: clinical data are generated during patient care (diagnosis and treatment), and physicians are those who conduct or supervise patient care. In addition, physicians are in a normatively special relation with patients: the physician-patient-relation. Because of these reasons, physicians can make a unique, significant, indispensable, and effective contribution to *SeConts*.

In the following, we analyze general duties as stated in official documents on professional ethics to assess whether these duties can be considered good reasons for a duty to support *SeConts*.

Physicians' Duty to Help Improve the Quality of Health Care

According to the WMA Declaration of Geneva, physicians have the duty to share their "medical knowledge for the benefit of the patient and the advancement of healthcare".[27] In addition, the WMA declares in its Declaration on Guidelines for Continuous Quality Improvement in Health Care that, "[p]hysicians and health care institutions have an ethical and professional obligation to strive for continuous quality improvement of services and patient safety… ."[28] Similarly, the *Charter on Medical Professionalism* declares a duty of physicians to be "dedicated to continuous improvement in the quality of health care. This commitment entails … working collaboratively with other professionals to reduce medical error … and optimize the outcomes of care."[29] The cited passages imply that physicians have a duty to help improve the quality of health care as part of their professional ethics. This view is supported by the bioethical literature: according to Brennan physicians' "professionalism represents a contract between highly trained physicians and the public". This contract creates special responsibilities for physicians, "the most critical of which is promoting quality of care."[30]

What is the relevance of *SeConts* for improving the quality of health care? *SeConts* does have a strong potential to improve the quality of health care. However, supporting *SeConts* is just one of many ways to fulfill the duty to help improve the quality of health care. In metaethics, a duty like the duty to help improve health care is sometimes called an imperfect duty. This means it does not specify the concrete actions[31] or addressees of the duty.[32] Here and, as we will see later, in the cases of the other general duties as well, there is no inherently necessary link between a general imperfect duty and the support of *SeConts*. Physicians may fulfill an imperfect duty by means of supporting *SeConts* but also by other means. Thus, reasons must be given as to why physicians should fulfill a general imperfect duty by supporting *SeConts*. One plausible condition for requiring a specific act (such as physicians' support of *SeConts*) with recourse to a general (imperfect) duty can be that the act very efficiently realizes the goal of the duty or that there is no other act by which the duty can be fulfilled more efficiently, i.e., in which the cost-benefit ratio is more reasonable for the actor. We follow this reasoning here in the case of the general imperfect duty to help improve the quality of health care and the support of *SeConts*: If the necessary IT infrastructure is in place, physicians can efficiently contribute to improving the quality of health care by supporting *SeConts*. Doing so has a favorable cost-benefit ratio: it is likely to benefit the quality of health care thanks to existing clinical data and it probably requires little effort from physicians. Our view that physicians' general duty to help improve the quality of health care demands physicians to engage in support of *SeConts* is confirmed by the Declaration on Guidelines for Continuous Quality Improvement in Health care by the WMA which explicitly includes an "obligation to collect data"[33] that can help improve health care.

Thus, we conclude that the duty to help improve the quality of health care is part of physicians' professional ethics and that it is a good reason for a physicians' professional duty to support *SeConts*.

Physicians' Duty to Promote Public Health

The *WMA Statement on Physicians and Public Health* proclaims that "[p]hysicians and their professional associations have an ethical and professional responsibility to [collaborate] with public health agencies to integrate medical care of individual patients with a broader promotion of the health of the public."[34] The *Charter on Medical Professionalism* determines that physicians should work to eliminate socio-economically induced barriers to access to health care and be committed to equity; the charter states that this commitment "entails the promotion of public health".[35] Without elaborating on the link between equity and public health — which is left rather undefined in the charter — we deduce from the WMA statement and the Charter that physicians have a professional *duty to promote public health*.[36] There is also a view in bioethics that physicians have a duty to promote public health.[37] This duty can be backed by referring to physicians' general duty under their contract with society to

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"address issues of societal concern, and be devoted to the public good."[38] It would seem reasonable that physicians would approach the duty to devote themselves to the public good by supporting public health.

What is the relevance of *SeConts* for promoting public health? Supporting *SeConts* promotes public health in at least two ways: (1) Some forms of *SeConts* have a particular focus on public health, such as, for example, epidemiology or epidemic surveillance using clinical data. *SeConts* thus complements existing learning activities that provide information for public health interventions, for instance by means of systematic reporting of infectious diseases. (2) Existing public health measures could be informed by rapid and continuous feedback from health care data and adapted, if necessary.

Given that *SeConts* contributes to public health, we argue that physicians should support *SeConts* to fulfill their general and imperfect duty to promote public health for two reasons: (1) Compared to other ways physicians can promote public health (e.g., participating in vaccination campaigns or giving lectures on smoking cessation), supporting *SeConts* has a good cost-benefit ratio because it is likely to help promoting public health and probably requires little effort from physicians. (2) *SeConts*, i.e., feedback from clinical data is critical, almost indispensable for informing and evaluating existing and new public health interventions.

We conclude that the duty to promote public health is a good reason for a physicians' professional duty to support *SeConts*.

