Kommittén för teknologisk innovation & etik

Komet Information

Processing personal data for sample size calculations prior to clinical research

Komet Information 2020:29, 2020-11-18

Processing personal data for sample size calculations prior to clinical research

The Committee for Technological Innovation and Ethics propose that sample size calculations prior to clinical research is laid down in law as a permitted purpose for processing personal data. A description and analysis of the legal conditions is presented in the report, especially regarding the General Data Protection Regulation. The Committee's proposals aim to contribute to greater clarity, facilitate clinical research planning and improve legal certainty. Another important aim is to protect people's right to privacy.

Remit of the Committee and premise for its proposals

The Committee for Technological Innovation and Ethics (Komet) is tasked with creating good conditions for Swedish innovation and competitiveness, while also helping to ensure that the development and dissemination of new technology is safe and secure, preserving a long-term societal perspective. The Committee will consider and build on priorities and results from the innovation partnership programmes established by the Swedish Government. The innovation partnership programme focused on health and life science has been especially relevant for the present proposals, along with other cross-sectoral and policy-development initiatives linked to precision medicine.

This report presents a description and analysis of the legal conditions for care providers to perform the processing of personal data required to calculate whether patient populations are large enough prior to initiate a clinical research study. The Committee's proposals aim to contribute to greater clarity, facilitate clinical research planning and improve legal certainty by ensuring equal and fair conditions throughout the country. Another important aim is to protect people's right to privacy with respect to the processing of personal data for sample size calculations.

Clear legal regulations can facilitate the preparations required for clinical research, which ultimately contributes to knowledge-building in disease prevention, diagnostics, treatment and rehabilitation for individuals in Sweden and internationally.

In a broader perspective, the proposals in this report contribute to Sweden's position as a strong knowledge-based nation in the life sciences area. Improving conditions for research, innovation and competitive business provides opportunities to improve health, develop health care and secure economic prosperity. Clear legal regulations can facilitate the preparations required for clinical research, which ultimately contributes to knowledge-building in disease prevention, diagnostics, treatment and rehabilitation for individuals in Sweden and internationally.

Calculating whether the sample size is large enough

Sample size calculation is part of planning clinical research. It is part of the preparatory work to examine strengths and weaknesses in conducting a future clinical research study. The calculation is made before any research has begun. At this early stage, an approximation is needed of the potential number of patients who could be included in a future study, not who they are or any detailed information about each individual.

Processing personal data is necessary to calculate the sample size. This calculation often requires processing data concerning a person's health which, according to the General Data Protection Regulation[1], is a special category of personal data[2]. Such data can, for example, be obtained from patient records or from quality registers kept by health care providers.

Higher education institutions, government agencies, municipalities and regions, as well as companies (especially in pharma and medtech), are examples of organisations that need to calculate sample size prior to clinical research. It has not been possible to obtain precise information on the number of such calculations conducted yearly in part because of lack of coherent statistics.

The current Swedish system needs to be reviewed, as there is uncertainty as to whether there is a legal basis for the processing of personal data when calculating sample size prior to clinical research. This problem has been highlighted in the Government's National Life Sciences Strategy, and by the Swedish Research Council. In preparing this proposal, we have found that regions and care providers have slightly different ways of handling inquiries about data intended for sample size calculations prior to clinical research.

In our view, a transparent and solid legal basis for processing sensitive personal data has an ethical dimension. A clear definition of the purpose of sample size calculations prior to clinical research may prevent such calculations, over time, from being applied inappropriately.

Ethical aspects

Processing personal data in order to calculate sample size prior to clinical research can affect several different stakeholders. One way to improve mutual understanding can be to involve the stakeholders in reviewing the regulatory framework, making sure to include a diversity of voices and consider different perspectives. Moreover, if the regulations are changed, good communication and adequate information will be needed, e.g. to the health care sector.

