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Injunction order against the Lazio Region - 15 September 2022

Record of measures

n. 304 of 15 September 2022

## THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, which was attended by prof. Pasquale Stanzione, president, Professor Ginevra Cerrina Feroni, vice president, dr. Agostino Ghiglia and the lawyer Guido Scorza, members and the cons. Fabio Mattei, general secretary;

GIVEN the Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, concerning the protection of individuals with regard to the processing of personal data, as well as the free circulation of such data and which repeals Directive 95/46 / EC, "General Data Protection Regulation" (hereinafter the "Regulation");

GIVEN the legislative decree 30 June 2003, n. 196 containing the "Code regarding the protection of personal data, containing provisions for the adaptation of the national system to Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relating to the protection of individuals with regard to to the processing of personal data, as well as to the free circulation of such data and which repeals Directive 95/46 / EC (hereinafter the "Code");

GIVEN the Regulation n. 1/2019 concerning internal procedures with external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor for the protection of personal data, approved by resolution no. 98 of 4/4/2019, published in the Official Gazette n. 106 of 8/5/2019 and in [www.gpdp.it](http://www.gpdp.it), doc. web n. 9107633 (hereinafter "Regulation of the Guarantor n. 1/2019");

GIVEN the documentation in the deeds;

GIVEN the observations made by the Secretary General pursuant to art. 15 of the Guarantor Regulation n. 1/2000 on the organization and operation of the office of the Guarantor for the protection of personal data, in [www.gpdp.it](http://www.gpdp.it), doc. web n.1098801;

Professor Ginevra Cerrina Feroni will be the speaker;

## WHEREAS

1. The complaint and the preliminary investigation

The Authority has received a complaint from Ms XX in which she complains that she has received an invitation from the Rieti Local Health Authority to participate in the cervical cancer screening program addressed to the daughter of the deceased complainant in 1995 (invitation on file).

In relation to the aforementioned complaint, the Office requested information with the note of the XX (prot.n.XX) from the ASL of Rieti regarding the origin of the personal data that were used to send the invitation to join the campaign screening and the measures adopted to ensure the accuracy and updating of the information relating to their clients used in the aforementioned awareness campaigns.

With a note of the XX u.s. (prot. no. XX), the aforementioned Company, stated, among other things, that the "Lazio Region establishes that" The Information System of Cancer Screening Programs (SIPSOweb) established with regional resolution no. G02879 of 11-03 -2014 is the regional platform made available to screening structures for the management and monitoring of organized paths ". According to what is represented by the aforementioned Local Health Authority" The aforementioned regional platform already contains in the database all the parameters necessary for the generation of invitations "and" is placed under the full and exclusive ownership of the Lazio Region which, technically, manages it through its subsidiary LazioCREA S.p.A. The screening coordination of all the ASL of Lazio use this platform, but do not create the regional database on the basis of which they operate nor can directly modify it ".

With specific reference to the case reported to the Authority, the aforementioned ASL highlighted that "by interrogating the system" assisted detail "card relating to the complainant's daughter (...) it emerged that the same was regularly included in the regional platform with" update source, XX, insertion date XX hours XX "both for what concerns the personal data and the address where to send the invitation to screening. For this reason, on the basis of the information made available to this ASL by the regional platform, at the time of sending the message, no obstacles to sending the invitation appeared, this also in consideration of the fact that the platform appeared to have undergone a recent update".

