'Big data analytics' and processing of health data for scientific research purposes : the Portuguese legal framework

Research Protocol by António Borges, CMBa, Cardo, Morais, Borges - Sociedade de Advogados, SP, RL

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1. Overview of the legal framework

First, we would like to get an overview of the current and upcoming legal framework applying to the processing of health data for research purposes in your country.

a. Which laws regulate the processing of health data for research purposes (the current regime, in force till 25 May 2018)

What are the relevant applicable provisions governing the processing of health data in your country? Please provide online references (also to an English version, if available), a brief description and any specific relevant information.

Law no. 67/98 of 26 October on Protection of Personal Data, implementing Directive n. 95/46/CE of the European Parliament and Council 24 October 1995.

This Act governs the protection of natural persons on what regards the collection and the processing of their personal data and the free circulation of such data. The Act was adopted in 1998, to implement Directive 95/46/CE on the protection of individuals with regard to the processing of personal data and on the free movement of such data. The Act was amended by Law 103/2015 of 24 August with the simple purpose of adding an article 45-A which created the crime of insertion of falsified data.

This Act foresees also the legal penalties for any breach of its imperative norms on protection of personal data.

It will be repealed by the new law executing the relevant aspects of the GDPR which project was only approved on the 28th of March 2018 by the government to be submitted to the legislative proceedings and final approval by Parliament, a process that will still take a few months on 2018.

The Act is complemented in its practical execution and interpretation by several Deliberations and Orientations rendered by the local DPA, which is designated as the National Data Protection Commission (CNPD – ***Comissão Nacional de Protecção de Dados***). With special relevance for the matter of data protection on the field of clinical research is

CNPD's Deliberation no. 1704/2015 – Applicable to the processing of personal data on the field of clinical research

This deliberation sets the terms under which CNPD intervenes on a previous control over the processing of personal data involved on clinical research under the norms established by the above Law 67/98.

Law 48/90 of 24 August (amended by Law 27/2002, of 8 November) - Law on the Fundamental Basics of Health (*Lei de Bases da Saúde*)

Base XVII of the above Law establishes and foresees that the increment and support for research of interest to health should be a reality in the services of the Ministry of Health, whether it is basic clinical research or clinical research applied to public health.

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Law 12/2005 of 26 January (amended by Law 26/2016 of 22 August) – Law on Individual Health and Genetic Information.

This Act defines the concept of health information and genetic information, the circulation of such information and intervention on the human genome in the health system, and the rules for the collection and conservation of biological products for the purpose of genetic testing or research.

Its article 3 (1) establishes that health information, including recorded clinical data, results of analysis and other subsidiary examinations, interventions and diagnoses, is the property of the individual, the health system clinical units being the custodians of such information, which cannot be used for other purposes than care and health research and other purposes established by law.

On what regards the patient's clinical/medical file, its article 5 establishes that:

- for the purposes of this law, medical information is health information intended to be used in medical care or treatment;
- "clinical file" means any record, whether computerized or not, containing health information on patients or their family members;
- each clinical file must contain all available medical information that pertains to the person, except for restrictions imposed on genetic information (governed under following article 6);
- medical information is entered in the clinical file by the attending physician or at least under his supervision by another professional also subject to the duty of secrecy, and in accordance with their respective ethical standards.

The clinical file may only be consulted by the physician responsible for performing health treatments to the patient or, under his supervision by another healthcare professional also subject to the duty of secrecy and by the strictly necessary to carry such health treatments, *without prejudice to the epidemiological, clinical or genetic research that can be made on such information* (Article 5.º § 5), and safeguarding the limitations on human genome research.

Article 4 (3) foresees that health information can only be used by the health system under the conditions expressed in *written consent of its holder* or by who represents him, and article 4 (4) establishes that access to health information may, provided it is anonymised, be provided for research purposes.

This Act is furthermore regulated in specific details by

Decreto-Lei 131/2014 of 29 August – Regulating Protection and Confidentiality of Genetic Information

This Act Regulates above mentioned Law no. 12/2005, of January 26, on what regards the protection and confidentiality of genetic information, human genetic data bases for the provision of health care and health research, supply conditions and genetic testing and the terms in which medical genetics consultation is ensured.

Its article 5 foresees that the processing of genetic information for the constitution of genetic databases can only be done if the following cumulative conditions are verified:

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- Their need for the purposes of predictive, preventive or curative medicine, medical diagnosis, medical care or treatment or for research purposes;
- Consent of the data subject, after information on the purpose of the treatment, in accordance with the provisions of this law, in particular the provisions of its Article 8;
- Authorization of the National Data Protection Commission (CNPD), according to the law.