Several ethical values need to be considered. One of the most obvious is protecting the privacy of the individual. Other ethical values include autonomy (e.g. having the choice not to be included in calculations of sample size prior to clinical research) and human dignity (e.g. not being reduced to a number). Yet another aspect is the opportunity for individual patients to contribute to developing new knowledge that can improve their own or other people's health.

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[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).

[2] In this document, we will henceforth use the term 'sensitive personal data', which is in line with the General Data Protection Regulation. According to the preamble (point 10), "the Regulation provides a margin of manoeuvre for Member States to specify its rules, including for the processing of special categories of personal data ('sensitive data')."

Stakeholders have different interests. The research sponsor[3] needs to make a reasonable assessment of the prerequisites for starting a clinical research project at an early stage to avoid investing too many resources into an idea that cannot be implemented. Health care providers and regions have an interest in participating in knowledge-building. Finally, equal treatment and justice must be considered, e.g. with respect to taking part in research at a later stage, and the need to carry out personal data processing in the same way throughout the country.

In our view, a transparent and solid legal basis for processing sensitive personal data has an ethical dimension. A clear definition of the purpose of sample size calculations prior to clinical research may prevent such calculations, over time, from being applied inappropriately.

Legal regulation of calculating potential patient populations prior to clinical research

The General Data Protection Regulation applies throughout the European Union and is directly applicable in Sweden.

The processing of sensitive personal data, which is carried out for sample size calculations prior to clinical research, is administrative in nature. It constitutes a subsequent use of data originally created in the health care system[4]. This processing of personal data for sample size calculation takes place at the request of a research sponsor. The purpose, as mentioned, is to estimate population sizes when considering the feasibility of conducting future clinical research in the health care sector.

Our assessment is that the legal basis for processing personal data complies with the General Data Protection Regulation and that there are applicable derogations from the prohibition on processing special categories of personal data concerning health for sample size calculations prior to clinical research. There is a need for supplementary provisions in national Swedish legislation on, among other things, specifying the purpose for the processing of personal data. According to the General Data Protection Regulation, such derogations may be provided by Member State law.

Our assessment is that the legal basis for processing personal data complies with the General Data Protection Regulation and that there are applicable derogations from the prohibition on processing special categories of personal data concerning health for sample size calculations prior to clinical research.

Proposal – sample size calculations prior to clinical research is laid down in law as a permitted purpose for processing personal data

We propose introducing new provisions in the Patient Data Act (2008:355) to allow the processing of personal data in order to calculate sample size prior to clinical research, i.e. how many individuals who – by fulfilling pre-established inclusion criteria – can potentially be included in a clinical research study.

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[3] An individual, company, institution or organisation that takes responsibility for the initiation, management and/or financing of a clinical trial or a clinical research project.

[4] Data for such calculations can be obtained, for example, by searching different databases, such as patient records or quality registers, that collect data originating from health care.

A clarification is proposed in the section specifying the application of the Patient Data Act, i.e. that the scope also includes processing personal data for sample size calculations prior to clinical research. An addition in the section specifying definitions of terms used in the Act is also proposed. The Government, or an authority designated by the Government, is authorised to issue further regulations on how personal data processing for this specific purpose is to be carried out.

Our assessment, as previously described, is that the legal basis for processing personal data complies with the General Data Protection Regulation. The specific legal basis is that such processing is necessary for the performance of a task carried out in the public interest. In our assessment, the proposal is also compatible with the Swedish Instrument of Government. It is proposed that the amendments enter into force on 1 January 2022. No transitional provisions are needed.

Providing explicit support for all processing of personal data in the health care sector is in line with both the general approach, the legislative history and the preparatory statements of the Patient Data Act.

Processing personal data to calculate sample size prior to clinical research already takes place today. Such calculations often provide crucial information in deciding whether to initiate a clinical research study. Providing clear rules for processing personal data – both for those responsible for personal data and for the individuals who carry out personal data processing in practice – and coming to terms with the current legal uncertainty are important reasons for revising the legislation.

The new provisions do not require any changes regarding personal data liability. The processing does not entail any disclosure of personal data; only information on the size of potential patient populations is presented. Hence, there is no need for new or amended legislation on confidentiality or secrecy.

