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

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1. Overview of the legal framework

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

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.

1) Data Protection Code - Legislative Decree no. 196/2003

The Data Protection Code (hereinafter referred to as "DPC") is the current legislation on data protection and processing of personal data in Italy. Italy's consolidated DPC came into force on 1 January 2004.The DPC brings together all the various laws, codes and regulations relating to data protection since 1996.

Health data are categorised as sensitive data by the DPC. Specific provisions are laid down in the DPC to regulate the processing of health data in the health care sector (Sections 75-94). A general relevant provision concerning health data is Section 76. Health care professionals and public health care bodies may process medical data (the Code refers to "data suitable for disclosing health"), firstly, within the framework of activities in the substantial public interest pursuant to Section 85. Secondly, processing of such persons may be based on data subjects' consent without the need of an authorisation by the Italian Data Protection Authority's (hereby referred to as the "Garante"), if the processing concerns data or operations that are imperative to the data subjects' health and/or bodily integrity. Conversely, they may process medical data without the data subjects' consent but instead with the Garante's authorisation, if the processing is indispensable to safeguarding public health. In the cases referred, the Garante's authorisation shall be granted after seeking the opinion of the Higher Health Care Council, except for emergencies.

The "further processing" of health data for research purposes is governed by Section 110 of the DPC, as specified in paragraph A of this report, as found below. This further processing is also subject to Authorisation 2/2014 by the Garante and to data subjects' explicit consent. Section 110 gives specific provisions about data subject's consent, Garante's Authorisation, legislative requirements for approved research programme.

The Code has recently been amended by the Legge 20 novembre 2017 n. 167 ("Legge Europea 2017") that has introduced the new Art. 110-bis heading '*Data reuse for purposes of scientific research or for statistical purposes*', according to which within the scope of scientific research or for statistical purposes the processing may be authorised by the Garante, including sensitive data but excluding genetic data, on the condition that preventive measures will be adopted to minimise and anonymise the data deemed suitable for the protection of the data subjects concerned. The Garante will communicate the decision taken on the request for authorisation within 45 (forty-five) days, after which the lack of a communication is equivalent to rejection. With the authorisation or even subsequently, on the basis of any verification, the Garante shall determine the conditions and measures necessary

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to ensure adequate safeguards for the protection of data subjects regarding the re-use of data, also in terms of their security.

Genetic data, as health data, are a particular category of personal data. The processing of genetic data is regulated by Section 90 of the DPC. This Section provides that processing of genetic data shall be allowed exclusively in the cases provided for in ad-hoc authorisations granted by the Garante. **Also, as per Section 37, the notification of processing to the Garante is needed when genetic data are processed.** The Garanted granted the General Authorisation No. 8/2014 for the Processing of Genetic Data.

The Code will soon be revised in order to implement the GDPR provisions. Recently, on 16 March 2018, the Italian Council of Ministers are in the process of approving a Legislative Decree scheme, which introduce provisions to amend the DPC, in order to implement the GDPR in Italy.

2) Code of conduct and professional practice applying to processing of personal data for statistical and scientific purposes (Code of Conduct), Annex A.4 of the DPC.

The DPC has enhanced the importance of codes of conduct and professional practice in respect to the protection of personal data. The main principle in this connection is that compliance with the provisions set forth in the relevant Code of Conduct is a prerequisite for the processing activities for scientific purposes to be lawful and a specific procedure is to be followed.

This Code of Conduct does not apply to processing activities for statistical and scientific purposes that are related to activities aimed at safeguarding health as carried out by health care professionals and/or health care bodies. ("public interest"). The aforementioned processing activities shall continue to be regulated by the DPC (ex. relevant provisions for health care professionals and health care bodies as per Section 98 of the DPC).

The Code of Conduct gives a complete overview for cases of processing of health data, included in the category of sensitive data.

The Code of Conduct also provides that private bodies may process sensitive data for scientific purposes if:

- the data subject has given his/her consent freely on the basis of the items that are required to be included in the information notice;
- the consent is given in writing, or if consent is collected in another manner it may be documented in writing;
- the processing has been authorised by the Garante either following a specific request according to Safeguards Applying to Sensitive Data - Section 26(1) of the DPC - or based on a general authorisation applying to certain categories of data controllers and/or processing activities that have been issued - pursuant to Section 40 of the DPC - also on the proposal of scientific bodies and societies.

In case of public bodies, The Code of Conduct sets forth that they may process sensitive data for scientific purposes, on the condition that they specify and publish the categories of data and processing activities that are absolutely

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relevant and necessary, by having regard to the purposes sought in the individual cases, and update this information regularly in pursuance of Section 20, paragraphs 2 and 4, of the DPC concerning the principles applying to the processing of sensitive Data.

3) **The Garante has granted the following Authorisations that apply to the processing of health data and the processing of health data for research purposes:**

a) Authorisation No. 2/2014 Concerning Processing of Data Suitable for Disclosing Health or Sex Life The Art.1, 2 a) of this Authorisation grants the authorisation to process health data also to **«** *natural or legal persons, bodies, associations and other private entities for scientific research purposes, including statistical purposes, if the research is aimed at protecting the health of the data subject, third parties or the community as a whole in the medical, biomedical or epidemiological field, whenever the relationships between risk factors and human health are to be assessed also in connection with clinical drug trials or investigations are scheduled concerning diagnostic, therapeutic or preventive medicine activities or else with regard to the utilisation of health care facilities, and the availability of exclusively anonymous data concerning population samples does not allow achieving the purposes of said research.".*

The same Authorisation set forth that *"the data subjects' consent shall be required as per Sections 106, 107, and 110 of the DPC and the data, once collected, shall be processed in such a way as to prevent data subjects from being identified even indirectly, unless matching of the research data with the data subjects' identification data is performed on a temporary basis, is fundamental for the research purposes, and is accounted for in writing. Research findings may only be disclosed in anonymous form".*

b) **Authorisation no. 9/2014 - General Authorisation to Process Personal Data for Scientific Research Purposes that we will analyse in detail in sections B and C of this report.**

c) Authorisation No. 8/2014 for the Processing of Genetic Data **that we will analyse in detail in next sections.**

d) Guidelines for the processing of personal data in the context of clinical trials of medicines'**.** These Guidelines focus on human studies in the context of clinical trials and are aimed at discovering or verifying the effects of experimental medicinal products. The Guidelines **establish that studies falling into this category are defined as *observational***, not strictly associated with health protection activities carried out by doctors or health institutions or – which do not have customised effects on the people concerned, fall within the scope of the provisions of the **Code of conduct and professional practice applying to processing of personal data for statistical and scientific purposes.** Also, in the context of the clinical studies, the processing of medical/clinical information can be carried out, generally speaking, for the research purposes with consent of the data subject, and applying all provisions foreseen by the DPC.

