



Research article

Attitude towards consent-free research use of personal medical data in the general German population

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ABSTRACT

Background: The design of appropriate consent procedures for the secondary use of personal health data is a key concern of current medical research. In Germany, the concept of ‘data donation’ has recently come into focus, defined as a legal entitlement to the research use of personal medical data without prior consent, combined with an easy-to-exercise right of the data subjects to opt-out.

Methods: Standardized online interviews of 3,013 individuals, representative of the German online population, were conducted in August 2022 to determine their attitude towards data donation for medical research.

Results: A majority of participants supported a consent-free data donation regulation, both for publicly funded (85.1%) and for private medical research (66.4%). Major predictors of a positive attitude towards data donation included (i) sufficient appreciation of the respective kind of research (i.e. public or private), (ii) a reciprocity attitude that patients who benefit from research have a duty to support research, and (iii) sufficient trust in data protection and data control.

Conclusion: People’s attitude towards data donation to medical research is generally positive in Germany and depends upon factors that can be curbed by legislation and internal rules of procedure. Worthy of note, designing data donation in the form of an opt-out regulation does not necessarily mean that the paradigm of informedness has to be abandoned. Rather the process of information provision must be shifted towards the creation of basic knowledge in the general population about the risks and benefits of data-intensive medical research (‘health data literacy’).

1. Introduction

The design of appropriate consent procedures for the secondary research use of personal medical data is a current issue in various national and international endeavours including, for example, the German Medical Informatics Initiative (MII) funded by the Federal Ministry of Education and Research, and the European Health Data Space (EHDS) endorsed by the European Commission. The latter, in particular, calls for a more detailed discussion of the topic not least because, in a proposal dating May 2022, the European Commission provided for a uniform type of consent for the EHDS that would be binding across Europe [1].

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Under the auspices of the MII, most German university hospitals are currently implementing so-called ‘broad consent’ procedures as the legal basis for the secondary use of patient data, with few restrictions in terms of the time and subject of the planned research. However, with the entry into force of the European General Data Protection Regulation (GDPR) and its permission for consent-free research use of personal data under certain conditions ([2], Art. 6), the concept of ‘data donation’ has also come into focus in Germany, defined as a combination of the legal permission to use the data and the right of the data subjects to object [3]. Data donation was not only recognized as a means to mitigate the organizational and methodological problems of consent-based procedures, including stress to patients and staff, therapeutic misconception and selection bias, but its implementation has also been contemplated against the background of a growing preparedness of patients and of large parts of the general population to support medical research by releasing their personal health data (e.g. Refs. [4–6]).

While a number of studies in Germany have revealed a great willingness of patients (e.g. Refs. [7,8]) and the general public (e.g. Refs. [9,10]) to share their own personal data for medical research purposes, despite simultaneous concerns about such use by commercial research institutions (e.g. Refs. [11–16]), only little is known about the specific attitude of the general population towards data donation in the above sense [8]. The aim of the present study was to close this gap by determining the overall level of support for such a legal regulation in Germany, not only in the case of personal medical data, but also of biomaterial left over from individual health care. In addition, potential predictors of support for a data donation regulation, including the participants’ personal values, attitudes towards medical research in general and trust in data protection, were examined for a possible influence upon their individual positions regarding this issue.

2. Materials and methods

2.1. Questionnaire and survey

The present study was aimed at determining the attitude of the general German population towards the consent-free research use of personal medical data (‘data donation’). To this end, a survey by way of standardized online questionnaires was conducted in August 2022 by the Forsa Institute, one of the largest private sociological research institutions in Germany (www.forsa.de), drawing upon Forsa’s population-representative ‘forsa.omninet’ survey panel (n = 3,013).

In collaboration with experts from the Forsa Institute, the questionnaire used in the present study was developed specifically for this purpose. It focussed upon the personal attitudes of participants towards medical research in general, and towards data donation in particular. The questionnaire comprised 10 items scored on a four-point Likert scale (1: very good/well/often/important, 2: rather good/well/often/important, 3: rather bad/badly/seldom/unimportant, 4: very bad/badly/seldom/unimportant). An even number of scores per item was chosen to encourage respondents to position themselves clearly towards the item in question. The resolution of people’s responses achievable with four scores was deemed sufficient for the purpose of the study. Specifically, the 10 items addressed the