Law 21/2014 of 16 April (amended by Law 73/2015 of 27 June) – Law on Clinical Research

This Act governs clinical research in Portugal, either interventional or non-interventional studies, including:

- the arrangements for conducting clinical trials with medicinal products for human use resulting from the implementing of Directive 2001/20/EC of the European Parliament and of the Council of 4 April on the approximation of the laws, regulations and Member States concerning the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;
- the system of clinical investigation of medical devices resulting from the partial implementing of Directive 2007/47/EC of the European Parliament and of the Council of 5 September;
- clinical studies on cosmetic and body care products;
- clinical dietary studies;
- clinical studies on non conventional therapies;

All clinical research is subject to a prior positive opinion issued by the competent ethics committee. Depending on the study, the competent committee may be the National Ethics Committee for Clinical Research or the local Ethics Committee in place at the centre involved with the study. If this committee does not exist, the competent ethics committee may be the National Ethics Committee or the ethics committee appointed by the National Committee.

Furthermore, authorization for the study must be granted by Infarmed [the Medicinal Products Regulatory Authority], whenever the study qualifies as clinical trial or as interventional study involving medicinal products, medical advices, cosmetic or body care products.

Under its article 2 (ff) the Promoter is defined as the single or collective person, institute or organization responsible for conceiving, executing, managing and financing the clinical study.

Furthermore, under its article 9 (i) and (k) the Promoter must ensure compliance with all notification, communication and information duties foreseen by the law and fulfil any other legal or regulatory obligations, here being included the proper notification to request authorization from the CNPD on the processing of sensitive data.

The appointed Investigator, under article 10 (g) is due to ensure confidentiality during all preparations, execution and conclusion of the clinical study, mainly on what regards all information related to the participating individuals.

As a pre-requirement for the authorization of any clinical study, under article 6 (d) the informed consent of the individual must be obtained in advance. This includes an informed consent for the clinical study and an informed and written specific consent for the processing of the individual's sensitive personal data.

Thus, as a principle, processing of personal data carried out within the framework of clinical trials or clinical studies are only legitimate and lawful if there is:

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- free,
- specific,
- and informed consent in accordance with Article 3 (h) of Law 67/98;
- consent which must be expressly stated - Article 7 (2) of Law 67/98 - and written, in the cases specified in Law no. 12/2005.

Norma 015/2013 dated 03/10/2013 (amended 04/11/2015) – Issued by the Health General Directorate (*Direcção Geral de Saúde*) of the Ministry of Health

Establishes the details and requirements of an informed, clear and free consent and how it should be given.

Informed consent, free and clear, can be expressed in an oral or written verbal form and contains in itself two inseparable notions of understanding and autonomy. The information shall be provided in a clear and accessible language, based on the state of the art and free from value judgments.

In addition to verbal communication and, whenever possible, information and clarification should be accompanied by a leaflet explaining the responsibility of the health unit and / or health professionals involved.

Furthermore, information and clarification require a period of reflection that emanates from the person's need to qualitatively evaluate the information and clarification received.

Information and clarification to minors should be appropriate, depending on their age and degree of maturity.

The informed consent is, in a negotiating logic, a continuous, participatory communication process, through the interaction established between the health professional and the person, extending in a useful time, defined in each case, by the health situation in question. Therefore:

- The health professional has a duty to ascertain whether the person has understood the information and clarification given to him;
- Revocation of informed, free and informed consent may occur at any time, without any formalities being required, and may not cause any harm to the person in his or her corresponding rights of care;
- Renewal of informed, clear and free consent is necessary whenever new diagnostic, prognostic or therapeutic data make it obsolete.
- The revocation of informed, clear and free consent must be registered in the patient's clinical file.

Decreto-Lei 16/93, of 23 January – Defines the general rules of the archives and archive's heritage

Under its article 17 (1) it is guaranteed the communication of the documentation preserved in public archives, save the limitations resulting from the imperatives of conservation of the species and without prejudice to the restrictions imposed by law.

Article 17 (2) foresees that documents containing personal data of a judicial, police or *clinical nature*, as well as those containing *personal data* which are not public, or of any nature that may affect the safety of persons, their honor or

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the privacy of the person concerned, their private and family life and their own image, shall not be communicated, unless

- personal data can be purged from the document containing them, without danger of easy identification,
- if there is unanimous consent of the holders of legitimate interests to safeguard,
- or 50 years have passed over the date of death of the person to whom the documents relate or, if that date is not known, 75 years after the date of the documents.

Law 26/2016, of 22 August - Approves the rules for having access to administrative and environmental information and re-use of administrative documents.

This Act implements Directive 2003/4/ EC of the European Parliament and of the Council of 28 January and Directive 2003/98 / EC of the European Parliament and of the Council of 17 November.

Its article 1 (3) defines that access to nominative information and documents, including when they include *health data*, produced or held by the bodies or entities referred to in Article 4 [mainly public entities], when procured by the data subject, by a third party authorized by the holder or by a person who demonstrates having a direct, personal, legitimate and constitutionally protected interest in the information, is governed by this law, without prejudice to the legal regime for the protection of personal data.