Following the aforementioned reply, the Office requested information from the Lazio Region (note of the XX, prot. No. XX), which replied with a note of the XX (prot. No. XX) in which it was, in particular, represented that:

"The Lazio Region with Resolution of 14 March 2014, n. G02879 (...), established the "Single Regional Information System of Oncological Screening for breast, cervical and colorectal cancers" into which the previous screening systems of the breast and uterine cervix were merged (...) providing unitary management through the "SIPSOweb" software, initially maintained and

developed by Laziosalute-ASP and, starting from 2016, by LAZIOcrea S.p.A. ";

"The assignment of the role of Data Processor was confirmed even after the entry into force of Regulation (EU) 2016/679 with the Resolution of 19 December 2017, no. 891 (annex 3), containing" CONTRACT-FRAMEWORK DI SERVICE BETWEEN LAZIO REGION AND LAZIOcrea S.p.A. (...) In the associated "Annual Operational Plan LAZIOcrea Year 2018" (attachment C to DGR no. 891/2017) the treatment "MANAGEMENT AND EVOLUTION OF THE SCREENING INFORMATION SYSTEM" "is expressly indicated at number 8.29;

"The owner of the treatment underlying the Regional Information System of Oncological Screening for breast, cervical and colorectal cancers is the Lazio Region, and that the in-house company LAZIOcrea operates as data processor, providing the SIPSOWeb software ";

"With respect to the processing in question, it is noted that the ASLs are enabled exclusively to view data (...), in order to be able to proceed with the identification of the subjects to whom the invitations to screening carried out and limited to this profile, operate as of authorized pursuant to art. 29 of the RGPD ";

"For the sake of completeness, it is represented that the Information System allows, as described in the Technical Document" Cancer Screening Programs in the Lazio Region "referred to in the Decree of the Commissioner ad Acta May 14, 2015, n. U00191 (...), the carrying out of further processing, including the management of the reports of the visits carried out for screening purposes, carried out as autonomous owners of the ASLs, as well as to fulfill the information obligations towards the Ministry of Health, through the 'Osservatorio Nazione Screening, technical body of the Ministry ".

"The legal basis of the processing in question can be found in Article 6, par. 1, lett. e), of the RGPD, as well as in Article 2-ter, paragraph 1-bis, of Legislative Decree no. 196/2003 ";

"In detail, the purposes are: identification, selection, invitation with respect to the reference population of the prevention program; diagnosis and treatment in the context of diagnostic-therapeutic paths that provide for user acceptance, collection of personal and family anamnesis, recall for further diagnostic tests, booking of visits and examinations, reporting, sending of the results of diagnostic procedures, recall for analysis of follow up";

"With reference to the case in point of complaint, it is noted that since 2005 onwards no access to the personal data of the complainant's daughter was registered, nor any changes had been made by the TS System, the erroneous initial importation into the Information System of the personal data of the complainant concerned had escaped both controls. To date, the

practices subject to automatic synchronization errors (synchronous and asynchronous) of the master data are only 0.3% of the total cases, which can in any case be managed by manual intervention by the operator ";

"In this regard, it is noted, in fact, that already following the first communication sent by this Authority to the ASL of Rieti relating to the complaint, LAZIO Crea verified the position of the complainant's daughter on the ASUR system which, carrying out a targeted query on the bank TS System data, has automatically received and updated the personal data relating to the death of the same on XX at XX hours. The manual updating carried out on the ASUR system consequently resulted in the automatic updating of the personal data also on the SIPSOWeb software ";

"In this regard, it should be noted that if the complainant had exercised the right of rectification within the terms set out in the short form contained in the letter of invitation to the screening program, she would have had more immediate and timely protection";

"The information on the methods of processing carried out for the purposes of information and awareness of the screening programs are provided in a short form, pursuant to art. 12 of the RGPD, in the invitation letter (see invitation letter format - attachment 6) ". Furthermore, at the time of any adhesion to the screening program, the Local Health Authorities provide complete information on the processing of personal data in the oncological screening activity pursuant to art. 13 of the RGPD". In relation to the results of the aforementioned investigation, the Office, with deed no. XX of the XX, notified the Lazio Region, pursuant to art. 166, paragraph 5, of the Code, the initiation of the procedure for the adoption of the measures referred to in Article 58, par. 2, of the Regulations, inviting the aforementioned holder to produce defensive writings or documents to the Guarantor or to ask to be heard by the Authority (Article 166, paragraphs 6 and 7, of the Code; as well as Article 18, paragraph 1, of Law no. . 689 of 11/24/1981).