Shared electronic health records are indirectly relevant in this context because they can potentially be an important source for health-related research.

In Italy the electronic medical records are regulated by various, complementary legal instruments*:* general rules arising from the DPC (Legislative Decree 196/2003); Annex B to the DPC on technical and organizational measures; Authorisation 2/2016 Concerning Processing of Data Suitable for Disclosing Health or Sex Life and, above all, the Italian Data Protection Authority Guidelines on Electronic Health Files issued on the 4th of June 2015.

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Processing of personal data via an Electronic Medical Record (EMR) is only aimed at prevention, diagnosis and treatment activities in connection to the data subjects; therefore, it should only be performed by health care practitioners. Regarding the processing for research purposes, Annex A of the Garante's Guidelines on Electronic Health Files states that "*[…] health data collected through the health dossier can be treated like any other clinical information, even for research purposes in compliance with the provisions of the Code for such processing activities, that is, as a general rule, after obtaining an informed patient's consent"(*Section 110 of the DPC)

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 Italy? What is the adopted legislative approach?

To ensure the Italian framework's compliance with the Regulation, the Italian Government will alling the DPC to the GDPR.

The Code will soon be revised and amended according to the GDPR provisions. For this reason, there is not a sufficient amount of updated information on several aspects where the GDPR has allowed for national derogations, where the Italian legislation has not yet taken a stand.

The Italian Parliament has delegated to the Government to implement the various – and in many ways innovative – provisions contained in the E.U. legislation; in this regard, article. 13(1) of Law of 25 October 2017 n. 163 (hereinafter the "Law n.163") decided that "*the Government shall adopt, within six months from the date of entry into force of this Act, [...] one or more legislative decrees in order to adapt the national legal framework to the provisions of Regulation (EC) 2016/679 of the European Parliament and the Council [...] on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC*".

In particular, the Italian Council of Ministers are in the final steps of approving a Legislative Decree scheme, not into force yet, which will introduce provisions to allying the DPC to the GDPR. As a general observation, the additions of the impact assessment requirement and the appropriate measures to safeguard personal data in the processing of health data for scientific purposes, can be categorized as a risk-based approach. The Italian legislators emphasise the risk-based approach, as is taken in the GDPR itself, and increase the requirements for the scenarios were consent is not required as a legal basis to process the aforementioned health data.

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?

The Garante is an independent administrative authority and was established in Rome. It is governed by the provisions of Chapter II of the DPC and its role is to implement all the principles concerning data protection, and

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especially where there the European legislators have allowed for the Italian national law to create further requirements, thus the Garante inherently takes a central role of implementation of the DPC.

In terms of the processing activities related to health data, mainly for research purposes, the Garante takes a very active role in the data controllers' conducting of such activities. The DPC already states a large variety of processing activities, under which the data controller must notify the Italian DPA of **intentions** in processing activities **prior** to their initiation. As an example, section 37(1) of the DPC requires a notification to the Garante when the processing concerns genetic data, biometric data, data enclosing health and sex life, or data in the phycological sphere, or in cases of diagnosis of mental, infectious and epidemic diseases, or HIV- positivity. The list is a long one, and apart from this, the legislators have given the Garante the freedom to specify, through a decision, additional processing activities that must be included in the mandatory prior notification, or processing activities that are exempted from such notification. This goes to show that the Italian DPA can have increasing control of activities that are taking place in the realms of research that includes health data.

Furthermore, any data controller, who processes data disclosing health due to scientific research activities, must send an additional communication to the Garante, ensuring that the processing is in pursuance of the biomedical or health care research programme referred to in section 110(1).

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

The Garante is governed by the provision of Chapter VI of the GDPR (Articles 51 to 59). Article 54 of the GDPR provides that each Member State must set in law the rules establishing the supervisory authority.

At this stage, we do not have the revised Italian framework's in its final approval.

However, in order to offer a complete overview of the proposed changes according to the GDPR, an unofficial version of the Italian Council of Ministers' Legislative Decree scheme will be used. The unofficial version seems to give the Garante the power to promote the adoption of deontological rules for processings under Art. 9(4) GDPR, verifying the conformity to the provisions into force. Those rules are essential prerequisites to consider lawful and compliant processing. Moreover, the processing of genetic data and health must be in conformity with the security measures provided for by the Garante.

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: "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."

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a. Transposition of Article 8(4) of Directive 95/46

The "further processing" of health data for "research purposes" is governed by Section 110 of the DPC. This further processing is also subject to Authorisation 2/2014 by the Garante and to data subjects' explicit consent.

The data subjects' consent is not required if the said research processing activities are expressly provided for by legislation that specifically refer to the processing, or are included in a bio-medical or health care research program pursuant to Section 12-bis of Legislative Decree no. 502 of 30.12.92, as subsequently amended, and if forty-five (45) days have elapsed since the communication of said activities to the Garante and the Authority did not object to it.

Additionally, consent shall not be necessary if data subjects cannot be informed on specific grounds and the research program has been the subject of a reasoned, favourable opinion by the geographically competent ethics committee as well as being authorized by the Garante. The cases where data subjects'consent is unnecessary is set forth by the Code of Conduct and specifically when it proves it is impossible – under the terms of section 110 of the Code, to inform data subjects on "ethical grounds", "methodological grounds" or otherwise "because it is organisationally unfeasible".

In case of public bodies, according to Section 98 of the DPC, the processing of health data carried out for scientific purposes by public bodies - such as Health care professionals and public health care bodies - shall be considered in the substantial public interest, and therefore the processing is allowed.

Considering genetic data, Section 90 provides that processing of genetic data, regardless of the entity processing them, shall be allowed exclusively in the cases provided for in ad-hoc authorisations granted by the Garante, after having consulted with the Minister for Health who shall seek, to that end, the opinion of the Higher Health Care Council.

Giving the above general principle,the processing of genetic data is authorised only to the entities in accordance with the requirements set forth in the General Authorisation No. 8/2014 for the Processing of Genetic Data.

Based on Sections 23 and 26 of the Code, *genetic data may be processed, and biological samples use for research purposes, on the condition that the person concerned has provided his/her written informed consent. Consent may be withdrawn freely at any time. Where a data subject withdraws his/her consent to the processing of data for research purposes, the biological sample will be also destroyed providing it has been collected for such purposes – except where the sample may no longer be related to an identified and/or identifiable individual either from the very beginning or because of the processing*.