On the specific matter of access to documents with health data, its article 7 establishes the following:

- Access to health information by the holder, or third parties with their consent or according to the law, is exercised through a physician if the holder of the information so requests, with respect to the provisions of the above mentioned Law no. 12/2005, of January 26.
- If it is not possible to establish the will of the holder regarding access, such access is always carried out with the intermediation of a physician.
- In the case of access by third parties with the consent of the data subject, only information expressly covered by the instrument of consent should be communicated.
- In other cases of access by third parties, only the information that is strictly necessary for the direct, personal, legitimate and constitutionally protected interest invoked by the third party can be transmitted.

b. Revision of the current legal framework under the GDPR

How are the necessary changes to the national data protection framework introduced by the GDPR addressed in your country? What is the adopted legislative approach?

Only in 28 March 2018 the Portuguese government approved a project of Bill that will now be submitted to the national Parliament in order to be discussed, further amended and approved within some months. Notwithstanding this disclaimer – that our comments are only based on a project of law – we may highlight the following aspects. When approved, this bill shall repeal the above mentioned Law 67/98.

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The approach followed by the Portuguese government is to set its rules in cross-reference to the GDPR articles and then determining any particular adaptations, procedures or penalties.

Chapter I set the scope of application of the bill in line with the GDPR.

Chapter II of the project bill keeps CNPD as the local data protection authority and sets its duties and functions.

Chapter III describes the Data Protection Officer's several duties in accordance with GDPR, and details some specificity on DPOs within public administrative entities.

Chapter IV sets the rules on accreditations, certifications and codes of conduct.

Chapter V regulates special provisions on minor's consent (concerning the direct provision of information services to minors they must have already reached the age of thirteen); deceased individuals; portability and interoperability of data; video surveillance; secrecy duty; timing for keeping data; and data transfers.

Chapter VI deals with specific data processing situations, mainly the ones referring to the sensitive data foreseen under article 9 of the GDPR.

Article 29 (1) of the proposed bill establishes that in the cases provided for in Article 9 (2) (h) and (i) of the GDPR, the processing of the data referred to in paragraph 1 of that article shall be carried out by a professional who is bound by secrecy, or by another subject to a duty of confidentiality, and appropriate information security measures must be guaranteed.

Article 29 (2) foresees that any directors, employees and service providers of the controller, the data protection officer, the students and researchers in the *health area* and all health professionals who have access to *health data* are subject to a duty of secrecy.

Article 29 (3) extends such duty of confidentiality mentioned in the preceding paragraph to all other directors and employees who, in the context of *monitoring, financing or supervising the activity of providing health care, have access to health data*.

Furthermore, article 31 (1) of the proposed bill establishes that processing for archival purposes in the public interest, for *scientific or historical research or for statistical purposes* shall comply with the principle of data minimization and include the anonymisation or pseudonymisation of data where the purposes for which it is possible to be reached by one of these means.

Chapter VII sets the administrative and judicial enforcement of GDPR's rules, mainly the penalties for any breaches.

The main innovation is the option of exempting all public entities from any possible penalties for breach of the GDPR. They will have to comply with any orders or recommendations coming from the CNPD, but CNPD will not be able to fine them. This exemption shall be reviewed by the legislator within 3 years of application of the approved bill.

The penalties are restricted to private entities or private persons.

The breaches to the norms of the GDPR are divided between very serious; serious; or light breaches.

As an example very serious breaches shall be punished by fines:

a) from € 5.000 to € 20.000.000 or 4% of annual worldwide turnover, whichever is the greater, for large companies;

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b) from € 2.000 to € 2.000.000 or 4% of the annual worldwide turnover, whichever is the higher, for small and medium companies;

c) From € 1000 to € 500.000, in the case of natural persons;

Of course the administrative application of these fines is subject to due process, exercise of defense rights and appeal for review by the courts.

c. The national data processing authority

Can you provide a short description of the role of the data protection supervisory authority in your country in the domain of processing health data for research purposes under the current legal framework?

In Portugal, the CNPD is an independent administrative authority currently governed by the provisions of Chapter IV of Law 67/98, mainly its article 21.

It operates associated with the Portuguese Parliament controlling and enforcing the legal protection of personal data, in strict respect of human rights and freedoms and guarantees enshrined in the Constitution and the law.

The CNPD is provided, under article 22 (3) of Law 67/98, with:

- investigative powers, and may access to all data subject to treatment and collect all information necessary for the performance of its supervisory functions;
- powers of authority, in particular that of ordering the blocking, deletion or destruction of data, as well as the powers to prohibit, temporarily or permanently, the processing of personal data, even if included in open transmission of data from servers located in Portuguese territory;
- power to issue prior opinions on the processing of personal data, ensuring their publication.

Can you describe the adopted or proposed changes to this role of the national data protection authority to ensure compliance with the GDPR?

The organic and composition of the CNPD is governed by a separate organic law, currently Law 43/2004 of 18 August. We do know at the moment if this law is going to be amended or how it may be amended.