In particular, the Office highlighted that the processing of personal data put in place by the Lazio Region appears to have been carried out in violation of the principles of lawfulness, correctness and transparency and accuracy of the data (Article 5, paragraph 1 letter a ), and d) of the Regulation), as well as the provisions concerning: the responsibility of the data controller (Article 24 of the Regulation), the legal bases of the processing (Articles 6 and 9 of the Regulation), the information to be provided to the interested parties and exercise of rights by the interested parties (articles 12, 13 and 14 of the Regulation). In particular, it was found that the roles covered by the subjects who in various capacities process personal data through the aforementioned information system (SIPSOWeb) have not been correctly identified in consideration of the fact that, based on

current legislation on health prevention programs , the Region is assigned the functions of planning the prevention offer, while the healthcare companies that of providing healthcare services (see, most recently, the National Prevention Plan (PNP) 2021-2025 and the Regional Prevention Plan (PRP) 2021 -2025).

With a note of the XX (prot. N. XX) the Lazio Region sent defensive writings representing in particular that it had adopted the Regional Determination on 23 March 2022 n. G03463 in which he declared that he had "accepted the remarks raised by this Authority" with the aim of "bringing the processing of personal data back within the regulatory perimeter".

This determination provides for the appointment of LAZIO Crea as data processor in relation to the information management of the Sipsoweb platform and of the Local Health Authorities, limited to patients of territorial relevance (ASL), in relation to all phases of the screening program. The aforementioned establishes that "personal data are collected by the Lazio Region, through the Sipsoweb platform, managed by Lazio Crea SPA, and used as data processor by the individual ASLs, limited to the population of territorial relevance, for institutional medical purposes. preventive and in particular for what is of interest here, of organizational management, diagnosis and treatment in the context of Oncological Screening Programs for the early diagnosis of cervical, breast and colorectal cancer. In detail, the purposes are:

- identification, selection, invitation with respect to the reference population of the prevention program;
- diagnosis and treatment in the context of diagnostic-therapeutic paths that provide for the management of the invitation, collection of personal and family anamnesis, recall for further diagnostic tests, booking of visits and examinations, reporting, sending procedure results, recall for analysis follow up;
- Monitoring and evaluation of the quality of the Screening Program;
- Fulfillment of information obligations towards the Ministry of Health, through the Observatory Nation Screening, the technical body of the ministry "(Article 3 of the determination).

Art. 2 of the determination also provided that "The processing of personal data is carried out pursuant to art. 6 paragraph 1, letter E) and art. 9 paragraph 2, letter H) of the GDPR, as well as art. 2 septies of Legislative Decree 196/2003. "

Art. 5 of the determination then provided that "The methods and instructions for the Processing of Personal Data given by the Data Controller to the Managers are contained in this discipline, as reported in the following articles, without prejudice to the provisions of the Framework Contract for Services for Lazio Crea SPA and may be declined by the Health and Social Health Integration Department with further and more detailed instructions in reference to the individual phases of the program ".

With regard to the information to be provided to the interested party referred to in Articles 13 and 14 of the Regulations, the Lazio Region declared that "by adhering to the findings of this Authority, it promptly amended the letter of invitation to participate in the screening, approving the new text, with regional determination no. G03463 of 23 March 2022 (attachment 2 to the same) ".

In the aforementioned briefs, the Lazio Region acknowledged that "in the first phase of selection of subjects in the target group (target population), recipients (or who were previously recipients) of cancer screening programs, personal data are processed", "while in subsequent phases of the screening program (...), data that can certainly be classified as health-related are processed ".