- attitude towards data donation to either public or private medical research institutions,
- confidence in data protection by public or private research institutions, either in Germany or in other European countries,
- understanding of medical topics and medical research by a self-assessment of their own knowledge and ability to understand, based upon the European Health Literacy Survey Questionnaire (HLS-EU-Q) [17],
- judgement of the importance of publicly and privately funded medical research,
- personal values as measured by a validated German version of the Short Schwartz’s Value Survey (SSVS) [18–20]. Schwartz’s theory identified 10 basic human values (Power, Achievement, Hedonism, Stimulation, Self-Direction, Universalism, Benevolence, Tradition, Conformity, Security) which are expressed in most cultures and determine individual behaviour and decision-making [21]. We adapted the validated query for the 10 sub-values in two ways: For better usability in the context of an online survey, (i) the description of each value was limited to two all-encompassing main terms, and (ii) the rating scale was reduced from six to four answer options (i.e. scores), also to be consistent with the rest of the questionnaire.
- personal attitude towards medical research, including one’s own responsibility to support medical research,
- possible reservations against the use of personal medical data by private research institutions.

In addition, demographic information on age, sex and education was ascertained via the questionnaire. The original (German) version of the questionnaire as well as an English translation are included in the Supplement to this article.

2.2. Statistical methods

In a previous study of Northern German outpatients [8], 75% of participants supported a consent-free regulation of the secondary research use of personal health data. The sample size of the present study (n = 3,013) would have allowed estimation of a similar rate in the general population with 1.5% accuracy, i.e. with a 95% confidence interval of (0.735; 0.765).

All statistical analyses were performed with R version 4.2.2 [22]. Absolute frequencies and percentages were calculated with R package `tableone` [23]. If necessary, adjacent Likert scores were combined into a single category to ensure that each category of scores ultimately had a frequency of $\geq 5\%$.

Principal component (PC) analysis was performed of the 10 SSVS sub-items included in question 5 (Q5) of the questionnaire (i) to facilitate the interpretation of the impact of personal values upon the participants’ attitude towards data donation and (ii) to ensure

non-collinearity of the former in the logistic regression analysis undertaken to identify significant predictors of the latter (see below). A Kaiser-Meyer-Olkin statistic was calculated with R package `psych` [24] to verify the suitability of the data for PC analysis. The first three PCs were found to have eigenvalues >1 and were thus retained for further analysis. Since the loading on one of these PCs was >0.5 for all 10 items, each item could be assigned reliably to that PC. The internal consistency of the assignment, i.e. the extent to which the items assigned to a particular PC received comparable responses, was assessed with Cronbach's alpha, using R package `ltm` [25].

Answers to questions Q9.1 and Q9.2 about data donation were dichotomized and subjected to multiple logistic regression analysis, adjusted for age, sex and education, and using the first three PCs and the individual scores of the following questions as predictor variables: Q1.1 and Q1.2, Q2.1 and Q2.2, Q3, Q4, Q6.1 to Q6.6, Q8.1 to Q8.3, Q11, Q12, Q13, Q14. Deviations of the predictor-specific odds ratio estimates from unity were assessed for statistical significance by a two-sided likelihood ratio test, and p values < 0.05 were deemed statistically significant. The final logistic regression model was obtained by backward selection adopting a p value threshold of 0.05 in each selection step.

3. Results

3.1. Study sample

Our study was conducted by way of an online interview with 3,013 members of the forsa.omninet panel, a sample of 100,000 individuals representative of the German online population (Table 1). The data were collected by the Forsa Institute as commissioned and sent to us for analysis in anonymised form. No ethics committee approval was thus required. Apart from a slightly increased education level observed among male participants (5% excess each in categories 'middle school' and 'high school'), the forsa_omninet subsample used in the present study matched population figures currently available for Germany [26].

3.2. Personal values of participants

The personal values of participants were assessed in question Q5 of the study questionnaire by 10 sub-items derived from a validated German version of the SSVS [18,21]. The personal ratings of the basic values corresponding to these sub-items were subjected to principal component (PC) analysis. The first three PCs had eigenvalues >1 and explained 21.4%, 17.6% and 12.1%, respectively, of the total variation. Each of the 10 basic values of the SSVS was then assigned to exactly one of the first three PCs, based upon maximum PC loading. Comparison of this assignment to the original grouping of the SSVS items by Schwartz et al. [21] suggests that the first three PCs can sensibly be assumed to measure 'Openness' (PC1), 'Self-Enhancement' (PC2) and 'Conservation' (PC3) of people (see Comment to Fig. S1 for further details). The Cronbach's α values of these assignments equalled 0.597 (PC1), 0.549 (PC2) and 0.410 (PC3), respectively. While such a level of internal consistency would not have been sufficient for the *ab initio* definition of new higher-order values, which was not the subject of our study anyway, it nevertheless (i) justified considering the first three PCs in subsequent logistic regression analyses, instead of all 10 original SSVS items, and (ii) ensured the interpretability of the results obtained.