On the project Bill above described, regulating some aspects of the GDPR, the main powers and duties of the CNPD are maintained, and in some cases amplified in compliance with the GDPR.

Therefore, CNPD will keep drawing up guidelines, deliberations and orientations, including to make available a list of processing activities subject to the impact assessment on data protection, in accordance with Article 35 (4) of the RGPD, also defining criteria for better concretizing the notion of high risk provided for in that Article.

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CNPD shall also accredit bodies to monitor codes of conduct under the GDPR, as well as revoke accreditation whenever the requirements are no longer complied with or the measures adopted violate data protection standards.

2. Transposition of Article 8.4 of Directive 95/46

Did your national legislator insert any additional exemptions for the processing of health data for research purposes? How is it/are they formulated? Please explain. Are there additional exemptions issued by the DPA?

Art. 8.4 of Directive 95/46: "4. Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority."

a. Transposition of Article 8.4 of Directive 95/46

In Portugal, article 8.1. of Directive 95/46 was implemented under article 7 (1) of Law 67/98 acknowledging the same prohibition on what regards processing of this special category of personal data, namely health data, designated as sensitive data.

However, same article 7 (2) of Law 67/98 immediately establishes that by means of a legal provision or by *authorization from the CNPD*, the processing of the data referred to in the previous number [§ 1 of article 7] may be allowed when, for reasons of *important public interest*, such treatment is indispensable to the exercise of the legal or statutory attributions of its controller, or when the *data subject has given the express consent to such treatment*, in both cases with guarantees of non-discrimination and with the security measures provided for in article 15.

Furthermore, article 7 (4) of Law 67/98 foresees that the processing of data on health and sexual life, including genetic data, is permitted where necessary for the purposes of preventive medicine, medical diagnosis, medical care or treatment or management of health services as long as the processing of such data is carried out by a health professional bound to secrecy or by another person also subject to professional secrecy, and such processing *is notified to the CNPD* in accordance with Article 27 and appropriate information security measures are ensured.

b. The regime applying to the processing of personal data for health research purposes

Is there a specific regime applying to data processing for research in the field of health purposes?

Clinical research focuses on the personal data of participants in clinical trials or clinical studies. In this context, information of any nature and regardless of its support is used in relation to an identified or identifiable natural person – for the purpose of article 3 (a) of Law 67/98.

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Such data are collected, recorded and processed, implying the clinical study, as a rule, a processing of personal data as per article 3 (b) of Law 67/98.

In addition, processing of personal data for the purpose of conducting clinical research necessarily involves sensitive data, such as personal health data relating to privacy and genetic data, which processing is in principle prohibited in accordance with above mentioned Article 7 (1) of Law 67/98, with the safeguards of article 7 (2) and article 7 (4) as above explained.

Therefore, pursuant to Article 28 (1) (a) of Law 67/98, the collecting and processing of the above sensitive data are subject to prior checking by the CNPD. Consequently, such processing cannot be initiated before obtaining a *specific authorization* from the CNPD, to be issued under the terms and conditions established after notification to this Commission.

In order for CNPD to grant such authorization, as a pre-requirement for the authorization of processing health data in a clinical study, it is in principle necessary the informed consent of the individual must be obtained in advance.

Therefore, processing of personal data carried out within the framework of clinical trials or clinical studies are only legitimate and lawful in order to obtain CNPD's prior authorization if there is free, specific, and informed consent by the data subject in accordance with Article 3 (h) of Law 67/98.

The special situations in which consent may be waived or dispensed must have a legal justification, e.g., the special situations foreseen under article 19 § 6 of Law 12/2005 of 26 January as below better explained.

From which generally applicable data protection provisions are researchers exempted and under what conditions?

Law No 12/2005 allows that in cases of retrospective use of biological material and DNA samples in which the consent of the data subject has not been collected, neither could it have been obtained due to the amount of data or death of the data subject, the ground of legitimacy for the lawful processing of personal data may derive from the provisions of Article 19 (6) of this law.

In this case, the processing of personal data for clinical research is subject to the legitimacy condition fulfilled by verifying the legal assumptions of this legal norm, (see Article 19 (6): *in the case of retrospective use of samples or in special situations from which it is impossible to obtain consent*), which means that the "special situations" must be fully explained and demonstrated. These *situations* must be truly special, not just arguments of greater convenience, advantage, ease or viability.

Whenever there is no consent under the terms above indicated, the CNPD may only authorize the processing of personal data for such retrospective study if it concludes that it is justified for the satisfaction of an *important public interest* and provided it is indispensable for the performance of the duties of the entity responsible for the study.

In order to convince CNPD to grant the necessary authorization, the existence and importance of the public interest of the study or research in question must be clearly demonstrated, a public interest that must be pursued immediately and directly by the research results (the research results must immediately and directly meet the public interest concerned, which must be of undoubted importance to the community, and it is not enough that the investigation continues the public interest in an indirect, reflex or remote way).

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c. Are there additional specific conditions governing the processing of data for scientific research purposes?