With regard to the quality of data accuracy and updating, the Region reiterated what was already indicated in the aforementioned note of the 20th, clarifying that "the first synchronization work between the two IT systems - ASUR and SistemaTS - did not result in the acquisition of the updated data , since the change in the registry data is prior to the start-up of the two systems. This misalignment was, therefore, caused by the obvious failure to change the registry of the person concerned since 1995, the year of the last change. Therefore, only through a timely query of the system on the individual personal data could real-time realignment be obtained, as happened following the complaint ".

On this point it was also highlighted that:

- "the complexity of the misalignment has been understood and in order to minimize the risk of further inaccuracies on personal data, Lazio Crea Spa carried out in two phases, a massive check on the synchronization of the personal data of all clients present on the SIPSOWeb platform with the ASUR System:
- Phase 1 - Check Deaths situation
- Phase 2 - Verification of all personal data ";
- "the incident subject of the complaint can be qualified as exceptional, since the failure to update the data on the SIPSOWeb platform was due to the failure to acquire the registry change on the ASUR system";
- "Lazio Crea, following the complaint, initiated all the necessary actions to identify, evaluate and resolve the specific problem, immediately verifying all the other data present in the SIPSOWeb platform, in order to minimize the risk of further episodes analogues ";
- "Finally, it should be noted that, in order to ensure greater accuracy in the management of personal data of persons entitled

to cancer screening programs, it is absolutely necessary and can no longer be postponed the possibility of using the National Resident Population Registry (ANPR) from part of the Regions. Only through direct access to this computer system can the accuracy of the data be guaranteed ".

## 2. Outcome of the preliminary investigation.

As a preliminary point, it should be noted that "personal data" means "any information concerning an identified or identifiable natural person (" data subject ") and "data relating to health" "personal data relating to the physical or mental health of a natural person, including the provision of health care, which discloses information relating to his state of health "(Article 4, paragraph 1, nos. 1 and 15 of the Regulation).

In relation to the case in question, it must be immediately pointed out that the information processed through the SIPSOWeb information system qualifies, without a shadow of a doubt, as information on the health of the interested parties, since, according to what is declared in the documents, they indicate health services provided in the comparisons of specific categories of interested parties, as well as in that through the aforementioned platform it is also possible to manage the "collection of personal and family anamnesis, recall for further diagnostic tests, booking of visits and examinations, reporting, sending the results of diagnostic procedures, recall for follow-up analysis "(Recital n. 35 and art. 4, par. 1, n. 15 of the Regulation; see provision 12 March 2020, web doc. n. 9310804, provision of 21 April 2021, web doc. no. 9591223).

Personal data must be processed in compliance with the principles applicable to the processing referred to in art. 5 of the Regulation. In this context, the principles of "lawfulness, correctness and transparency" and "accountability" are particularly relevant, on the basis of which the data controller must be able to prove compliance with the aforementioned principles, with a logical reasoning, concrete evidence and proactive behavior (Article 5, paragraph 1, letter a) and paragraph 2 and 24 of the Regulation).

Personal data must also be processed in compliance with the principle of transparency (Article 5, paragraph 1 letter a) of the Regulation), providing the data subjects in advance with the information referred to in art. 13 of the Regulation, in the case of data collected directly from them, or pursuant to art. 14, in the case of data collected from third parties. The information must be made in a concise, transparent, intelligible and easily accessible form, with simple and clear language (Recital 58 and Article 12 of the Regulation).

The principle of lawfulness requires that each treatment be based on a specific legal basis (Article 6 of the Regulation). In

relation to the particular categories of data, including health data, art. 9 of the Regulation establishes a general prohibition on the processing of such data unless one of the specific exemptions to this prohibition applies, including the processing of data necessary for prevention purposes and for reasons of significant public interest (Article 9, paragraph 2 letters h) and g)).

Another extremely important profile regarding the protection of personal data is the identification of the roles of owner (articles 4, n. 7 and 24) and manager (art. 4, n. 8 and 28), with respect to which the Regulation is in line with the provisions of Directive 95/46 / EC. From this, in fact, derives not only the distribution of the relative responsibilities but also the possibility for the interested parties to know the person to whom they can turn to exercise the rights referred to in Articles. from 15 to 22 of the Regulation.