Physicians' Duty of Cost-Effectiveness

The *WMA International Code of Medical Ethics* declares a duty of physicians to "strive to use health care resources in the best way to benefit patients and their community."[39] Although not explicitly stated in this quote, the duty clearly alludes to the problem of limited resources and can be understood as a call for physicians to use available resources in an economical, or more specifically, cost-effective manner. Such a professional duty to cost-effectively use health care resources is explicitly recognized in the *Charter on Medical Professionalism:* "While meeting the needs of individual patients, physicians are required to provide health care that is based on the wise and cost-effective management of limited clinical resources."[40] One could understand the duty of cost-effectiveness narrowly in the sense that physicians have a duty *to not waste resources*. However, we believe it is plausible to understand the duty in a broader sense that also includes a *duty to actively promote cost-effectiveness* (i.e., the economic use of resources) in the health care system. It is plausible to assume, as Minogue does, physicians, in particular those operating in a public health care system, do have the professional responsibility to "balance the interests and wishes of the patient with the welfare of the health care system in which they practice"[41]. Cost-effective use of health care resources is a form of balancing these interests and thus also reflects physicians' "dual stewardship"[42] and responsibility for the resources for health care of future patients. As a result, considering the relevant professional duties and responsibilities we can state that physicians have a professional duty of cost-effectiveness in the health care system, which comprises the duty not to waste resources, and to actively promote efficiency, saving of resources, and cost-effectiveness in the health care system.

What is the relevance of *SeConts* for promoting cost-effectiveness in the health care system? Supporting *SeConts* can promote cost-effectiveness in two ways: (1) The knowledge generated in *SeConts*, e.g., in comparative effectiveness or quality improvement studies, can make the health care system more efficient and thus contribute to conserving limited resources. In addition, it is possible to test results from interventional clinical trials for reproducibility with the help of *SeConts* (e.g., phase 4, post marketing drug safety and efficacy studies). (2) Cost-effectiveness implies that all available resources are identified and (maximally) utilized. These resources also include existing clinical data that can be used to improve health care through *SeConts* (possibly even very quickly if one thinks of quality improvement studies). Not using clinical data in *SeConts,* on the other hand, creates opportunity costs for quality, safety, and effectiveness of health care.

But why should physicians fulfill their duty to cost-effectiveness specifically by supporting *SeConts* and not by some other means? Similar to the other professional duties already discussed, the support of *SeConts* has a favorable cost-benefit ratio: it is likely to effectively and efficiently promote cost-effectiveness of care (e.g., if *SeConts* in the form of comparative effectiveness studies allows to identify the more effective treatment and thus to save resources).

Thus, we conclude that physicians' professional duty of cost-effectiveness is a good reason for a physicians' professional duty to support *SeConts*.

Physicians' Duty to Support Research and Create New Knowledge

The *Charter on Medical Professionalism* explicitly declares that "[p]hysicians have a duty to uphold sci-

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entific standards, to promote research, and to create new knowledge and ensure its appropriate use."[43] A similar explicit declaration of physicians' duty to support research and create new knowledge does not exist in WMA documents. We do not know the reasons or motivation that led the WMA to refrain from stating a physicians' duty to support research and create new knowledge. However, this is of little importance for our question because, as we will show, the duty to support research and create new knowledge does not constitute a reason on its own in favor of physicians' duty to support *SeConts*. This might come as a surprise since the duty to support research and create new knowledge appears to perfectly underpin a duty to support *SeConts*, for *SeConts* aims to gain new and generalizable insights and knowledge. In this sense, it is true that a duty to support research and create new knowledge implies and very well applies to a physicians' professional duty to support *SeConts*. However, the main and most plausible moral justification of the duty to support research and create new knowledge consists in improving health care: physicians should support research to help improve (future) health care. As we have already referred to physicians' professional duty to help improve health care as an important reason in favor of a physicians' duty to support *SeConts*, we cannot refer to physicians' duty to support research as a reason on its own, because it, in turn, ultimately and mainly is founded on the objective to help improve health care. The same holds true for physicians' duty to promote public health and cost-effectiveness in the health care system: they, too, can be understood as grounds for a professional duty to promote research and create new knowledge, so that they, too, already imply to some extent a physicians' duty to support research. As such, the question is: are there any stark moral reasons that constitute a physicians' professional duty to promote research independently from the duties to help improve the quality of health care, promote public health and cost-effectiveness and can count as additional reasons on their own to underpin a physicians' professional duty to support *SeConts*? The answer is no. One possible additional reason could be that physicians have a *professional duty* to base their treatment decisions on scientific evidence and thus have good reasons to support research that helps to create such evidence. However, the need for empirical evidence in medicine is also directed toward improving the quality of treatment and thus cannot be viewed as clearly distinguished from the corresponding duty of physicians. Another additional reason might be that the image of the scientifically based healer is part of the self-image of physicians and that physicians see themselves as part of a community in which scientific arguments matter and count as an inherent value on its own, independent of its instrumental value for health care. However, this is a rather weak argument.