3.3. Knowledge about medical research

Most participants rated their knowledge about medical research as rather low or very low, both for publicly funded (81.7%) and for privately funded research (85.0%; Table S1). At the same time, however, the participants were almost unanimous that both pursuits are important (public: 96.7%; private: 88.4%; Table S1). Notably, while a majority (62.7%) have rarely or never dealt actively with medical topics, e.g. by reading books or articles from magazines or the internet, the vast majority of participants (83.0%) ranked their ability to follow medical explanations by their doctors as very good or rather good (Table S1).

Table 1
Demographic characteristics of study sample (n = 3,013).

Age group (years)	Male (%)	Female (%)
16–29	208 (14.1)	212 (13.8)
30–44	307 (20.9)	293 (19.0)
45–59	403 (27.4)	382 (24.8)
60 or older	554 (37.6)	654 (42.4)
Highest education level		
Primary or secondary school	319 (21.7)	496 (32.2)
Middle school	501 (34.0)	470 (30.5)
High school	601 (40.8)	512 (33.2)
None	21 (1.4)	27 (1.8)
Other	30 (2.0)	36 (2.3)
Total (%) ^a	1,472 (48.9)	1,541 (51.1)

^a Percentage of all participants.

3.4. Attitude towards medical research with personal health data

A clear majority of participants (80.0%) had a reciprocity attitude towards medical research in the sense that whoever benefits from such research as a patient should also contribute to it, e.g. by allowing research to use their own data (Table 2, question Q6.1). At the same time, more than two-thirds (67.9%) thought that medical research with patient data should not be linked to direct personal benefits (Table 2, Q6.2). Interestingly, most participants (71.9%) thought that every citizen is responsible for informing themselves well enough to be able to decide about the use of their data for medical research (Table 2, Q6.6), and a similar proportion (73.1%) wished for more information about medical research on patient data to be publicly available (Table 2, Q6.3).

In a previous study undertaken in a clinical care context [8], we noted that around 50% of patients had reservations against the use of their medical data by private research institutions. In line with these findings, only a minority (42.7%) of participants in the present survey of the general German population thought that personal medical data should be made available for research by commercial companies (Table 2, Q6.4). Finally, a slim majority (58.4%) agreed that patient data should be shared with medical researchers in other European countries (Table 2, Q6.5).

Participants who objected to commercial companies using patient data for research (i.e. who rather or completely disagreed with Q6.4, $n = 1,628$) were also asked for the nature of their reservations (Table 3, Q7). The fear that commercial companies may sell patient data to third parties was by far the most frequently chosen item (81.5%), followed by doubts that the use of patient data is sufficiently well controlled (64.4%) and that the data themselves are sufficiently well protected in commercial companies (62.0%). Of lesser importance were the views that commercial companies do not research for the common good (55.3%), or that the use of patient data by commercial companies is not sufficiently well regulated by law (44.6%).

Previous studies have shown that confidence in data protection is a key determinant of the willingness to allow personal health data to be used for medical research (e.g. Refs. [8,27,28]). To investigate this connection in more detail in the general German population, we asked participants in the present study about their level of confidence in data protection in Germany (Table S2, Q8.1), in Europe (Q8.2) and in commercial companies (Q8.3). While 63.0% expressed a very or rather high level of confidence in data protection in Germany, this was only the case for 38.4% when other European countries were concerned. Even stronger distrust became evident when it came to data protection in commercial companies, which only 23.1% had very or rather high confidence in.

3.5. Support for a data donation regulation

Following an introductory presentation of the envisaged legal and organizational framework, participants were asked in question Q9 about their support, or not, for 'data donation', defined as a combination of the legal entitlement of researchers to the consent-free use of such data, and the right of patients to object (see Table 4 for full text). More specifically, question Q9 clearly stated that every research project using donated data would be reviewed independently, and that the data would be encrypted before release.

If the beneficiaries of data donation were publicly funded research institutions, such as universities (Q9.1), a vast majority of the 2,854 respondents found data donation 'very good' (41.8%) or 'rather good' (44.3%); only a minority deemed it 'rather bad' (10.0%) or 'very bad' (3.9%). If the data were to be used for privately funded research e.g. by drug manufacturers (Q9.2), the level of support among the 2,820 respondents was somewhat lower, but still considerable (very good: 21.9%; rather good: 44.5%; rather bad: 24.7%; very bad: 8.9%).