The owner is the subject who, in light of the concrete context in which the processing takes place, determines the basic decisions relating to the purposes and methods of a processing carried out on the basis of one of the conditions of lawfulness referred to in Articles. 6 and 9 of the Regulation (see "Guidelines 07/2020 on the concepts of controller and processor in the GDPR", adopted by the European Data Protection Committee, on 7 July 2021).

The figure of the manager, on the other hand, remains characterized by the performance of personal data processing operations delegated by the owner who, following his own organizational choices, can identify a person who is particularly qualified to carry out the same in terms of specialist knowledge, reliability and resources. to implement technical and organizational measures that meet the requirements of the Regulation (see recital 81 of the Regulation), delimiting the scope of the respective attributions and providing specific instructions on the treatments to be carried out.

In order to concretely identify the role played, in terms of owner or manager, of the figures who process personal data, it is therefore essential to examine the activities actually carried out by these subjects on a substantial and non-formal level. In this sense, this Authority has repeatedly expressed itself (see by way of example, Unsolicited telephone services - February 16, 2006, point 6 [web doc. No. 1242592], provision on vehicle location systems within the employment report - 4 October 2011, point 5 [web doc. 1850581], Guidelines for the processing of data of private employees of 23 November 2006 [web doc no. 1364099], provision of 19 July 2018 [web doc 9039945 ] and the clarification provided to the National Council of Labor Consultants, of 22 January 2019).

With specific reference to the health context, specific indications were made by the Guarantor as part of an investigation procedure initiated against the Lazio Region which ended with the adoption of the injunction order of January 14, 2021, n. 9



(web doc. 9542113).

Having said this, in acknowledging the adoption of the aforementioned resolution of 23 March 2022 by which the Lazio Region intended to overcome the critical issues identified by the Office in the aforementioned notice of dispute and that the Region itself also agrees that in the " phases of the screening program (...), data that certainly qualify as health are processed ", it is noted that the following critical issues remain:

## 2.1 Purpose and definition of the roles of the processing

In the aforementioned response to the Office's request for information, the Lazio Region highlighted that, as data controller, with the decision of 11 March 2014 it established the "Single Regional Information System for Oncological Screening for Breast Cancers, of the uterine cervix and colorectal "and adopted" the SIPSOWeb software as the only regional tool for the detection, management and transmission of data on cancer screening and, consequently, the only way to fulfill the information obligations provided for by the regulations in force ". In particular, the aforementioned Region recognized the ownership of the treatments carried out for the purpose of "sending communications to the population belonging to the Lazio region aimed at illustrating the screening programs", specifying that the aforementioned information system also allows for "further processing between which the management of the reports of the visits carried out for screening purposes, carried out as independent owners by the ASL ".

With regard to what is represented by the Lazio Region, in the act of initiation of the sanctioning procedure of 25 February 2022, the Office found some contradictions. In particular, the Region, on the one hand, indicated that the ownership of the treatments carried out in the context of the provision of health services linked to screening is attributable to the Local Health Authorities, on the other, it declared that it pursues the purpose of "diagnosis and treatment in scope of diagnostic-therapeutic pathways that provide for user acceptance, collection of personal and family anamnesis, recall for further diagnostic tests, booking of visits and exams, reporting, sending out of diagnostic procedures, recall for follow-up analysis ". A further contradiction emerges with reference to the role played by the ASL in the processing of the data in question, which, although they have been defined as data controllers of the data collected as part of the screening, would be enabled "exclusively to view the data, in order to proceed with identification of the subjects to whom the screening invitations made and who, limited to this profile, therefore operate as authorized pursuant to Article 29 of the GDPR ". In this regard, it is noted that already in the aforementioned provision of 14 January 2021, no. 9 adopted by the Guarantor precisely in relation to the Lazio Region it was

represented that "it is not possible to designate natural persons who operate exclusively in companies external to the data controller and data processor as data processors, since they are not subject to" direct authority "Of the owner or manager of the treatment".