Therefore, we cannot consider the physicians' duty to support research a good reason for a physicians' professional duty to support *SeConts*.

Physicians' Duties Against a Duty to Support SeConts

After having considered professional duties that might be good reasons for a physicians' professional duty to support *SeConts*, in the following we analyze professional duties of physicians that might conflict with such a duty.

Physicians' Duty to Respect Patients' Informational Rights

Part of the Geneva Declaration of the WMA[44] is the duty of physicians to respect the autonomy of their patients.[45] This duty is also one of the foundations of the *Charter on Medical Professionalism*.[46] An important aspect of patients' autonomy, especially with respect to *SeConts*, is the freedom to decide how information related to one's own person is used. This aspect of autonomy can be referred to by the term informational self-determination. The protection of patient privacy is also explicitly mentioned in the *WMA Declaration of Lisbon on the Rights of the Patient*.[47] Unlike the rather recently established right to informational self-determination, medical confidentiality has traditionally been a core element of physicians' professional ethos. Medical confidentiality has its own status in penal medical law and many other regulations of medicine.[48] Despite the differences between informational self-determination and medical confidentiality, in the following, for reasons of space, we will discuss informational self-determination and medical confidentiality together under the term informational rights.

As *SeConts* uses clinical data, i.e., data generated in the protected context of the patient-physician relationship, the question naturally arises as to whether physicians impair their patients' informational rights if they share or support the sharing of their patients' data to support *SeConts*.

(1) In the *anonymous data scenario*, informational rights are not affected, since solely non-personal (anonymous) data are shared and used.[49]

(2) The same is true for the *code to data scenario*, where only aggregated results data are shared with researchers.

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(3) In the *consent scenario*, the personal (non-anonymous) data to be shared and used for *SeConts* are subject to patients' informational rights. However, patients are informed and asked to give their consent (via informed specific consent, broad consent, or dynamic or meta consent) to the sharing and usage of their data in *SeConts*. By giving consent, patients authorize certain usages of their data at the cost of their informational rights. If the information process is carried out appropriately, if patients give consent and if the governance structure sufficiently guarantees data protection and control rights for patients (e.g., the right to withdrawal), using their data for *SeConts* infringes neither patients' informational rights nor physicians' pertaining duties. Rather, patient consent to data use is an explicit expression of informational self-determination. There is thus no reason against physicians supporting *SeConts*.

(4) In the *opt-out scenario*, patients' informational rights are infringed, for their data are used for other purposes than their individual treatment without explicitly asking them for consent and without them explicitly giving their consent. However, the infringement is rather low if appropriate measures are taken, such as: information is broadly offered to patients[50]; patients have the opportunity to have individual consultations with professional staff like physicians or study nurses if they wish; patients have very low-threshold opt-out options (or multi-tiered opt-out options); other control rights are also warranted; an effective and comprehensive data protection governance framework is in place. As the opt-out scenario of *SeConts* implies a slight infringement of patients' informational rights, physicians supporting *SeConts* in the opt-out scenario would not fully respect these rights and thus not fully comply with their pertaining professional duties towards their patients. We point out that the implementation of the opt-out scenario as the standard scenario of *SeConts* is only politically feasible and ethically acceptable if society has decided in favor of it within the course of public debates and democratic legislative processes. Looking at medical confidentiality as a legal (penal) matter, the public and legal process to implement the opt-out-scenario should determine that physicians' support of *SeConts* in the opt-out scenario does not violate their legal duty of medical confidentiality or any other applicable law either. Still, some physicians might even then conceive their support as an infringement of their professional and moral duties to respect the informational rights of their patients. In the bioethical literature, there is a general debate on the question whether the opt-out scenario is ethically permissible despite its infringements of patients' informational rights. There is much reason to believe that in principle this scenario is ethically justifiable as long as it is combined with a detailed governance structure to minimize the infringement of patients' rights.[51] In a survey of cancer patient preferences, the opt-out scenario ranked second, behind the broad consent model but ahead of the dynamic consent model.[52] However, the question of whether the infringement of patients' informational rights implied in the opt-out scenario is a reason against a physicians' professional duty to support *SeConts* is a slightly different one. In this regard, we conclude that the professional duty to respect patients' informational rights is in principle a weak reason against a physicians' professional duty to support *SeConts* if *SeConts* is implemented in the form of the opt-out model.

In summary, we can state that in the scenarios *anonymous data*, *code to data* and *consent* there is no violation of physicians' duties and thus no reason against a physicians' professional duty to support *SeConts*. Only in the opt-out scenario is there a weak reason against such a duty.

In summary, we can state that in the scenarios *anonymous data*, *code to data* and *consent* there is no violation of physicians' duties and thus no reason against a physicians' professional duty to support *SeConts*. Only in the *opt-out scenario* is there a weak reason against such a duty.