Health data and genetic must be also subject to the safeguards laid down in the Garante's general authorisations n. 2/2014 and n. 4/2016 as well as in the Code of Conduct and DPC (Annex B), in particular, to the standards to be implemented in order to prevent data subjects from being identified in the study phases following data extraction as well as to the rules of conduct data processors and persons tasked with data processing should abide by.

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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?

The relevant legal framework applying to processing data for research in the field of health is a combination of DPC's provisions, Code of Conduct prescriptions– as already exposed in section A of this report - and also the following specific Authorisations of the Garante.

In fact, the processing of health data for research purposes should also be subject to the safeguards laid down in both Authorisations, regarding health data and health data for research purposes.

The Garante's authorisations have been granted in the form of an instrument applying to several entities and/or processing operations, by various categories of data controllers.

1) **Authorisation no. 9/2014 - General Authorisation to Process Personal Data for Scientific Research Purposes,** *concerning the medical, biomedical or epidemiological* **research.**

The authorisation shall stipulate that the processing of health data for research purposes, can be carried out **even in the absence of consent**. The authorisation in fact concerns the processing of data of data subjects to be included in research, that cannot be contacted in order to provide information. The authorisation shall be issued to universities, other research bodies or institutes, and scientific societies, as well as to researchers and to those specifically in appointed in charge of processings; such as managers, therefore including researchers.

The research must be aimed at the protection of public health or for the execution of previous research projects. Processing must be necessary for the conduct of studies, which do not have significant impact on the data subject, carried out with data collected previously.

The research must be carried out on the basis of a project, subject to a motivated favorable opinion of the competent ethical Committee at the regional level, under the conditions set out in art. (3) of the Code of deontology and good conduct for the processing of personal data for statistical and scientific purposes (annex A.4 to the DPC).

In general, for this Authorisation to apply, in principle the data controllers falling within its scope are not required to submit an application for authorization to the Garante, if the processing activities comply with this Authorisation's prescribed instructions.

2) The Authorisation of the Garante n. 2/2016 Concerning Processing of Data Suitable for disclosing Health or Sex life**:**

This Authorisation must be taken into account as it applies to health data and is also issued to those conducting research aimed at protecting the health of data subjects or of the community in the fields of *medicine, biomedical or epidemiological* studies. Furthermore, this authorisation also includes studies of clinical trials on drugs, or investigations of diagnostic, therapeutic or preventive-type health interventions, or on the use of social health

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facilities, in cases where the availability of only anonymous data on samples of the population does not permit the research to achieve its purpose.

As regards to the legal basis, in such cases, it will be the consent of the data subjects, in conformity with the requirements of Art. 106, 107 and 110 of the DPC with regard to the obligation to obtain their consent;

Furthermore, following the data's collection, the processing must not allow the identification of the involved data subjects, even indirectly, unless such identification is temporary and essential for the result of the research, and is also motivated in writing. The research results may only be desseminated in anonymous forms.

In general, for this Authorisation to apply, in principle the data controllers falling within its scope are not required to submit an application for authorization to the Garante, if the processing activities comply with this Authorisation's prescribed instructions.

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

In Italy, the general exemptions to the processing of data for research purposes, according to the DPC and Code of Conduct, apply. As already explained in detail in sections A and B, the first exemption is stated in Art. 110(1(c)) of the DPC where the data subjects' consent is not required if the research activities are expressly provided for by legislation that specifically refer to the processing, or are included in a bio-medical or health care research program pursuant to Section 12-bis of legislative decree no. 502 of 30.12.92, as subsequently amended, and forty-five (45) days have elapsed since the notification of such activities has been communicated to the Garante.

The second exemption contained in the same Article states that additionally, consent shall not be necessary if data subjects cannot be informed on specific grounds and the research program has been the subject of a reasoned, favourable opinion by the regional competent ethics committee as well as being authorised by the Garante. This provision is allined with the conditions set out in Art. 3 of the Code of Conduct (annex A.4 to the DPC).

Except for those exemptions, general principles on data controllers' obligations and data subjects' rights apply.

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 text of Article 8(4) of the Directive requires that the processing of sensitive data, when authorised by the Member States for reasons of significant public interest, are subject to suitable safeguards. In the Italian legal framework, in relation to the processing for scientific research in the field of health, Art.110(1(c)) of the DPC and ***Authorisation no. 9/2014 - General Authorisation to Process Personal Data for Scientific Research Purposes***, give particular safeguards. For example, excluding genetic data for which additional measure are taken, the Authorisation set out that "*prior to starting or carrying on the processing, information systems and computer software shall be configured by minimising the use of personal data and identifying information so as to rule out their processing if the purposes pursued in the individual cases can be achieved by relying on anonymous data and by implementing suitable*

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mechanisms that only allow identifying data subjects where necessary, respectively, in accordance with Section 3 of the DPC"

For genetic data, specific precautions and additional security measures such as encryption and other measures that allow genetic and medical data to be processed separately from any other personal data that can identify the data subjects directly, must be taken if possible.

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?

Personal data concerning health is protected by professional secrecy. The processing for research purposes has legal obligations that prohibit the revelation without a just cause and the use of the personal data, at their own or others' benefit, is covered by professional secrecy; as well as by the expected ethical obligations envisaged by the code of medical ethics, adopted by the National Federation of Medical Surgeons and Dentists.

Generally, safeguards of sensitive data apply also to our case, when health data and not general personal data are processed for research purposes. In fact, sensitive data may only be processed with the data subjects' written consent and the Garante's prior authorisation, by complying with the prerequisites and limitations set out in this DPC as well as in laws and regulations.

With regard to the express consent for specific data, Section 107 of the Code applies, whereby the data subjects' consent for processing sensitive data may be given, if required, in accordance with simplified arrangements as set out in the DPC referred to in Section 106 without prejudice to Section 20 – regarding the processing of sensitive data - and except for specific statistical or scientific research investigations or surveys that are provided for by law, whilst the relevant authorisation may be granted by the Garante also in pursuance of Section 40.

Specific provisions are established for genetic data by the Authorisation n. 8/2016 – "General Authorisation to the Processing of Genetic Data". The Authorisation provides that when the processing is necessary in order to protect the life and physical integrity of the data subject, and the latter cannot give his/her consent because he/she is physically unable to do so, legally incapable or unable to distinguish right and wrong, the consent for the processing of genetic data and in relation to biological samples shall be given by the entity legally representing the data subject, or else by a next of kin, a family member, a person cohabiting with the data subject or, lacking these, the manager of the institution where the data subject is hosted in accordance with the provisions of Section 82 of the DPC.