In the defense brief, the Region represented that it had adopted the aforementioned resolution of 23 March 2022 to overcome the critical issues raised by the Office regarding the processing of personal data processed as part of the screening campaigns. In this regard, it should be noted, however, that although the aforementioned resolution intervened on the attribution of the roles of the aforementioned treatment and of the purposes that can be pursued by the subjects involved in various capacities, these profiles are not correctly defined given that in art. 3 of the determination, the Lazio Region is identified as the owner of the data processing and the Local Health Authority as the data controller also for purposes that can only be pursued by health companies, such as "diagnosis and treatment in the context of diagnostic-therapeutic paths that provide for management of the invitation, collection of personal and family anamnesis, recall for further diagnostic tests, booking of visits and exams, reporting, sending of procedure results, recall for follow-up analysis ".

In this regard, it is represented that the regulation scheme for the processing of sensitive and judicial data pertaining to the regions and health companies on which the Guarantor has expressed its favorable opinion (Prov. 13 April 2006, web doc. No. 1272225 and Prov. of the Guarantor of July 26, 2012 web doc. 4, annex B)). Similarly, the aforementioned regulatory context provides that some of the purposes pursued by the Region (e.g. Monitoring and evaluation of the quality of the Screening Program or Fulfillment of information obligations towards the Ministry of Health, through the Observatory Nation Screening, technical body of the Ministry ) can only be prosecuted through aggregate information.

In particular, for the data protection aspects related to the complaint received, it is necessary to highlight that, based on the current legislation on health prevention programs, this Region is assigned planning functions for the prevention offer, while companies health care that of provision of healthcare services (see, most recently, the National Prevention Plan (PNP) 2021-2025 and Regional Prevention Plan (PRP) 2021-2025). In relation to these purposes, it is up to this Region, as data controller to ensure that through the aforementioned information system the subjects involved in various capacities in the processing access only the information necessary for the pursuit of the legitimately pursued purposes (principle of data minimization , Article 5, paragraph 1 letter c) of the Regulation).

In view of this, it is believed that through the aforementioned resolution of 23 March 2022 the findings raised by the Office with

the notice of dispute have not been overcome as the roles covered by the subjects who process personal data for various reasons have not been correctly identified. the aforementioned information system.

## 2.2 Legal basis of the processing

In the aforementioned response to the Office's request for information, the Lazio Region highlighted that "the legal basis of the processing in question can be found in Article 6, par. 1, lett. e), of the RGPD, as well as in Article 2-ter, paragraph 1-bis, of Legislative Decree no. 196/2003 ".

In this regard, the Office, in the aforementioned act of initiation of the sanctioning procedure of 25 February 2022, highlighted that the legal basis of the treatments carried out as part of the screening activities cannot be identified in Article 6, par. 1 letter b) of the Regulations and in art. 2-ter of the Code, taking into account that, as highlighted above, the activities carried out by the Region, as owner, involve the processing of data on the health of the interested parties, while the provisions cited by the Region refer to the processing of different personal data from those on health.

The unclear definition of the roles of the subjects involved in various capacities in the data processing in question did not allow to correctly identify the legal basis of the processing which must be identified, for the various subjects involved, in one of the exceptions to the general prohibition to process data on health indicated in art. 9, par. 2, of the aforementioned Regulation. With the aforementioned decision of 23 March 2022, the Region established that "The processing of personal data is carried out pursuant to art. 6 paragraph 1, letter E) and art. 9 paragraph 2, letter H) of the GDPR, as well as art. 2 septies of Legislative Decree 196/2003 "(art. 2).