Physicians' Duty to Respect the Principle of Primacy of Patients' Well-Being

In medical professional ethics, there is a widespread consensus that patients' individual well-being should always come first. However, the precise normative weight of this principle is not that clear: Is the well-being of the individual patient a categorically inviola-

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ble and absolute priority or may it be weighed against other moral considerations, and if so, how? This uncertainty is reflected in the various terms used to express it. For example, in the Declaration of Geneva, physicians pledge that "the health and well-being of [their] patient will be [their] *first consideration*".[53] In turn, the Charter of Medical Professionalism uses the term "*[p]rinciple of primacy of* patients' *welfare"* and states that, as one of the core principles of professionalism, it is "based on a dedication to serving the interest of the patient. … Market forces, societal pressures, and administrative exigencies must not compromise this principle."[54] We will use the latter formulation here: the principle of primacy of patients' well-being — in short: primacy principle. Before we can evaluate its specific relevance for our question, we first need to clarify what this principle means.

The interpretation of the exact normative weight of the primacy principle is a recognized problem.[55] A precise conception of the principle needs to clarify its weight in cases in which there are conflicting ethical considerations (e.g., rights or duties). In a strong conception (1), it could be argued that the primacy principle requires a lexical ordering[56] of all ethical stakes, with the patient's well-being always and completely taking precedence over the others. Accordingly, this conception of the primacy principle would mean that all other physicians' duties, rights, and interests apply only after the primacy principle has been 100% fulfilled. This "maximal" conception seems to be plausible, for instance, as a strong protection of patients from potentially dangerous selfish behavior of physicians. However, the interpretation would place patients' well-being categorically and completely above all other duties and rights of physicians. For example, since quarantine is detrimental to the patient's well-being, physicians would be prohibited from quarantining highly infectious patients to protect other patients or society. Therefore, we deem it more plausible to conceptualize the primary principle as based on a preliminary distinction between interests that qualify as potentially legitimate reasons for compromising patient well-being and interests that do not. A criterion for identifying the first stake is whether they are recognized as legitimate professional duties, rights, or values in physicians' ethos.[57] A criterion for identifying the second kind of stakes is whether they are motivated by interests external to physicians' ethos such as one's own individual economic or career interests. The latter interpretation of the primacy principle is supported by the fact that the Charter of Medical Professionalism specifically mentions certain interests, such as market forces, against which the well-being of patients is to be prioritized. Moreover, in documents such as the Geneva Declaration, the duty to respect the primacy principle is only one of many duties, and the Declaration does not contain a weighting of the individual duties indicating that the primacy principle always takes precedence over all others. The spirit of the Declaration of Helsinki also seems to support the third interpretation when it does not categorically preclude research that might imply risks and burden for patients or research participants.[58]

To what extent do physicians violate the primacy principle if they support *SeConts*? In our view, there are three possible potential negative effects on patients that can be counted as a violation of the primacy principle: (1) informational risks; (2) negative effects on treatment quality; (3) false hopes by patients that providing the data will directly benefit them. In assessing these risks, it is important to note up front that we understand that *SeConts* has no therapeutic benefit for the data-giving patients themselves in most cases,[59] so no self-benefit can be weighed against the potential risks for patients. Regarding (1), informational risks for patients associated with *SeConts* include loss of informational self-determination through data leaks and subsequent secondary risks ranging from annoyance by personalized advertising, via discrimination or stigmatization based on information in clinical data to blackmail and identity theft. However, these risks already exist with hospital digital health records and are unlikely to be significantly increased by *SeConts* if appropriate data protection and governance are in place.[60] Additionally, in the consent scenario and to a limited extent in the opt-out scenario, patients are informed about risks and can decide to consent or withdraw their consent according to their own personal risk perception. We therefore consider the informational risks not to be a relevant violation of the primacy principle. Regarding (2), physicians' support of *SeConts* might have a negative impact on treatment quality if it involves significant additional workload for physicians. We will deal with the aspect of additional work in more detail in the next section, as it also has an impact on physicians' legitimate interests. However, the potential negative impact on treatment quality results from the pursuit of certain legitimate goals that are consistent with the physician's ethos, rather than from the pursuit of illegitimate interests. Thus, under the aforementioned conception of the primacy principle, whether this impact could be justifiable considering potential benefits that come with physicians supporting *SeConts* depends on the extent of said impact. As for (3), a study suggests that some patients indeed

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hope to benefit from providing data to *SeConts* even if they were told that no such benefit can be expected.[61] However, the potential harm to patients that might result from unjustified hopes is rather small. Most importantly, if the information material clearly states that no individual benefit for patients' can be expected, at least in the consent scenario (if the physician addresses the matter in the individual discussion with the patient) physicians cannot be held responsible for the false hopes and thus cannot be blamed to have violated the primacy principle.

In conclusion, physicians only violate the primacy principle by supporting *SeConts* if that support involves additional work that negatively impacts patient care (see chapter "Physicians Legitimate Interests in a Reasonable Workload"). Informational risks and risks of false hopes do not contradict the primacy principle.