About genetic data subjects' consent and information other specific provisions are set forth by the Authorisation. Art. 8 of the Authorisation says that biological samples and genetic data that were collected and processed, respectively, for health care purposes **may be retained and used for scientific research purposes** subject to the need of obtaining the data subjects' informed consent – unless the scientific researches are provided for by law, or if the scientific purposes are related directly to the purpose for which the data subjects' informed consent had been initially obtained.

The Code of Conduct (Annex A.4 of the DPC) set out in Section 11(5) that in any medical, bio-medical, and epidemiological research, the data subjects' consent shall not be required if, pursuant to Section 110 of the DPC:

a) it is not possible to inform the data subject on ethical grounds – the data subject is unaware of his/her condition, or on methodological grounds – informing the data subject on the assumptions underlying the research and/or the

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circumstances that he/she was selected for – or because it is organisationally unfeasible;

b) the research project has been the subject of a reasoned favourable opinion issued by the regional competent ethics committee;

c) the processing has been authorised by the Garante, also pursuant to Section 40 of the Decree, or upon the proposal of relevant scientific bodies and societies.

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

The general principle is that data subjects' consent has to be given directly or to the person from whom the data was collected, in accordance to Section 13 of the DPC.

The data subjects' information must contain: the nature of the information transmitted, the purpose of the processing, the consequences of not giving the consent, the natural or legal person to whom the data is addressed and the data subjects' rights.

As already described in our previous point of analysis, there are cases where the personal data are collected without prior consent, according to Authorisations already analysed, which can have exceptions.

The Code of Conduct (Annex 4 of the DPC) sets out in Art 11(3) that the information notice shall enable data subjects to make a distinction between research activities and health care-related activities.

In case of genetic data, under Art. 5 of the Authorisation n. 8/2016 – "General Authorisation to the Processing of Genetic Data", and with regards to processing activities for scientific and statistical research purposes, the information notice shall also specify the following:

a) that the consent must be freely given and can be withdrawn at any time without any detrimental and/or prejudicial effect to the data subject, except where the data and biological samples do not allow the data subject in question to be identified any longer whether from the start or due to the processing;
b) the arrangements made to ensure that the data subjects are only identifiable for no longer than necessart for the purposes of data collection and/or for the subsequent processing (section 11(1(e)) of the DPC);
c) whether the data and/or biological samples may be retained and used for other scientific and statistical research purposes, to the extent that this is known, whereby such pruposes shall be specified appropriately also with regards to the categories of the data that may be communicated, and/or the samples transferred;
d) how data subjects can access the information contained in the research project, where they request to do so.

Considering informed consent, the Authrosiation set forth that, *where it is impossible to inform data subjects on specific grounds and all reasonable efforts have been made to contact them, it shall be allowed to retain and conduct further processing of the previously collected biological samples and genetic data*. This is only in the case that a research for similar purposes cannot be performed by processing data relating to individuals that can or have been able to provide their informed consent, and:

a) the research project entails the use of biological samples and genetic data that either per se or due to their processing, **do not permit the identification of data subjects and there is no proof that the said data subjects had objected thereto**; or

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b) **the research project was authorised** specifically by the Garante in pursuance of section 90 of the DPC, after obtaining a reasoned, favourable opinion by the regional competent ethics committee

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?

The DPC penalises any conduct in contradiction to its provisions, such as the unlawful processing of personal data, the failure to adopt the necessary security measures, as well as non-compliance with the provisions of the Garante, or untruthful declarations to the Garante. Additionally, administrative sanctions are provided in cases of omitted or incomplete notification of the processing to the Garante, or in cases of non-compliance with the Garante's requests, or for non-disclosure to the data subjects. The administrative fines are contained in Section 161 to 162 ter. of the DPC and the crimes are regulated in Section 167 et seq.

d. 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?

In some cases, and for certain processing activities, there is a compulsory notification to the Garante. The notification consists of filling out an electronic form prepared and sent by the Garante prior to initiation of the processing activities to be notified. The mandatory notification shall be provided in accordance with Section 37 of the DPC, in cases of data processed by means of electronic instruments aimed at defining the profile or the personality of the person concerned (i.e. profiling) or to analyse lifestyles or choices of consumption, or to monitor the use of services of electronic communication, with the exclusion of processing that is technically indispensable for the provision of such notification. The notification is provided for the following processing activities:

- Biometric data (finger prints, eye recognition);
- Genetic data;
- Geolocation data (GPS);
- Health data processed for the purpose of assisted reproduction;
- Provision of health services electronically;
- Epidemiological investigations;
- Detection of mental illnesses, infectious and contagious diseases, seropositivity, organ and tissue transplantation and monitoring of health expenditure;
- Data managed by the main risks on economic solvency risks.

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

As seen above, the "**further processing**" of health data for "research purposes" is governed by Section 110 of the DPC. This processing is also subject to Authorisation 2/2014 by the Garante and to data subjects' specific consent.

For further processing, Section 11 of the DPC states that, in order for it to be lawful, the processing of personal data cannot exceed the scopes under which the data were collected or further processed. Precisely, according to Section 11(b) personal data shall be "collected and recorded for specific, explicit and legitimate purposes and used in further processing operations in a way that is not inconsistent with [the] said purposes" and in also that it must be "[…] relevant, complete and not excessive in relation to the purposes for which they are collected or subsequently processed". However, Section 11(c(1)) of the DPC establishes that the processing of personal data carried out under the scope of scientific purposes is considered to be compatible with the purposes of the initial processing or collection of such data. The same Article at paragraph 2 specifies that personal data, processed for research purposes, can be assigned to another data controller if the processing of such data has been terminated.

The further processing of personal data is, as the initial processing, subject to general conditions and other specific conditions concerning the health data and scientific research purposes, as specified below.

The data subjects' consent is not required if the said research activities are expressly provided for by legislation that specifically refers to the processing, or are included in a bio-medical or health care research program pursuant to Section 12-bis of legislative decree no. 502 of 30.12.92, as subsequently amended, and forty-five days have elapsed since communication of said activities to the Garante (and the Authority did not object to it). Additionally, consent shall not be necessary if data subjects cannot be informed on specific grounds and the research program has been the subject of a reasoned, favourable opinion by the regional competent ethics committee as well as being authorised by the Garante.

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

For further processing, Section 11 of the DPC states that, in order for it to be lawful, the processing of personal data cannot exceed the scopes under which the data were collected or further processed.

However, Section 99, c.1 of the DPC establishes that the processing of personal data carried out under the scope of scientific purposes is considered to be compatible with the purposes of the initial processing or collection of such data. The same Section at paragraph 2 specifies that personal data, processed for research purposes, can be assigned to another data controller if the processing of such data has been terminated.

The further processing of personal data is, as the initial processing, subject to general conditions and other specific conditions concerning the health data and scientific research purposes, as specified below.