What are the suitable safeguards applied to the exemption foreseen by Article 8.4 of the Directive in your country?

The mainly safeguards are the obtaining of a prior authorization from CNPD as above detailed, and the objective identification and detail of the purpose of the processing considering the clinical study protocol. The purposes for processing the specific categories of sensitive data identified in the study protocol must be determined, explicit, justified and legitimate.

Are there any specific provisions concerning: (i) professional secrecy, (ii) express consent for specific data, or specific provisions for (iii) deceased data subjects, or (iv) specific provisions for minors or persons subject to guardianship?

As above explained all persons involved – promoter; investigator; monitoring agent – in the clinical study's protocol are bound by professional secrecy (article 17 (1) of the Law 67/98).

The express, free and clear consent from the data subject, specifically obtained not only for the performance of the clinical study, but also specifically to consent on the processing of his personal sensitive data, is in principle a basic requirement to obtain CNPD's authorization.

On the specific case of deceased data subjects please check answer given above under Law No 12/2005.

On the case of minors, apart from having to comply with the requirements foreseen in article 7.º of Law 21/2014 of 16 April (Law on Clinical Research), there's a specific orientation issued by the National Ethics Commission for Clinical Research, on 13th November 2015, which recommends the following:

- The consent for the minor is always given and agreed by both parents or legal representative;
- When the minor has an age between 5 and 15, the minor should be explained and informed of the study's contents in accordance with his maturity, and give at least his assent together with the parents or legal representative's legal consent;
- When the minor is at least 16 of age he should be explained and informed of the study's contents in accordance with his maturity, and give his consent together with his parents' (or legal representative) legal consent.

Are there specific requirements about the data subject's information or about the person from whom the data was collected?

Where a study can be carried out without the processing of personal data, i.e. identified or identifiable data (as per Article 3 (a) of Law 67/98) this should be the first of the researcher's choice.

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In other words, whenever the study can be done with irreversibly anonymous data, in those situations where the data owners are not identified or cannot be identified, this should be the option taken for the clinical research.

In this case no prior notification to the CNPD or authorization from CNPD shall be required.

In case the study cannot be carried out with irreversibly anonymised data, the use of coded data should be preferred, even if these can be converted to personal data by means of a decoding key. Access to this key must necessarily be limited to the main investigator which is bound by professional secrecy.

Only in the latter case and in the case of strict necessity, duly demonstrated, can the use of data identified for clinical research purposes be allowed. Therefore, the entity responsible in the notification of the processing of personal data must justify to CNPD the need to carry out the study in an identified or identifiable manner.

Moreover, the categories of specific sensitive data listed in notification aiming for authorization from CNPD must be justified as adequate, pertinent and not excessive for the purpose of the concrete research. Therefore the sensitive categories of personal data to be processed in the context of the research should be the ones indispensable to perform and satisfy the concrete purpose of the clinical study.

CNPD will refuse authorization for the processing of certain categories of sensitive data that may seem irrelevant or disconnected with the purpose of the research.

Are there specific penalties if the conditions for processing for scientific research in the field of health purposes are not respected? What do those penalties entail?

Article 37 (2) of Law 67/98 foresees that failing to request authorization for processing of personal data subject to CNPD's previous control – which is the case of sensitive data like health data – duplicates the limits of the regular fines foreseen in article 37 (1) (a) and (b). Which means that a breach committed by an individual person may cause him a penalty between € 500 and € 5000; and if committed by a collective entity may involve a penalty between € 3000 € 30.000. (Please note that these penalties will be significantly increased under the current project of Bill)

3. Formalities prior to processing: the general regime under the current framework

Is there a regime requiring the fulfilment of certain conditions prior to any processing activities different from that applicable to research in the field of health? If yes, what does that regime entail?

Out of the specific regime of prior control/authorization applicable to research in the field of health, there is a general regime applicable to the common processing activities of personal data which do not involve sensitive data.

Regular processing of personal data (if not exempted of notification by prior orientation published by the CNPD), which does not include sensitive data are subject to simple prior notification to the CNPD, under article 27 of the Law 67/98.

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In any case, both this simple notification of the general regime, or the notification aiming to obtain a prior authorization for processing sensitive data, are required under article 29 of the Law 67/98 to be filed with CNPD containing at least the following relevant information:

- Identification and address of the entity responsible for the processing and identification of any sub-contractors involved on the processing;
- The purposes of the processing;
- Categories of data subjects involved and categories of personal data to be collected;
- Addressees to whom the above data may be revealed or communicated and under which conditions;
- Information on any inter-connections of data;
- Timing during which the data are to be stored;
- Form and conditions of access to the personal data by the data subjects;
- Information on possible transfers to third countries;
- General description of the security measures, physical and logical, to be implemented and which must be adequate to ensure safety of the data processing.

4. Further processing of health data (for research purposes): the current regime

How is the notion of further processing regulated in your national framework?