We have now reached the end of the analysis of medical professional ethics as expressed and codified in certain prominent documents. Three general professional duties listed in the documents, i.e., the duties to help improve the quality of health care, to promote public health, and the duty of cost-effectiveness, provide strong reasons for a physicians' professional duty to support *SeConts*. The general professional duty to respect patients' informational rights and the primacy principle provide only limited or weak reasons against the duty: The duty to respect patients' informational rights provide weak reasons against a professional duty in the opt-out scenario and the primacy principle might provide a reason against *if* the additional workload will be significant and detrimental for the quality of patient treatment. We therefore come to the overall conclusion that physicians' professional ethics justify a professional duty to support *SeConts* in almost all scenarios if certain conditions are met and if certain measures, such as effective data protection, are in place. This is a central result of the article. However, the result may be challenged with respect to its practical relevance and applicability since it does not take into consideration objections that refer to everyday practice of health care and pertaining claims and interests not based on professional ethics alone. Therefore, in the following section, we point out and briefly address three practice-related concerns or objections that can be found in the empirical literature.

Practice-Related Concerns Against a Duty to Support *SeConts*

Physicians' Legitimate Interest in a Reasonable Workload

Society has high expectations for physician commitment and workload. Nevertheless, physicians have a legitimate interest in maintaining a reasonable workload and work-life balance, both in their own interest and in the interest of their patients and the sustainability of the health care system: excessive workloads can negatively affect physicians' well-being and health[62] and thus become detrimental to the quality of patient care. The WMA pledge states that physicians ought to attend to their "own health, well-being, and abilities [again] in order to provide care of the highest standard."[63] Physicians express some concern about *SeConts* adding to already existing high workloads in daily work.[64]

In the context of supporting *SeConts*, an additional workload could result from (1) extended documentation; (2) initial effort due to adaption to new documentation software suitable for *SeConts*; or (3) informing patients and obtaining consent for participation in *SeConts* (relevant only in the consent scenario). Regarding (1), by definition, *SeConts* only uses data that are collected in the treatment context anyway. However, concern about additional workload is a major issue and challenge. Not only do physicians express this concern directly, but researchers also express concerns about the quality of data from current clinical documentation, which may be taken as an indication that additional work is needed to improve the quality of clinical data.[65] However, improving the quality of clinical data in terms of interoperability and structure could be achieved not only by additional work but also through well-designed documentation software. Additionally, well-structured data could also benefit patients by improving their care. Furthermore, improved data quality can increase the efficiency of physicians' activities in treating and managing patients. Thus, there should be no significant additional workload for physicians that is solely due to *SeConts* and solely benefits *SeConts*. As for (2), an initial effort on the part of physicians to familiarize themselves with new software is likely, but this would only be temporary. In the medium term and if it is well planned with early participation of physicians and all relevant future users, it is likely that new software can increase the efficiency of medical documentation and, as mentioned, reduce the workload.[66] Regarding (3), in all scenarios except the *consent scenario*, *SeConts* does not create any effort for obtaining informed consent. Current practice shows that the consent model (in form of broad consent) is frequently used in the context of *SeConts*, which suggest a potential additional workload for physicians. However, current practice also shows that the information and consent process can be delegated to other professionals as study nurses, which is also the process preferred by

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the majority of physicians according to a study on physicians' attitudes towards *SeConts*.[67]

We conclude that support for *SeConts* is likely to imply moderate additional effort for physicians — at least in area (3) — and can potentially conflict with physicians' legitimate interest in a reasonable workload unless certain measures are taken to avoid unreasonable additional effort (see chapter "Conditions for a Physicians' Professional Duty to Support SeConts").

Physicians' Worries about Benchmarking of their Work

SeConts allows information about treatments to be obtained and might thus allow for insights regarding the work of individual physicians, departments, and hospitals. In interviews, some physicians express concerns about their work being controlled and compared in benchmarking activities using their patients' clinical data in *SeConts*.[68]

Within professional ethics there is no direct reference to benchmarking of physicians' work. However, the professional duties to help improve the quality of health care, to cost-effectiveness, and, last but not least, the principle of *non nocere* provide a strong normative basis for the case that physicians should not only accept benchmarking activities but even actively engage in them. In a recent quantitative study, physicians expressed openness and interest in feedback systems to improve the quality of care in their own department or practice.[69] However, from an ethical perspective, some conditions must be met when advocating benchmarking and feedback systems: the control or benchmarking activities must be designed to generate insights to help understand and potentially improve the quality, safety, and cost-effectiveness of care and must not contribute to further unjust economical pressure or dangerous incentives for physicians to provide treatment according to economic rather than medical criteria. The limits of benchmarking activities must be known and shared. Benchmarking activities should also ensure transparency and fairness and allow physicians to participate directly in their planning.

Physicians' Claim to Data Ownership

Physicians sometimes claim ownership of their patients' clinical data.[70] If physicians owned the data, they could claim that they have the right to disseminate it freely including the right not to support *SeConts* with *their* data. This claim is not entailed in professional ethics as represented in the analyzed documents.