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

Regarding the health purpose of a scientific research we make a reference to Authorisation n.2 /2014. This Authorisation apply, among others, *to natural or legal persons, bodies, associations and other private entities for scientific research purposes, including statistical purposes,* ***if the research is aimed at protecting the health of the data subject, third parties or the community as a whole in the medical, biomedical or epidemiological field,***

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whenever the relationships between risk factors and human health are to be assessed also in connection with clinical drug trials or investigations are scheduled concerning diagnostic, therapeutic or preventive medicine. In this case the data subjects' consent shall be required as per Sections 106, 107, and 110 of the DPC, therefore all the general provisions regarding processing of data for research purposes.

In particular at this regard Section 106 refers to the Code of Conduct. The Code of conduct and professional practice applying to processing of personal data for statistical and scientific purposes(Annex 4 of the DPC) sets out that if the data are collected from third parties or the processing for statistical and/or scientific purposes concerns data that have been collected for other purposes, and the provision of information entails a disproportionate effort compared with the right to be protected, the data controller shall ensure publicity of the processing through newspaper with nation-wide audience, a radio and TV company with nation-wide reach or regional reach and the data controller shall notify the Garante in advance of the publicity mechanism it has adopted.

When the research is carried out for scientific purposes in the field of health and it is carried carried out by public bodies, it shall be considered in the Substantial Public Interest as set forth by Section 98 of the DPC and therefore the processing of health data (Section 20 of the DPC) is authorized.

We also want to add what Section 104 (2) specifies and apply to scientific research: "*account shall be taken with regard to identification data of all the means that can be reasonably used by a data controller or others to identify the data subject,* ***also on the basis of the knowledge acquired in connection with technological developments*****."**

To this regard we also would like to mention, the specific provision about genetic data, relevant to the AEGLE project and in particular the re-use of data coming from biobanks. When sharing and dissemination of this data, Art.9 of the *Authorisation on Genetic Data* privdes that genetic data may not be communicated and biological samples may not be shared with third parties unless this is indispensable for the purposes of the research and exclusively within the framework of joint projects. In the absence of joint projects, only to the extant that the information does not include identifiable data, and this is done for scientific purposes that are directly related to those for which the said data and/or samples were initially collected, whereby the purposes in question must be clearly specified in writing in the request for the data and/or samples. In this case, the requesting entity shall undertake not to process the data and/or use the samples for purposes other than those speicifc in the said request as well as not to communicate or transfer the data to third parties.

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

Data subjects may in every moment exercise their rights as per Section 7 of the DPC and this Section applies also in case of further processing. As examples, the following rights apply: to be able to update, rectificy or, where interested therein, integrate the data; moreover, to be informed of the source of the personal data, of the purposes and methods of the processing, of the identification data concerning the data controller, data processors and the representative designated, to obtain an erasure, anonymisation or the blocking of data that have been processed unlawfully.

The data subjects must be notified about any intention to transfer his/her data outside the EU, and the duration for which the data will be stored therein.

According to Section 43 of the DPC health data may be transferred with data subjects' consent in writing. Health data may be transferred without the data subjects' consent

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- if the transfer is necessary for the performance of obligations resulting from a contract to which the data subject is a party, or to take steps at the data subjects' request prior to entering into a contract, or for the conclusion or performance of a contract made in the interest of the data subject;
- if the transfer is necessary for safeguarding an important public interest that is referred to by laws or regulations, or that is specified in Sections 20 and 21 of the DPC, where the transfer concerns sensitive or judicial data; or if the transfer is necessary to safeguard a third party's life or bodily integrity.

If this purpose concerns the data subject and he/she cannot give his/her consent because (s)he is physically unable to do so, legally incapable or unable to distinguish right and wrong, **the consent shall be given by the entity legally representing the data subject**, **or by a next of kin, a family member, a person cohabiting with the data subject or, failing these, the manager of the institution where the data subject is hosted.**

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

Considering Section 110 bis DPC, data subject's rights and further processing for scientific research purposes are regulated through the same provisions under Section 7 of the DPC. Besides of the rights set out in Section 7 of the DPC, The Code of conduct and professional practice applying to processing of personal data for statistical and scientic purposes (Annex 4 of the DPC) provides an exemption: "*with regard to data that are processed for scientific purposes, the data subject may access the archives concerning him or her in order to request that they be updated, rectified and/or supplemented, providing such operations do not prove impossible because of either the nature or the status of the processing or else entail the use of clearly disproportionate means*".

Regarding the transfer outside the EU, Section 43 of the DPC sets out, in cases of transfer outside the EU, data may be transferred if the transfer is necessary, pursuant to the relevant codes of conduct referred to in Annex A) of the Code, exclusively for scientific or statistical purposes.

4. 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?

The unofficial scheme of the Legislative Decree proposes that the data subject's consent for the processing of health data for scientific purposes in the medical, biomedical and epidemiological sectors shall not be required when the research is provided for by a national legal or regulatory provision or by E.U. law in conformity with Art. 9(2(j)) of the Regulation, including where the research programme is provided for in Art. 12 bis of the Legislative Decree 30

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December 1992 n. 502, and when **an impact assessment is conducted and made public** (i.e., published) pursuant to Articles 35-36 of the GDPR.

When compared with the original section 110 of the DPC, one can see the crucial change is a single one. **In order for consent to not be required in the cases of medical, biomedical and epidemiological research, an additional requirement of conducting and publishing an impact assessment is placed.** This proposal for an amendment to section 110, duly reflects the rising importance of impact assessments, which is noticed in the GDPR. It is a factor that undeniably forces the relevant legal or natural persons to conduct a correct balancing test, and as proof of it, make it public.

Furthermore, the data subject's consent will also not be necessary when, due to particular reasons, informing data subjects proves impossible or involves a disproportionate effort, or could make impossible and affect the achievement of the purposes of the research. In such cases,

- the data controller **shall adopt appropriate measures**, including preventive forms of minimising and anonymising data, to protect data subjects' rights, fundamental freedoms, and their legitimate interests (in accordance with Art.89 GDPR)
- the research programme shall be the subject of a favourable opinion by the competent ethical committee and authorised by the Garante, or submitted to its prior consultation according to Art. 36 of the GDPR.

Upon the published official Legislative Decree, the revised section 110 DPC, will **emphasise the focus of appropriate security measures,** following the GDPR provision on safeguards (Art.89 GDPR). Previously from this proposed amendment, there was not such a specific reference to measures to protect the health data.