Interestingly, this rather positive attitude towards private research deviated markedly from the answers given to previous question Q6.4 (see Table 3). The latter resembled Q9.2 but did not explicitly mention the conditions of the research use of the data. Thus, when asked plainly whether patient data should be available for medical research in commercial companies at all, only 42.7% of the participants agreed, a result consistent with our earlier survey of German patients [8].

Table 2
Personal attitude towards medical research (question Q6 of study questionnaire).

Level of Agreement ^a	fully agree ^b	rather agree ^b	rather disagree ^b	completely disagree ^b
Q6.1 (n = 2,890): Whoever benefits from medical research should contribute to research themselves (e.g. by allowing research use of their data).	803 (27.8)	1510 (52.2)	437 (15.1)	140 (4.8)
Q6.2 (n = 2,782): Medical research with patient data should not directly benefit individual patients.	786 (28.3)	1102 (39.6)	745 (26.8)	149 (5.4)
Q6.3 (n = 2,829): More information about medical research on patient data should be publicly available.	689 (24.4)	1378 (48.7)	592 (20.9)	170 (6.0)
Q6.4 (n = 2,843): Patient data should also be available for medical research by commercial companies.	225 (7.9)	990 (34.8)	1137 (40.0)	491 (17.3)
Q6.5 (n = 2,850): Patient data should also be available for medical research in other European countries.	375 (13.2)	1287 (45.2)	832 (29.2)	356 (12.5)
Q6.6 (n = 2,884): Every citizen is obliged to acquire sufficient knowledge to be able to decide upon the use of their data for medical research.	637 (22.1)	1437 (49.8)	685 (23.8)	125 (4.3)

^a Total number of respondents in brackets.

^b Number of respondents in answer category (percentage of total number in brackets).

Table 3

Reservations about the use of patient data for research in commercial companies (Q7).

Q7 (n = 1,628): You indicated that patient data should (rather) not be available for medical research by commercial companies. What are your reservations against such data use (multiple answers allowed)? ^a	
Commercial companies may sell patient data to third parties.	1,327 (81.5)
The use of patient data by commercial companies is not sufficiently well controlled.	1,049 (64.4)
Patient data are not sufficiently well protected in commercial companies.	1,009 (62.0)
Commercial companies do not research for the common good.	901 (55.3)
The use of patient data by commercial companies is not sufficiently well regulated by law.	726 (44.6)

^a Percentages in brackets relate to those 1,628 participants who disagreed with Q6.4.**Table 4**

Support for data donation a regulation (Q9).

Q9: At present, the use of patient data for medical research requires the consent of patients. However, it is often difficult or even impossible to obtain such consent. Therefore, there are considerations in Germany to legally allow medical research without consent on encrypted patient data after an independent review of the research project. In return, it should be possible for every citizen to simply object to this so-called 'data donation'.				
How would you find such a legal regulation ... ^a	very good ^b	rather good ^b	rather bad ^b	very bad ^b
Q9.1 (n = 2,854) ... for publicly funded research (e.g. by universities)	1,193 (41.8)	1,265 (44.3)	285 (10.0)	111 (3.9)
Q9.2 (n = 2,820) ... for privately funded medical research (e.g. by drug manufacturers)?	618 (21.9)	1,254 (44.5)	697 (24.7)	251 (8.9)

^a Total number of respondents in brackets.^b Number of respondents in answer category (percentage of total in brackets).

3.6. Predictors of participant attitude

We identified various statistically significant predictors of a positive attitude towards data donation for publicly funded research (Table S3a). The three most credible predictors, as judged by the respective p values and odds ratios, were recognition of the value of publicly funded medical research in general (Q2.1), a reciprocity attitude that whoever benefits from medical research as a patient should contribute to research themselves (Q6.1), and a high level of confidence in data protection in Germany (Q8.1). Notably, neither age, sex nor education were found to be significant predictors of the answer given to question Q9.1.

Statistically significant predictors were also found for a positive attitude towards data donation for privately funded medical research (Table S3b). Most important were the view that privately funded medical research is important (Q2.2), a reciprocity attitude towards medical research (Q6.1), support for the use of medical data for privately funded research in general (Q6.4), and confidence in data protection in commercial companies (Q8.3). Again, neither age, sex nor education were included in the final regression model.