The argumentation from data ownership against a physicians' professional duty to support *SeConts* encompasses at least the following three levels: (1) data ownership is a viable concept in general; (2) physicians are owners of their patients' data; (3) physicians' data ownership grounds their right to reject supporting *SeConts*. We reject the data ownership argument for we see significant flaws on all three levels. As for the first level (1), there is a vivid discussion on the question if data ownership is a viable concept[71] and there are fundamental concerns about the concept of data ownership. (2) A reasonable approach for physicians to make ownership claims follows the Lockean notion of ownership[72], which assumes that ownership is acquired by a person investing labor in a natural resource and thus having a claim to the product of that labor.[73] If we translate this approach to clinical data, physicians appear to be the ones who may claim ownership as they generate the data during their work. At second glance, however, the use of Locke's notion to justify physicians' ownership of their patients' data is unconvincing for several reasons: (a) Patients are obviously not a *natural resource*. (b) Physicians' ownership claims collide with patients' right to informational self-determination. (c) Many clinical data are generated by external laboratories or other staff, not by the physician herself so that laboratory employees (and potentially other staff) would thus also have a claim to (partial) ownership of clinical data. (d) Physicians working in hospitals are not the owners of the equipment such as the MRI, the ultrasound machine, or software tools they use for diagnostics and treatment and thus for the generation of clinical data.[74] (e) Physicians *do not invest* (unpaid) labor in generating clinical data but generate it as part of their professional work they are paid for. Even if it should turn out in the future that, contrary to expectations, *SeConts* entails a considerable additional workload for physicians it does not justify a full data ownership claim of the (treating) physician in any case. It might, however, justify some right to recognition for support of *SeConts*, e.g., in the form of financial compensation, acknowledgements, or co-authorships. As for the third level (3) of the argument, it is not so obvious that physicians could derive the right to refuse any support of *SeConts* from ownership. There are many morally and legally granted *rights* that are justly constrained by duties, e.g., ownership of income is constrained by income taxes.[75]

Summarizing the three practice-related concerns, we conclude that, if certain measures, which we present in the next chapter, are taken during implementation, these concerns do not constitute serious reasons against a physicians' professional duty to support *SeConts* as established above based on the documents on professional ethics.

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Table 1

Measures to mitigate conflicts between a physicians' professional duty to support *SeConts* and physicians' other duties and practice-related concerns.

General Measures	
Maximization of potential benefits of *SeConts* and minimizing risks for patients • Demand of strict compliance with the criteria of Good Scientific Practice and Open Science • Creation of a governance structure that protects data and effectively ensures the exercise of patients' informational self-determination rights (including transparency, right to deletion, etc.)	
Measures to Mitigate Specific Conflicts with Duty to Support *SeConts*	
Conflicting duty / practice-related concern	**Mitigation measures**
Duty to respect patients' autonomy (in opt-out scenario)	• Large-scale information campaigns to inform people about the possibility of data use in *SeConts* before, during, and after medical treatment, e.g., with TV commercials or poster campaigns. • Provision of simple, informal, and very low-threshold opt-out opportunities.
Duty to respect the principle of primacy of patients' well-being	• Development of software to enable the most efficient data collection possible and possibly even increase the efficiency of everyday documentation, e.g., speeding up the creation of doctors' letters by using fixed text modules or accelerating communication within (and also between) hospitals by digitally networking clinical data. • In the consent scenario: Hiring of professional staff to specifically address patient information and obtaining consent.
Legitimate interest in a reasonable workload	
Worries about benchmarking of physicians' work	• Ensuring that control and comparison of physicians' work is implemented in such a way that their legitimate interests are considered: from direct involvement of physicians themselves to conditions in contracts with data users, etc. • If applicable, specification that information allowing conclusions to be drawn about individual physicians or departments is removed from the data.

Conditions for a Physicians' Professional Duty to Support *SeConts*

We have argued that, based on the professional ethics documents we examined, physicians have the professional duty to support *SeConts*, provided that certain steps are taken to mitigate potential conflicts with physicians' other professional duties as well as practice-related concerns. In the following, we first briefly recap how the aforementioned professional duties and practice-related concerns might conflict with a physicians' professional duty to support *SeConts* and then illustrate measures that avoid or mitigate potential conflicts or trade-offs.

- In the opt-out scenario, a physicians' professional duty to support *SeConts* conflicts with physicians' *duty to respect patients' autonomy*.
- If *SeConts* entails significant additional effort for physicians at the expense of patient care, a physicians' professional duty to support *SeConts* might conflict with the *principle of primacy of patients' well-being*.
- If *SeConts* entails relevant additional effort for physicians, a physicians' professional duty to support *SeConts* might conflict with physicians' *legitimate interest in a reasonable workload.*
- Some forms of *SeConts* might conflict with physicians worries about benchmarking of their work.

These potential conflicts or tradeoffs can be addressed by targeted measures as illustrated in table 1.

Limitations

The argument of this paper has some limitations in terms of the applied *methods* (limitations of scope are already discussed in the introduction).

First, it is difficult to capture "the" ethos of physicians. For the reasons mentioned in the methods section, the documents we analyzed on professional ethics provide a good insight. However, we had to limit

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ourselves to the analysis of relevant international documents. The specifics of national declarations on the professional ethos of physicians could therefore not play a role.