As a general observation, the additions of the impact assessment requirement and the appropriate measures to safeguard personal data in the processing of health data for scientific purposes, can be categorized as a risk-based approach. The Italian legislators emphasise the risk-based approach, as is taken in the GDPR itself, and increase the requirements for the scenarios were consent is not required as a legal basis to process the aforementioned health data.

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

The newly amended Section 110 bis on of the DPC on the re-use of data for scientific research, introduced by the Law 20 November 2017, n. 167 has already been analysed. In short, Section 110 bis has maintained the scheme and the Authorisation of the Garante, with the exclusion of genetic data.

The unofficial proposal of the Legislative Decree, to implement the GDPR, should not have too many consequences on the national legal framework regarding data re-use for scientific research or statistical purposes. The Italian legislator seems to introduce stricter requirement since it allows for the Garante to give an Authorisation to re-use data, even for processing of special categories of data as laid down in Art. 9(2(j)) GDPR, but places a clear barrier of exclusion for such re-use of genetic data.

According to the unofficial Legislative Decree, in the cases where the Garante grants such Authorisation, data subjects' consent is unnecessary; but only when informing the data subjects proves impossible or involves disproportionate efforts or could make impossible or seriously affect the purposes of the research.

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It is important to point out that this Scheme is yet to be approved in a definitive way by the Italian legislators, however, after the approval form the permanent Committees of the Parliament and upon the opinion of the Garante, this will become part of the new official scheme after the GPDR.

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

According to the unofficial Legislative Decree scheme, the "general authorisations" referred to in Section 40 of the DPC are subject to a transitional regime because they do not have a legal framework within the GDPR. It is specified that each category of data is elaborated in an ad hoc manner, in relation to specific processing needs.

The unofficial Decree's Scheme provides the relevant transitional rules regarding General Authorisations of the Garante. On this note the Garante must create a measure of general nature, within 90 days of the official Decree's entry into force and after a public consultation. In this measure, the Garante must identify the General Authorisations in force, relating to the execution of legal obligations, processing activities of public interest or related to the exercise of public powers or otherwise concerning the specifications provided for in Chapter IX of the GDPR (freedom of expression and information, access to documents, national identification number, employment reports, archival, historical, statistical, and scientific research, obligations of secrecy, religious contexts) that are considered compatible with the new legal framework, or those that need updating or annulment as a whole.

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

In the context of this study, there is no valuable information as to how the GDPR will be implemented with regard to the right of the data subject and the obligations of the data controller, but the Italian legislator will amend the DPC and the changes will be duly reflected in the official Legislative Decree.

5. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

Further processing can be defined as "the processing of personal data for purposes other than those for which the personal data has been initially collected". Further processing is allowed only when its purpose is compatible with the purpose for which the data has been initially collected. Further processing for a compatible purpose of personal data is possible using the same legal basis as the one used for the initial processing. For example, if personal data is initially processed based on the data subject's consent, then further processing for a compatible purpose is possible on the same legal basis. It is, in other words, not required to contact the data subject again for a new consent authorising the further processing of the same data.

How to measure the compatibility of purpose of the further processing:

Further processing for a purpose other than that for which the personal data has been collected is governed by Article 6 (4) of the GDPR. In particular this article tries to address how to measure whether or not the purpose of the

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further processing is "compatible". This is particularly relevant to big data analytics. Article 6 (4) establishes a test to measure such compatibility.

Where this processing is not based on the data subject's consent, or EU or Member State law, but on another legal ground, the controller will ascertain the compatibility of the processing's purpose with the initial purpose stated during the data collection. To do so the controller will take several elements into account, in particular: any link between the initial purpose and the further processing purpose, the context of the collection and the relation between the data subject and the controller, the nature of the data, in particular if it is considered to be sensitive data under Article 9 of the GDPR. The controller will also consider the possible consequence of further processing for the data subject and the existence of appropriate safeguards. If the result of the test is positive for the controller and shows none of the elements have been significantly altered to make the further processing unfair or illicit, no further legal basis is necessary for the further processing. If this is not the case, then the further processing will have to rely on a separate legal basis.

If this test is successfully met, then the further processing is possible. However, it will be up to the data controller to demonstrate the compatibility of the purposes.

The particularities of scientific research: a presumption of purpose compatibility

However, the processing for scientific research purpose is an exception. Indeed, under Article 5 (1) (b) of the GDPR the compatibility of the processing purpose of further processing with the initial purpose of the collection is presumed under Article 89 (1). Here, the GDPR establishes a presumption of compatibility of purposes for scientific research purposes. The reasoning behind this exception can be easily understood. Scientific research is very often based on existing data, this is why allowing the processing of personal for different (if not incompatible) purposes is fundamental for scientific research.

This assumption made for the benefit of scientific research is linked to the derogation of the principle of data minimisation for scientific research purposes. However, this presumption is limited by some requirements, which are set out in Article 89(1) of the GDPR: the appropriate safeguards for the data subject's rights and freedoms, and ensured technical and organisational measures, such as pseudonymisation. Although, a different scenario would require different technical and organisational measures to ensure the safeguards for the data subject's rights and freedoms. This is clearly indicated in recital 156 of the GDPR: "The further processing of personal data for (…) scientific (…) research purposes (…) is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which does not permit or no longer permits the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data)."

Additionally, further processing of personal data is connected to the principle of storage limitation (Article 5(1)(e) of the GDPR), as it also constitutes a derogation to that principle, "personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject".

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

The Italian Council of Ministers, in the unofficial Legislative Decree scheme, have proposed rules for the re-use of data for scientific research or statistical purposes, in order to comply with the GDPR. The newly amended Section

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110 bis on the re-use of data for scientific research, introduced by the Law 20 November 2017, n. 167 has already been analysed. In short, Section 110 bis has been maintained in the proposed unofficial scheme and the Authorisation of the Garante, with the exclusion of genetic data.

As we said before the Italian legislator has introduced a stricter requirement since it allows for the Garante to give an Authorisation to re-use data, even for processing of special categories of data as laid down in article 9(2(j)) GDPR but places a clear barrier of exclusion for such re-use of genetic data.

In the cases where the Garante grants such Authorisation, the proposed unofficial Scheme provides that data subjects' consent is unnecessary; but only in the cases where informing the data subjects proves impossible or involves disproportionate efforts or could make impossible or seriously affect the purposes of the research.

6. 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?

Art. 15 on Security Measures of the Code of Conduct (Annex A.4 of the DPC) sets out that in taking security measures as per Section 31 of the DPC, and Annex B of the DPC, the data controller shall also specify the different levels of access to the personal data by having regard to their nature and the tasks discharged by the entities involved in the processing. The new Section 110 bis about the re-use of data for scientific research - excluding genetic data - as largely commented and reported in previous questions, refers explicity to the compulsory adoption of anonimisation and minimisation measures. The latter is a requirement for the Garante's Authorisation.