For the first time in a survey on data donation in Germany, participants were also asked for their attitude towards the extension of such a legal regulation to biomaterials (e.g. blood or urine) left over from clinical care (Q10, Table S4). A large majority of more than 80% of the 2,868 respondents turned out to be in favour of making biomaterial available for medical research in the same way as data, i.e. without consent but with the possibility of simple objection.

4. Discussion

4.1. Support for a data donation regulation

The present survey of the general attitude towards data donation for medical research in Germany was conducted in August 2022 at a time when the world-wide efforts to develop vaccines against SARS-CoV-2 had been crowned with success, and when a second booster vaccination had already been given to large parts of the German population. The research work underlying these achievements, especially by pharmaceutical companies, received unprecedented media coverage, from the development to the testing and approval of the different vaccines. For the first time in decades, the impact of medical research was thus felt immediately by the general public.

At the beginning of the pandemic, when the first lock-downs had been ordered in Germany and elsewhere, we studied the support for a data donation regulation among patients from a local outpatient clinic in Northern Germany [8]. Comparing the results of that study to those of the present one should, therefore, allow insights into both the stability of the attitude of people and the potential relevance of the pandemic for easing previously expressed concerns. What is more, despite the wide thematic overlap between the two studies, there was also one notable difference: Demands for better regulation of the consent-free research use of personal health data, as raised previously by the patients themselves, were addressed in the present study by phrasing the corresponding question in a more differentiated way. It was thus explicitly mentioned that only pseudonymised data are concerned, that research projects requesting donated data would be independently reviewed beforehand, and that it would be possible to object to data donation simply and permanently.

The main finding of our population-based study has been that support for a data donation regulation for medical research is high in Germany. Moreover, wide-spread approval also became apparent of the consent-free research use of left-over biomaterials, a topic

addressed in this form for the first time in a German study. Both attitudes were notably better than previous surveys would have suggested [8,9] and must be seen against the background that the vast majority of participants rated their knowledge of medical research as low, and that confidence in data protection was modest at best. We surmise that the positive attitude towards data donation revealed by our study is therefore likely to reflect a generally strong trust in medical research, not least because this kind of endeavour was considered important by the majority of participants. At 66%, the approval rate of data donation was particularly surprising in the case of privately funded medical research because, in our 2020 survey [9], no more than 14% of participants supported the use of personal medical data by commercial research institutions.

4.2. A role for the SARS-CoV-2 pandemic?

At first glance, the increased support for a data donation regulation, particularly for privately funded research, could be a result of the extraordinary experience of the SARS-CoV-2 pandemic. Such a connection does not seem implausible because several studies have suggested that strong trust in research and expectations of immediate personal benefit had a significant influence on people's decision-making during the pandemic itself, such as whether or not to get vaccinated [29]. In addition, it has already been shown that reciprocity, i.e. an attitude that personal benefit from research entails an obligation to reciprocate, is a strong motivation for approving the research use of one's medical data (e.g. Ref. [8]). Therefore, the widely recognized role of the pharmaceutical industry in the development of SARS-CoV-2 vaccines could indeed have increased people's support for a data donation regulation.

However, our results suggest that situational effects, even on the scale of the life-threatening SARS-CoV-2 pandemic, are less critical in this context. Instead, a detailed representation of the design of the data donation process itself appears to be much more important to increase the level of its support. Participants' attitude towards data donation for privately funded research was asked twice in our study in slightly different ways (Q6.4 and Q9.2), and it was only when promises were made to meet people's demands for adequate protection and control over the use of their data that a significant increase in support occurred.

The critical view of research with personal medical data by commercial companies that was documented before the pandemic by us and by others (e.g. Refs. [30,31]) thus does not necessarily have to have changed significantly, and the generally acknowledged contribution of the pharmaceutical industry to overcoming the pandemic may not have paid off, an insight also supported by various other international studies (e.g. Ref. [32]). Our conclusion of the subordinate role of the interim research successes during the pandemic is reinforced by the very low self-perceived level of knowledge about the procedures and results of both public and private research that was noted in the present study. Moreover, the actual nature of people's reservations about private research remained widely unchanged compared to our earlier survey of outpatients [8], namely (i) fear of data being sold by commercial companies, combined with the perception of both (ii) a lack of data protection and (iii) insufficient control over the use of the data.