Second, as an investigation into physicians' professional ethics, the paper relies on the interpretation and application of general and abstract norms in relevant code of conducts and declarations. The application of general norms to a concrete question is always challenging. In the paper, among other aspects, the application relies on the assessment and interpretation of empirical circumstances, in particular the assessment of the potential benefit of *SeConts* for the improvement of the quality of health care, of the promotion of public health and of cost-effectiveness in health care. Likewise, the application also relies on the assessment of the informational risks for the data subject (patient) potentially implied in *SeConts*. We tried to assess the relevant facts and circumstances to our best knowledge. However, the empirical evidence for these assessments was limited. New evidence or differing perspectives may lead to divergent assessment of facts and empirical circumstances, and ultimately to diverging answers to our central question.

Third, there is very little empirical research on physicians' attitudes and concerns regarding the sharing of clinical data for *SeConts* on which we could draw in this paper. It is possible, therefore, that some concerns or worries that may be raised by physicians with regard to the support of *SeConts* have not been adequately addressed.

Conclusion

Since physicians play a key role in implementing *SeConts*, which is widely considered as having the potential to expand biomedical knowledge and improve patient care, we investigated the question of whether physicians have a professional duty to support *SeConts*. To answer this question, we examined official documents on the professional ethics of physicians and searched for professional duties recognized therein that might underpin or contradict a physicians' professional duty to support *SeConts*. We found that the professional duties to help improve the quality of health care, to promote public health, and the duty to cost-effectiveness argue in favor of a duty to support *SeConts*. Professional duties that at first glance might contradict a professional duty to support *SeConts* provide reasons against the duty only to a very limited extent. It is namely the duty to respect patients' informational rights that is not fully respected in the opt-out scenario of *SeConts* and the potential conflict with physicians' duty to the principle of primacy of patients' well-being. From this, we come to the first normative result, namely that physicians' professional ethics justify a professional duty to support *SeConts*. Three practical concerns raised in the literature provide very limited reasons against the feasibility and applicability of this result. Therefore, we conclude that physicians have a professional duty to support *SeConts*, provided that targeted measures are in place.

Our analysis and its results are of high relevance in at least two ways: (1) With regard to current efforts to

Our analysis and its results are of high relevance in at least two ways: (1) With regard to current efforts to establish a (governance) infrastructure for *SeConts*, we highlight that physicians have a duty to support *SeConts* if certain measures are put in place. (2) Our analysis informs how physicians should define their role in *SeConts* based upon their ethos. There is a strong case for medical associations to include physicians' professional duty to support *SeConts* in their official ethical documents. Explicit codification of this duty can help to anchor it in physicians' normative and self-binding self-image and give it more weight and visibility. It might also address other concerns such as that other professional duties necessarily contradict the duty to support *SeConts*. To foster physicians' support for *SeConts* in practice, the relevance of physicians' professional duty to support *SeConts* as well as the potentials and risks of *SeConts* should be part of the training of physicians.

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Note

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17. Such approaches are already implemented in individual cases (see <https://www.modernhealthcare.com/information-technology/mayo-clinics-new-data-sharing-initiative-launches-first-project> last visited March 6, 2024) and are particularly recommendable in the context of international data sharing

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(see A. Thorogood, H. L. Rehm, P. Goodhand, A. J. H. Page, Y. Joly, M. Baudis, J. Rambla, A. Navarro, T. H. Nyronen, M. Linden, E. S. Dove, M. Fiume, M. Brudno, M. S. Cline, and E. Bimey, "International Federation of Genomic Medicine Databases Using GA4GH Standards," *Cell Genomics* 1, no. 2 (2021): 100032). However, they are associated with a large demand for resources for the data provider (see C. Suver, A. Thorogood, M. Doerr, J. Wilbanks, and B. Knoppers, "Bringing Code to Data: Do Not Forget Governance," *Journal of Medical Internet Research* 22, no. 7 (2020): e18087).