On what regards further processing in the context of non-interventional retrospective studies and in the choice of the sample study, when it depends on the verification of certain parameters, it may be necessary to have access to pre-existing information held by the health unit or the data subject's attending physician.

Because even than the law requires the data subject's consent, in the terms described above, whenever it is necessary to access this information without that consent having been previously granted by the data subject for further processing, the researcher will have to rely on the cooperation of the holder of the information to achieve this goal - obtaining of consent. That is, the entity responsible for the processing must request from the health unit or the person who has the custody of the personal data to contact the holders and obtain their competent consents before carrying out the study, in order for CNPD to allow this treatment.

Are there specific conditions to the further processing for scientific research in the field of health purposes?

The main specific condition in order to get authorization from the CNPD is obtaining the data subject's consent, as above explained.

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See also above, when consent is impossible to obtain, the answer on page 10 explaining under which terms CNPD may waive necessity of consent on well founded "special situations" and authorize the processing of personal data for such retrospective study if it concludes that it is justified for the satisfaction of an important public interest and provided it is indispensable for the performance of the duties of the entity responsible.

What are the rights of the data subject when it comes to further processing?

Under article 10 (1) of Law 67/98 the controller must inform the data subject about its identity, the purpose of the processing, the nature of the answers given (compulsory and optional), the identity of the recipient(s), of the data subject's rights to object, rectify and to be informed. The data subject must be notified about any intention to transfer his/her data outside the EU, and the duration for which the data will be stored.

Article 10 (5) of Law 67/98, on the other hand, establishes that the obligation to provide information may be waived, by means of a legal provision or deliberation by the CNPD, for reasons of State security and criminal investigation or prevention, as well as when, particularly in the case of data processing for *statistical, historical or research* purposes information is impossible or involves disproportionate efforts, or where the law expressly provides for the recording or dissemination of data.

What about the data subject's rights and further processing for scientific research purposes?

See answer above, with the specificity that the right of access to health data by the data subject should, in principle, when applicable, be made through his physician in accordance with article 11 (5) of Law 67/98.

5. The GDPR's impact on the current regulatory framework for the processing of health data for research purposes

a. The impact of the GDPR on the rules applying to processing for research in the field of health

Please provide a summary of the main relevant characteristics of the new law/Bill (as far as it is relevant for processing health data for research purposes). How is (or will be) Article 9(2)(j) implemented in your country?

Article 31 of the project Bill will implement Article 9 (2) (j) of the GDPR stating in its § 1 that processing for the purpose of archives of public interest, for purposes of *scientific or historical research or for statistical purposes* shall respect the principle of data minimization and include the anonymisation or pseudonymisation of data where the purposes for which it is possible to be reached by one of these channels.

On the other hand its § 2 foresees that in the context of the above mentioned data, mainly for scientific research purpose, the rights of access, rectification, limitation of treatment and opposition provided for in Articles 15, 16, 18 and 21 of the GDPR shall be prejudiced to the extent necessary, if such rights are likely to make the achievement of those ends seriously impossible or are seriously detrimental to such ends.

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On the matter of consent § 4 of same Article 31 establishes that consent to the processing of data for scientific research purposes may cover *several areas of research* or be given only to *specific fields or specific research projects*, which is an innovation in face of CNPD's current strict interpretation of consent, also adding that in any case the ethical standards recognized by the scientific community must be respected.

b. Modification to the processing authorisation procedure applying to research in the field of health

The project Bill does not contain any processing authorisation procedure applying to research in the field of health and makes a simple cross-reference to the notifications or authorizations that may be required under the GDPR.

It is possible that the processing authorisation procedure may be the subject of a future guideline or deliberation from the CNPD, but currently the information is very scarce.

How will the processing authorisation procedure (if any exists) be affected by the implementation of the GDPR? Can you describe any such change?

See answer above.

What about the right of the data subject and the obligations of the controller?

See above answer to question A. on rights of access/rectification and consent from the data subject.

6. Further processing for research purposes under the GDPR

Given the regime applied to further processing in the GDPR, can you describe the consequences, if any, in your national legal framework?

Apart from the provisions above described under the answer to section IV.A, the only other legal consequence on further processing for research purposes under the GDPR in the project Bill is on its Article 21 (2) on timing for data storage which states that where, by the nature and purpose of the treatment, in particular for the purpose of archives of public interest, for the *purposes of scientific or historical research* or for statistical purposes, it is not possible to determine in advance the time when it is no longer necessary, it is lawful to maintain the storage of personal data.

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7. Health data sources for research purposes

a. Sources of data and their regulation

Does your national framework contain specific provisions for anonymised or pseudonymised health data?

Health data that are irreversibly anonymised are considered to be out of the scope of the CNPD and of Law 67/98 on data protection. Pseudonymised or codified health data keep falling on the scope of CNPD's intervention and authorization under Law 67/98.

What are the different sources of health data that can be used for research purposes?