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.

The Code of Conduct must be followed by researchers working under scientific institutions and it must be respected by researchers at every stage of the study even if the scientific institution to which it belongs has not signed it. (Art. 2., 2 of the Code of Conduct).

Reserchers can process health data for "research purposes" according to Section 110 of the DPC. This process is also subject to Authorisation 2/2014 by Garante and to data subjects' specific consent. The data subjects' consent is not required if the said research activities are expressly provided for by legislation that specifically refer to the processing, or are included in a bio-medical or health care research program pursuant to Section 12-bis of legislative decree no. 502 of 30.12.92, as subsequently amended, and forty-five days have elapsed since communication of said

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activities to the Garante (and the Garante did not object to it). Additionally, consent shall not be necessary if data subjects cannot be informed on specific grounds and the research program has been the subject of a reasoned, favourable opinion by the regional competent ethics committee as well as being authorized by the Garante.

According to the Italian Data Protection Authority Guidelines on Electronic Health Files issued on the 4th of June 2015.processing of personal data via an Electronic Medical Record (EMR) is only aimed at prevention, diagnosis and treatment activities in connection to the data subjects; therefore, it should only be performed by health care practitioners. Regarding the processing for research purposes, Annex A of the Garante's Guidelines on Electronic Health Files states that "*[…] health data collected through the health dossier can be treated like any other clinical information, even for research purposes in compliance with the provisions of the Code for such processing activities, that is, as a general rule, after obtaining an informed patient's consent"(*Section 110 of the DPC)

The data subjects' consent has to be given to the person from whom the data was collected (the researcher), in accordance with Section 13 of the DPC.

The data subjects' information must contain: the nature of the information transmitted, the purpose of the processing, the consequences of not giving consent, the natural or legal person to whom the data is addressed and the data subject's rights.

The Code of Conduct (Annex A.4 of the DPC) stated in art.11.3 sets out that the information notice shall enable data subjects to make a distinction between research activities and health care related activities.

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 Italian Council of Ministers, in their unofficial Legislative Decree scheme bring about changes in the field of Research with purposes on medical, biomedical and epidemiological; providing that data subjects' consent for the processing of health data for scientific purposes in the medical, biomedical and epidemiological field is not necessary when the research has its basis on a legal or regulatory provision or on E.U. law in conformity with Art. 9(2(j)) of the Regulation, including the case where the research programme provided for in Art. 12 bis of the Legislative Decree 30 December 1992 , n. 502 and impact assessment pursuant to Articles 35 and 36 of the Regulation is conducted and made public (i.e., published).

As we can see from this draft, the Authorisation of the Garante has been substituted with the impact assessment as per Art. 35 and 36 of the Regulation.

It is important to point out that this Scheme is yet to be approved in a definitive way by the Italian legislators, however, after the approval form the permanent Committees of the Parliament and upon the opinion of the Garante, this will become part of the new scheme after the GPDR.

- **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.

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Collection by health professionals and health institutions for research purposes can be considered a further processing under Section 11 of the DPC and other related Sections. This Section states that, to be lawful, the processing of personal data cannot exceed the scopes under which the data were collected for or further processed.

Even if section 99, paragraph 1 of the DPC establishes that the processing of personal data for research purposes is considered to be compatible with the purposes of the initial processing or collection of such data and Section 99, paragraph 2 specifies that personal data, in case of research purposes, can be assigned to another data controller if the processing of such data has terminated,the further processing of personal data is subject to the same general conditions as the initial processing, considering also the provision under Section 13 of the DPC.

Therefore, general principles on health data's informed consent previously collected from medical staff and hospitals regarding the research purposes, must apply.

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

Italy will implement the prescriptions of the GDPR. The DPC may be amended in order to provide a new procedure applying to data processing for research purposes and health data, which will replace the existing mechanism. Please refer also to our analysis already done above at Title IV, Section A of this report.

- **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.

Creating a private database is allowed. According to General Authorisation to Process Personal Data for Scientific Research Purposes "*secure communication protocols must be implemented as based on encryption standards to electronically transmit study data to a centralized database where they will be stored and/or archived as well as to transmit such data via electronic networks to the promoter and/or any external entities that co-operate with the latter in conducting the study*". The use of private databases is subject to suitable authentication methods and authorisation mechanisms for the persons tasked with processing data according to the function of their roles and the respective access or privileges. As specified in the same Authorisation, validity of the respective credentials other authorized persons must be limited to the study period and such credentials must be disabled upon completion of the study.

It is also important to remember that, provided that other general principles and provisions applied on health data apply as specified in this report:

- it is allowed to forward research data to the coordinator of the research and/or any external entities that co-operate with the coordinator of the research in conducting the study;

- consent of the data subjects, except for the cases where this consent is not required by DPC and General Authorisations.

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

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Italy will implement the prescriptions of the GDPR. The DPC may be amended in order to provide different conditions applying to the setting up of a private data base, that will replace the existing mechanism. Seeing as appropriate security measures are already taken into account in the existing procedure, it is highly unlikely that the mechanism will change substantially. However, since the Garante has not made any explicit statements with regards to the processing activities for research, one cannot judge, at this stage, the relevant amendements or abrogations.

- **PUBLIC DATABASES**

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

In general, public data bases and the exchange of data among public administration are regulated by Security measures and methods of exchange of personal data between public administrations – 2 July 2015 of Garante **and** Section 58, 2. of the Code of Digital Administration.

The modalities of access and usability of the data are governed by specific "framework agreements" open to the accession of all the administrations concerned on the basis of the Guidelines by the Agency for Digital Italy, in accordance with the Garante.

Regarding sensitive data, the Garante remarks that this data must be encrypted through algorithms and identification codes that guarantee security according to Section 22(6) of the DPC and explicity provide that the transfer of health data must be encrypted in order for the data to be temporarily unintelligible and allow for identification of the data subject only in case of necessity.

If researchers have suitable authentication and authorisation mechanisms in order to process health data contained in a public database, then they can have access to this database. As a general rule, it is important to keep in mind that Art. 17 of Code of Conduct of the "rules of Conduct" provides that **data processors and persons in charge of the processing, that can lawfully access the personal data processed for statistical and/or scientific purposes on grounds related to their work and/or research(es), must use personal data for the purposes set forth in the research project.**

The Ministry of Health in its website – (http://www.salute.gov.it/portale/documentazione/p6_2_8_1.jsp?lingua=italiano) - has a section called "Database and Relevant Registries" containing various items and subjects concerning Health. For those databases the access is free, and without any conditions.