18. The question of whether consent is required for the *code to data scenario* is also a legal one. Consent may be already required for the sole storage of patients' data in the hospitals' local data center for potential future research use (see M. Spitz and K. Cornelius, "Einwilligung und gesetzliche Forschungsklausel als Rechtsgrundlage für die Sekundärnutzung klinischer Daten zu Forschungszwecken," *Medizinrecht* 40 (2022): 191–98.)
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35. See Project Medical Professionalism, *supra* note 29.
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45. The principle of patient autonomy is often linked to the Declaration of Helsinki (World Medical Association, "World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects," *Bulletin of the World Health Organization* 79, no. 4 (2001): 373-374), in which it plays a prominent role. However, since the Declaration of Helsinki addresses researching physicians and does not describe the ethos of physicians in their role as practitioners, it has not been considered here. The same applies to the Taipei Declaration (World Medical Association, "WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks," (2016)) which deals with database management but does not formulate duties for physicians in their role as treatment providers.
46. See Project Medical Professionalism, *supra* note 29.
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48. See World Medical Association, *supra* note 27; World Medical Association, *supra* note 47; World Medical Association, *supra* note 34; World Medical Association, *supra* note 39; Project Medical Professionalism, *supra* note 29.
49. The question could be raised here as to whether the anonymization of data is already a form of data processing for which the consent of the patients concerned must be available. This discussion is being conducted at the legal level. From an ethical point of view, we see no reason to assume that anonymization is a process requiring consent.
50. See A. Cumyn, J.F. Ménard, A. Barton, R. Dault, F. Lévesque, and J.F. Ethier, "Patients' and Members of the Public's Wishes Regarding Transparency in the Context of Secondary Use of Health Data: Scoping Review," *Journal of Medical Internet Research* 25, e45002.
51. F. G. Miller, "Research on Medical Records Without Informed Consent," *Journal of Law, Medicine & Ethics* 36, no. 3 (2008): 560-66; S. Hoffman and A. Podgurski, "Balancing Privacy, Autonomy, and Scientific Needs in Electronic Health Records Research," *SMU Law Review* 65, no. 1 (2012): 85-144.
52. See Köngeter et al., *supra* note 4.
53. See World Medical Association, 2017, *supra* note 27, emphases by the authors.
54. See Project Medical Professionalism, *supra* note 29, emphases by the authors.
55. R. S. Saver, "Physicians' Elusive Public Health Duties," *North Carolina Law Review* 99, no. 4 (2021): 923-84.

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56. With regard to the concept of lexical ordering, see J. Rawls, *A Theory of Justice* (Cambridge: The Belknap Press of Harvard University Press, 1999).
57. See Pellegrino, *supra* note 37.
58. See World Medical Association, 2001, *supra* note 45.
59. Notice that with this position we do not state that it is, as a matter of fact, impossible for the patient providing data (data subject) to retrieve benefit from *SeConts*. Patients may sometimes benefit personally, for instance, from incidental findings or the translation of knowledge from *SeConts* to health care practice that takes so little time that it can inform the care of the data subject with an enduring health condition, for instance chronically ill patients. However, we deem the potential personal benefits for data subjects to be highly unlikely. For instance, the likelihood of incidental findings from research use of data that *has already been clinically analyzed for diagnostics and treatment*, as it is the case of clinical data, appears very low. Therefore, and to avoid (therapeutical) misunderstandings, potential personal benefits should not be mentioned in the information (and consent) process with patients and, for the sake of ethical clarity and patient protection, as a standard approach to *SeConts*, potential personal benefits should be given no weight in weighing costs and benefits for patients nor in the overall ethical assessment of *SeConts*.
60. We already discussed the probability of informational risks in the context of patients' duties to support *SeConts* (see Jungkunz et al., *supra* note 6).
61. See A. Köngeter et al., *supra* note 4.
62. R. S. Patel, R. Bachu, A. Adikey, M. Malik, and M. Shah, "Factors Related to Physician Burnout and its Consequences: a Review," *Behavioral Sciences* 8, no. 11 (2018): 98.
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65. See Köngeter et al., 2022, *supra* note 64.
66. This tendency could also be observed with the use electronic health records after the implementation phase (J. Bae and W. E. Encinosa, "National Estimates of the Impact of Electronic Health Records on the Workload of Primary Care Physicians," *BMC Health Services Research* 16, no. 1 (2016): 1-11) although evidence on efficiency of EHR is ambivalent (A. Boonstra, A. Versluis, and J. F. Vos, "Implementing Electronic Health Records in Hospitals: a Systematic Literature Review," *BMC Health Services Research* 14, no. 1 (2014): 1-24; K. Hoeyer and S. Wadmann, "'Meaningless Work': How the Datafication of Health Reconfigures Knowledge about Work and Erodes Professional Judgement," *Economy and Society* 49, no. 3 (2020): 433-54.)
67. See Köngeter et al., *supra* note 3.
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69. See Köngeter et al., *supra* note 3.
70. See Köngeter et al., 2022, *supra* note 64; Köngeter et al., *supra* note 3.
71. P. Hummel, M. Braun, and P. Dabrock, "Own Data? Ethical Reflections on Data Ownership," *Philosophy & Technology* (2020): 1-28.
72. A. Martani, L. D. Geneviève, B. Elger, and T. Wangmo, "'It's Not Something You Can Take in Your Hands'. Swiss Experts' Perspectives on Health Data Ownership: an Interview-Based Study," *BMJ open* 11, no. 4 (2021): e045717.
73. J. Locke, *Two Treatises of Government* (London: Aldine Press, 1975).
74. The question arises as to whether the owners of these *means of production* themselves might have a partial claim to these data. If this were the case, then the public would also have a (partial) claim to ownership of the data generated in publicly funded hospitals (A. Ballantyne, "How Should We Think About Clinical Data Ownership?" *Journal of Medical Ethics* 46, no. 5 (May 2020): 289-94.).
75. Some physicians claim a privileged research use of their patients' data (see Köngeter et al., *supra* note 3). We believe that this claim is not justified for reasons similar to those why we reject a physicians' claim to ownership of their patients' data.

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