- **DIRECT COLLECTION FROM PATIENTS:**

Under the current legal framework: please explain the currently applying rules that a researcher, who intends to collect health data directly from individuals (e.g. via a survey, or by asking patients to wear a monitoring device, etc.), should follow.

Before collecting any health data directly from individuals, apart from having to comply with all authorizations and positive opinions required under the Law on Clinical Research – this is, positive opinion on the study's protocol issued by the competent Ethics Committee and authorization for the study granted by Infarmed [the Medicinal Products Regulatory Authority], whenever the study qualifies as clinical trial or as interventional study involving either medicinal products, medical advices, cosmetic and body care products – the researcher must obtain in advance from CNPD the authorization for processing sensitive data (in accordance with the proceedings of article 28 and article 29 of the Law 67/98), for which he must have in place the necessary free, clear and informed consent declarations issued and signed by each of the data subjects.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

According to the information available on the project Bill and whilst CNPD does not issue a new guideline or deliberation on the processing of data in the context of clinical research, the existing procedures do not seem to have any substantial change.

- **COLLECTION FROM HEALTH PROFESSIONALS AND HEALTH INSTITUTIONS**

Under the current legal framework: please explain the rules currently applying that a researcher, who intends to obtain health data from medical staff, hospitals, etc., should follow.

As a principle if the health data is not anonymised, the law 67/98 always requires the data subject's consent, in the terms described above, whenever it is necessary to access health data from medical staff or hospitals. Therefore, unless that consent has been previously granted by the data subject for further processing on other research activities, the researcher will have to rely on the cooperation of the holder of the information to achieve this goal. That is, the researcher responsible and aiming for the new processing must request from the health unit or the

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person who has the custody of the personal data to contact the holders and obtain their competent consents before carrying out the study, and in order to obtain prior authorization from CNPD.

Notwithstanding the above, article 5 (5) of Law 12/2005, after stating that the clinical file may only be consulted by the physician providing medical care to the patient, or by other healthcare professional subject to professional secrecy, also foresees the assumption that the medical file should be available for epidemiologic, clinical or genetic investigation, with the limitations of article 16 on what regards investigation on the human genome, and always subject of course to prior authorization from the CNPD.

Another possibility, as above explained, may be under article 19 § 6 of same Law No 12/2005 which allows that in cases of retrospective use of biological material and DNA samples in which the consent of the data subject has not been collected, neither could it have been obtained due to the amount of data or death of the data subject, the ground of legitimacy for the lawful processing of personal data may derive from the provisions of said Article 19 (6).

In this case, the CNPD may authorize the processing of personal data for a retrospective study if it concludes that it is justified for the satisfaction of an important public interest and provided it is indispensable for the performance of the duties of the entity responsible. The existence and importance of the public interest of the study or research in question must be clearly demonstrated

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The project Bill does not substantially modify the conditions of access to data gathered by health professionals and health care units.

- **PRIVATE DATABASES**

Under the current legal framework: please explain the rules currently applying for the setting up of and the use of a private database with health data for research purposes.

Establishing a private database with health data for research purposes, requires prior authorization granted by the CNPD. As a basic condition, specific informed consent shall have to be collected from the data subjects involved, including:

- information about the purpose of the database;
- the entity responsible;
- the types of research developed and their potential risks and benefits;
- the conditions and duration of data storage;
- measures taken to ensure privacy and confidentiality;
- and the information on the possibility of communicating or transferring any of the results obtained with such data base. The use and location of any servers hosting the data base shall have to be disclosed to CNPD and the contractual arrangements with a sub-contractor may also have to be disclosed and verified under the conditions set by the authorization.

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Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The project bill does not effectively change the conditions applying to the setting up of a private data base.

- **PUBLIC DATABASES**

Under the current legal framework: do public authorities make available health data for research purposes in your country and under what conditions?

The Health General Directorate (*Direcção Geral de Saúde*), a department of the Ministry of Health, publishes and makes available online a directory of national and international databases, mainly covering several diseases, classes of therapeutic and treatments, statistical information, etc.

http://dis.dgs.pt/category/bases-de-dados-nacionais/

The access is normally subject to a prior contact with the entity responsible for each database and in accordance with their conditions.

On the other hand Law 21/2014, regulating clinical research, not only set the creation of the National Network of Ethics Committees for Health (RNCES) but also created the National Registry of Clinical Studies (RNEC). RNEC is an electronic platform for registration and dissemination of clinical studies, which aims to strengthen the resources for visibility, national and international collaboration, maximization of earnings and social responsibility of clinical research, creating the basis for a research repository of protocols, data collection tools and anonymised databases.

http://www.rnec.pt/31a

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The project bill does not effectively change the access to public databases.

b. Application of the national framework to the AEGLE cases

1. Type 2 diabetes

The AEGLE project uses, after pseudonymisation, existing databases with health data collected from patients who expressed their consent to their data being used for research purposes.

According to the information above this clinical study seems to be non-interventional. If this is the case, no authorization will be required from Infarmed – the Medicines Regulatory Authority.