4.3. Predictors of support for a data donation regulation

The three most important predictors of a positive attitude towards data donation, as identified in the present study, were found to overlap noticeably between publicly and privately funded medical research. In both cases, support seems to be reinforced by a sense of responsibility that whoever benefits from research as a patient should give something back in return. While this view is likely determined mostly by personal values and experience, the other two factors suggest measures that could potentially increase the level of support for a data donation regulation even further, namely the relevance ascribed to the respective kind of research (public or private) and the level of trust in data protection in Germany in general, and in the private sector in particular. Notably, the latter type of credence, in conjunction with a need to increase people's knowledge about data protection, has been shown before to be essential for a wide support for secondary health data use (e.g. Refs. [28,33]).

4.4. Limitations and strengths

One possible limitation of our study could have been selection bias due to the recruitment of participants from a pre-existing pool that is regularly used for research. This panel may have been enriched with individuals who have a more positive attitude towards research in general, and hence towards data-sharing in particular. However, the forsa.omninet panel is one of the best samples available for population-based opinion research in Germany, using electronic media, and places particular emphasis upon representativeness. The Forsa Institute enjoys a very good reputation in the field, and its resources are often used by governmental and other official institutions. The risk of sample bias in the forsa omninet panel has been minimized by ensuring that >90% of members are not represented on any other comparable panel. Moreover, to our knowledge, there is no evidence that affinity for electronic media *per se* is in any way associated with a particularly research-friendly attitude. On the contrary, the SARS-CoV-2 pandemic has shown that many unscientific positions and fake news are indeed spread via social media. When it comes to privacy and data security, one could even argue that those who are computer literate are even more concerned. Anyhow, the main motivation for people to participate in the forsa omninet forum is just "to be heard", which has little to do with digital versatility.

One of the strengths of our study is that it not only determined the level of support for a data donation regulation. Rather, we also identified possible factors that influence people's attitudes towards the consent-free use of personal health data. These results will allow stakeholders in data-rich medical research to specifically address and, if necessary, eliminate reservations about data donation as well as strengthen positive predictors of its support in the population.

4.5. Outlook

Our findings highlight once more that information may be one of the keys to promoting data-rich medical research. However, creating a widespread understanding and awareness of the importance of such research, and of its technical, ethical and legal peculiarities, goes well beyond hasty information provision in the acute health care context, and requires long-term efforts by all stakeholders, especially the researchers themselves. Since an opt-out regulation would result in patients no longer being informed directly during health care, alternative ways of providing information therefore need to be explored in the context of data donation if the paradigm of informedness is to be maintained. As a way forward, we recently introduced the concept of “health data literacy” [34], defined as the ability to find, understand and evaluate information about data-rich medical research. Even if general health data literacy can be advocated independently of the issue of data donation, its consideration is particularly urgent for the latter, i.e. if the mechanisms of consenting were to change from opt-in to opt-out.

Future research should focus upon what kind of information people actually need and want, and to what extent the provision of such information actually achieves the desired purpose, namely increasing their level of informedness. It will also be of great interest to research whether and how the use of more comprehensive information influences the users’ attitudes towards data donation. And finally, it will be important to determine the extent to which results from the German population can be transferred to other countries within and outside the EU.

5. Conclusions

- People’s attitude towards data donation to medical research depends critically upon their appreciation of such research and upon possible concerns about data safety and control.
- Situational effects, even on the scale of the life-threatening SARS-CoV-2 pandemic, appear to be less critical for the support of a data donation regulation.
- Existing concerns about data donation could be addressed by legislation or internal rules of procedure, including reliable data protection, strict control of data usage and prevention of the commercialization of data.
- Better knowledge of the risks and benefits of the secondary research use of personal health data could contribute to a high level of support for a data donation regulation.
- Data donation in the form of an opt-out regulation does not necessarily mean abandoning the principle of informedness. Rather, the process of information provision must be adapted to such a legal regulation, e.g. by promoting ‘health data literacy’ in the general population.

Ethics approval and consent to participate

Data were collected by the Forsa Institute as commissioned and sent to us for analysis in strictly anonymised form. No ethics committee approval was thus required.

No additional consent was necessary for participation in the present study because members of the forsa.omninet panel have generally agreed to participate in Forsa surveys.

All methods were carried out in accordance with relevant guidelines and regulations.

Consent to publish

Not applicable.

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Availability of data and materials

The datasets used and/or analysed during the current study is available from the corresponding author upon reasonable request.

CRedit authorship contribution statement

Gesine Richter: Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Nourane Trigui:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Amke Caliebe:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Michael Krawczak:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing

interests: Gesine Richter reports financial support was provided by Technologies, Methods and Infrastructure Platform for Networked Medical Research (TMF e.V.). If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.heliyon.2024.e27933>.

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