The Ministry of Health has also created an Open Data website - http://www.dati.salute.gov.it/dati/homeDataset.jsp - connected to the Italian Government project regarding open data for Public Administration (https://www.dati.gov.it/). This data base is also for public and free online access.

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

Italy will implement the prescriptions of the GDPR. The DPC may be amended in order to review the current legal framework and rules applying public databases.

We do not know at this stage the relevant changes, even we have elements to think that those rules will not change.

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b. Application of the national framework to the AEGLE cases

In the AEGLE project, the "research objective is to establish the use of Big data analysis in the prediction of outcomes in three working scenarios: Chronic Lymphotic Leukemia (CLL), Intensive Care Units and type 2 diabetes for the prediction of adverse outcomes. The research methodology is Big Data analysis to establish predictive values that may apply in three clinical scenarios and to see if this can be generalised to other healthcare disease models". [1]

To achieve its objective, the AEGLE project must base its approach on the study, and thus the processing, of data concerning health. This section aims to address each of the three proposed AEGLE cases, and to determine the requirements in general terms for access and the processes relevant to data under the Directive (the current framework) and the GDPR.

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.

Since the data subjects have already expressed their consent for research purposes, the AEGLE project can use the aforementioned health data collected, with the informed consent of the data subjects specifically for research purposes. Such data processing operations seem to be currently with the research purposes for which they were collected and subject to data subjects' consent.

Even if these processing activities would be considered as further use of personal data this still seems compatible with the research purposes. Factually, the general principle is that the data subjects' information must contain, among others, the purpose of the processing and the natural or legal person to whom the data is addressed. The Section 13 of the DPC sets forth also that the subjects' consent has to be given directly or to the person from whom the data was collected.

However, the Garante, as explicitly mentioned in its *Authorisation no. 9/2014 - General Authorisation to Process Personal Data for Scientific Research Purposes*, takes in consideration that a considerable number of processing activities concerning health data, indispensable for research purposes, may be performed by different data controllers to carry out scientific research studies in the medical, bio-medical or epidemiological sectors. Moreover, a lot of times such studies rely on data that either was collected beforehand in order to treat the data subjects and/or carry out previous research projects. In these cases, if the studies do not entail any significant personalised impact on data subjects, the collection of data subjects' consent is not nececessary, when it proves it is impossible – under the terms of section 110 of the DPC, to inform data subjects on "ethical grounds", "methodological grounds" or else because it is "organizationally unfeasible" and been granted the Authorisation by the Garante.

[1] AEGLE Grant Agreement, Annex 1, p. 83.

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Once the GDPR has been implemented:

It is highly unlikely that the rules will change substantially, as has been noted by the unofficial Legislative Decree Scheme that we analysed in detail above. The general Authorisation procedure will change as we referred in detail in paragraph B.

2. Intensive Care Unit (ICU)

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

Intensive Care Unit and relative health data are processed by public health care bodies and health care professionals as expressively authorized by the law (refers to Section 20 of the DPC). When the processing operations are carried out by health care public bodies for scientific purposes they shall be considered to be carried out for purposes in the substantial public interest, as set forth in Section 98 of the DPC.

Simplified arrangements to information of data subjects shall apply as set forth in Section 77 of DPC. Specific provisions, laid down in the DPC to regulate the processing of health data in the health care sector (Sections 75-94), shall also apply. At this regard it is important to remember that public health care bodies and health care professionals can process health data with the data subjects' consent and without the Garante's authorisation if the processing concerns data and operations that are imperative to the data subjects' health and/or bodily integrity; and instead, they may process medical data without the data subjects' consent but with the Garante's authorisation if the processing is indispensable to safeguard public health.

On consent, *Authorisation no. 9/2014 - General Authorisation to Process Personal Data for Scientific Research Purposes* also applies to health care practitioners and health care bodies. Therefore, if the studies do not entail any significant personalised impact on data subjects, the health data for research purposes may be procesed also without the data subjects' informed consent.

If the provision of the DPC and the Code of Conduct are met, and the requirements/application of the Authorisation are met, where applicable, other authorization is not required.

Once the GDPR has been implemented:

It is highly unlikely that the rules will change substantially, exept for the Authorisation procedure of the Garante already analised in detail in paragraph B.

3. Chronic Lymphocytic Leukaemia (CLL)

The AEGLE project re-uses, after pseudonymisation, data originating 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.

Regarding to CLL project and biobanks, we have a specific re-use of genetic data coming from biobanks, that are porcessed for a new project, in this case the AEGLE project. The general principle is that the re-use of genetic data is excluded (Section 110 bis of the DPC as introduced by by the Law 20 novembre 2017, n. 167).

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According to this principle and as laid down in the *General Authorisation No. 8/2014 for the Processing of Genetic Data*, the information notice must also specify whether the data and/or biological samples may be retained and used for other scientific and statistical research purposes, to the extent this is known, whereby such purposes must be specified appropriately also with regard to the categories of entity the data may be communicated and/or the samples transferred to. **This means that specific data subjects' written consent according to a specific information notice is needed.**

At this regard, there is an exemption contained in the same Authorisation. Art. 8.1, which sets forth that biological samples and genetic data that were collected and processed for health care purposes may be retained and used for scientific or statistical research purposes subject to the need for obtaining the data subjects' informed consent. Where it is impossible to inform data subjects on specific grounds and all reasonable efforts have been made to contact them, **it is allowed to retain and make further use of previously collected biological samples and genetic data with a view to implementing research projects other than the initial ones.** That is in case a research for similar purposes cannot be performed by the processing of the data relating to individuals that can or have been able to provide their informed consent and, adding to this: the research programme entails the use of biological samples and genetic data that either per se or following their processing do not allow identifying data subjects (and there is no proof that the said data subjects had objected) or the research programme was authorised specifically by the Garante in pursuance of section 90 of the DPC after obtaining a reasoned favourable opinion by the regional competent ethics committee.

When considering genetic data and/or biological samples collected for scientific and statistical research purposes, they may be shared or transferred to research bodies and institutions, associations, and other public or private bodies pursuing research purposes exclusively within the framework of joint projects. In the absence of joint projects, only to the extent that the information does not include identifiable data, and this is done for scientific purposes that are directly related to those for which the said data and/or samples were initially collected, whereby the purposes in question must be clearly specified in writing in the request for the data and/or samples. In this case, the requesting entity shall undertake not to process the data and/or use the samples for purposes other than those specified in the said request as well as not to communicate or transfer the data to third parties.

Once the GDPR has been implemented:

It is highly unlikely that the rules will change substantially according to unofficial Legislative Decree Scheme, which we analised in detail above.

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