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On what regards the application of Law 21/2014 of 16 April (Law on Clinical Research), the promoter of the study shall have to comply with the duties foreseen in its article 9.º:

- File a request for a positive opinion on the envisaged study and protocol with the Competent Ethics Committee with all the requirements foreseen in article 16.º of the law above and using the templates and following the instructions approved by the National Ethics Committee for Clinical Research (CEIC) [http://www.ceic.pt/pagina-inicial] - which for non-interventional studies is, in principle, the Ethics Committee of the centre involved in the study; if the centre has no Ethics Committee then the competent ethics committee will be either the National Ethics Committee for Clinical Research or the Ethics Committee appointed as competent by that National Committee;
- If necessary, execute the financial contract involved in the terms of article 13.º;
- Appoint the leading Investigator and its qualifications;
- Inform of the existence of other opinions on the study already delivered by other Ethics Committees;

Before the GDPR CNPD would evaluates if the pre-existing consent given by the data subjects was satisfactory enough to allow its authorization.

CNPD could also conditionally authorize the processing of some of the categories of sensitive data, with the exclusion of other categories of sensitive data not deemed relevant for the study.

Otherwise, either CNPD would require for new specific consent to be obtained from the data subjects, or CNPD would concede on waiving such new specific consent as long as it was served with strong fundamentals that would sustain the evident public interest of the clinical study, under the requirements of Law 12/2005 of 26 January as above explained.

After the implementation of the GDPR, the promoter shall have to evaluate and assess if the pre-existing consent is satisfactory enough, together with complying with all the duties above on what regards a positive opinion from the competent ethics committee.

Also, the applicant may benefit of the more generous legal draft contained in Article 31 (4) of the project Bill which seems to admit the validity of more broader consents given to several research areas: “Article 31.º § 4: Consent relating to the processing of data for scientific research purposes *may cover several areas of research* or be given only to specific fields or research projects, and in any case the ethical standards recognized by the scientific community.”

The Investigator designated in the study shall have to comply with the duties foreseen in article 10.º of Law 21/2014.

If any changes to the study protocol are required during the performance of the study, the competent ethics committee must be consulted again. Also, if those changes have impact on the categories of sensitive data processed, the promoter shall have to re-assess if the pre-existing consent is satisfactory enough to cover new categories of sensitive data processed.

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The conclusion of the clinical study must be notified to the competent ethics committee in accordance with the requirements of article 19.º of Law 21/2014 of 16 April (Law on Clinical Research).

In principle, all filing of templates, documents, additional information and final reports with the competent ethics committee is performed electronically through the RNEC (National Registry of Clinical Studies – *Registo Nacional de Estudos Clínicos*). [http://www.rnec.pt/]

Finally, the disclosure of the study's conclusions by the research team, mainly with the public, must follow the requirements of articles 40.º and 42.º of Law 21/2014.

The competent ethics committee keeps having legal supervision over the study, namely overseeing its disclosure terms in case any legal requirements are breached. (article 43.º of Law 21/2014)

2. Intensive Care Unit (ICU)

AEGLE uses data generated by ICU devices without collecting the patient's consent (after pseudonymisation).

The approval procedure and the study's performance in liaison with the competent ethics committee will follow the same steps as above described under the requirements of Law 21/2014.

On what regards processing of sensitive personal data, with the implementation of the GDPR, the promoter shall have to evaluate and assess if the pre-existing consent is satisfactory enough for the performance of a clinical study involving processing of sensitive personal data. However, in principle the applicant may invoke, as lawful condition for the study in place of consent, articles 5.º (5) and 19.º (6) of Law 12/2005 which assumes the availability of medical file information for epidemiologic, clinical or genetic research, under strict requirements of professional secrecy, for special situations, in order to obtain CNPD authorization waiving the consent requirement.

3. Chronic Lymphocytic Leukaemia (CLL)

The AEGLE project re-uses, after pseudonymisation, data coming from biobanks. In this instance, patients have given their informed consent for the samples and for the processing of their data. But this consent was given in general terms and not specifically for AEGLE.

The approval procedure and the study's performance will follow the same steps as above described under the requirements of Law 21/2014, with intervention of the competent ethics committee.

On what regards processing of sensitive personal data, with the implementation of the GDPR, the promoter shall have to evaluate and assess if the pre-existing consent is satisfactory enough. The applicant may also invoke, if the consent given is deemed too broad and generic, article 19.º (6) of Law 12/2005 which consents on the retrospective use of samples for epidemiologic, clinical or genetic research, in order to obtain CNPD authorization.

Also, the applicant may benefit of the more generous legal draft contained in Article 31 (4) of the project Bill which seems to admit the validity of more broader consents given to several research areas: "Article 31.º § 4: Consent relating to the processing of data for scientific research purposes *may cover several areas of research* or be given only to specific fields or research projects, and in any case the ethical standards recognized by the scientific community."

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