The specific legal basis is that such processing [i.e. special categories of personal data concerning health for sample size calculations prior to clinical research] is necessary for the performance of a task carried out in the public interest.

The General Data Protection Regulation specifies measures that limit the processing of personal data, and the Patient Data Act already contains provisions on the required protective measures that also can be applied to processing personal data to calculate sample size prior to clinical research. The Swedish regulations state that a provider of health care is responsible for assigning authorisation and for setting up routines that ensure that the authorisation of health care staff is restricted to what is necessary. In addition to protective measures achieved through rules on authorisation, personal data in health care is also protected by the way it is stored and made accessible in database systems. Additional examples of ensuring the appropriate security of the personal data are protection against unauthorised or unlawful processing, such as passwords and physical protection of the database systems. Setting up an adequate system of governance can also be part of providing appropriate technical and organisational measures to ensure that the correct action is taken at the right time, using the correct procedure. Our assessment is that the Swedish health care system already has a range of established structures and procedures in place to ensure the secure processing of personal data.

Our assessment, therefore, is that no additional legislative protection measures are required for sample size calculations prior to clinical research. On the other hand, an information provision should be introduced on the right of the Government (or an authority designated by the Government) to regulate more specifically how personal data processing for this purpose may be carried out.

Consequences of the proposals

The Committee's report contains proposed amendments to Swedish legislation. A primary aim is to eliminate the current uncertainty in the legal regulation of personal data processing for sample size calculations prior to clinical research.

Regions and municipalities have an obligation to participate in research in the health care and public health sectors; contributing to the preparatory steps for clinical research is part of this task. The financial impact of the proposed amendment for regions and municipalities is estimated to be small and no additional funding is required. Since the health care sector already provides processing of personal data for sample size calculations prior to clinical research, the proposal is not considered to affect the need for resources within regions or municipalities. Nor does it entail any increased risk of resources being taken from patient care.

In our assessment, it is not is possible for strictly private health care providers (lacking all connection to the public health care sector) to process personal data for sample size calculations prior to clinical research. In our assessment, no exceptions under Article 9.2 of the General Data Protection Regulation can be applied to such private health care providers. Thus, it is not possible to conduct the pre-research preparatory step that sample size calculations entail for recruiting potential clinical research study participants from this group of health care providers.

The risk to the individual is deemed to be small when the processing of personal data for sample size calculations prior to clinical research is conducted in accordance with our proposal, i.e. when all processing of personal data is done entirely in the health care sector, and only information on the number of people is submitted to the research sponsor.

Non-maleficence, beneficence, justice and respecting the autonomy, integrity and privacy of the patient are all important ethical principles in all health care. The risk to the individual is deemed to be small when the processing of personal data for sample size calculations prior to clinical research is conducted in accordance with our proposal, i.e. when all processing of personal data is done entirely in the health care sector, and only information on the number of people is submitted to the research sponsor.

In the long term, the proposals can be assumed to have positive socio-economic consequences, as they are expected to contribute to increased quality and reliability in research, thus increasing confidence in Swedish research, both nationally and internationally. The Committee's proposals are expected to contribute to innovation by facilitating responsible utilisation of health data. Improving conditions for research, innovation and a competitive business sector provides opportunities to improve health, develop health care and secure stable economic prosperity.

Reference

Delbetänkande av Kommittén för teknologisk innovation och etik (KOMET). 2020. Personuppgiftsbehandling vid antalsberäkning inför klinisk forskning (SOU 2020:53).

The full report (in Swedish) is available at the Government Offices of Sweden: www.regeringen.se/rattsliga-dokument/statens-offentliga-utredningar/2020/09/sou-202053/

***The Committee for Technological Innovation and Ethics** (Komet) is tasked with creating good conditions for Swedish innovation and competitiveness, while also helping to ensure that the development and dissemination of new technology is safe and secure, preserving a long-term societal perspective*

This information has been compiled by the Committee's Secretariat.
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