The indication provided in the aforementioned resolution does not exceed the observations of the Office regarding the incorrect identification of an appropriate legal basis for the processing. In fact, the Region has again cited provisions governing the processing of personal data other than those on health (Article 6) and referred to art. 2 septies of the Code which does not concern the processing of the data in question, also referring to guarantee measures for the processing of genetic, biometric and health data.

As already indicated in the notice in relation to the particular categories of data, including health data, the correct legal basis of the processing must be found in art. 9, par. 2 lett. g) of the Regulations for processing carried out by the Region for reasons of public interest on the basis of national law and in art. 9, par. 2, lett. h) for the prevention, diagnosis and treatment activities carried out by the health facilities involved in the screening activity.

### 2.3 Information to be made to interested parties and exercise of the rights recognized by the Regulations

In the aforementioned response to the Office's request for information, the Lazio Region stated that "Information on the methods of processing carried out for the purpose of information and awareness of screening programs are provided in a short form, pursuant to art. 12 of the RGPD, within the invitation letter (see invitation letter format - annex 6) ". However, this message was devoid of any reference to the characteristics of the processing of personal data carried out and, specifically, of all the elements required by articles 13 and 14 of the Regulation, bearing only the following generic reference to the current regulations on the subject: "Your personal data are processed in accordance with current legislation (EU Regulation 679/2016 and Legislative Decree 196/2003 and subsequent amendments)".

Having acknowledged that, as declared by the Region according to which "at the time of any adhesion to the screening program, the Local Health Authorities shall provide complete information on the processing of personal data in the oncological screening activity pursuant to art. 13 of the RGPD ", it is pointed out that it is up to the Region to provide the information required by art. 13 and 14 of the Regulation with reference to the treatments it owns.

With the aforementioned determination of 23 March 2022, the Region modified the reference to the information to be returned to the interested party on the model of the letter of invitation to screening and prepared a model containing "Information on the processing of personal data oncological screening activities" (Annex 2 to the aforementioned resolution). However, these changes still present significant data protection issues. In particular, the concise formula on the invitation model highlights the incorrect identification of the roles and purposes of the processing indicated in par. 2.1, while the model attached to the resolution does not distinguish the legal bases of the processing in relation to the different purposes pursued. Even the description of the scope of communication does not appear to comply with the regulations on data protection as it is excessively generic, not specifying in particular the processing carried out in relation to the various purposes pursued by the subjects in various capacities involved in the screening activity.

The text of the "information" attached to the aforementioned resolution also presents an erroneous indication of the rights exercisable by the interested party in relation to the various purposes pursued with particular reference to the exercise of the right to data portability (Article 20), as the processing is not carried out by automated means, it is not based on data provided by the interested party and only partially on the consent of the interested party (see Recital no. 68) and on the rights to delete data (Article 17, par 1 and 3 of the Regulation) and to the opposition (Article 21 - Recital 69), by reason of the legal basis of the

processing.

The aforementioned text of the "information" attached to the resolution also shows elements of contradiction referring to the revocation of the consent of the interested party which was not considered as the legal basis of the processing.

In the text of the aforementioned "information" and in the same it also determines the retention times of the data, which are only generically formulated, without taking into account their necessary differentiation in relation to the different purposes pursued by the subjects involved in various capacities in the treatment.

#### 2.4 Accuracy of the data

As highlighted above, the data controller must ensure that the data are accurate and, if necessary, updated, adopting all reasonable measures to promptly delete or rectify inaccurate data with respect to the purposes for which they are processed (principle of "accuracy", pursuant to art.5, par. 1 letter d) of the Regulation). In the present case, the measures adopted by the Lazio Region did not ensure the accuracy of the data of the complainant's daughter which were processed through the aforementioned platform. The fact that the data subject had died for over 15 years makes it clear that the measures adopted by the Region, as data controller, were not suitable for ensuring the updating of the data processed through this information system.

With regard to the circumstance that the processing in question concerns a deceased person, it should be noted that the Guarantor has repeatedly represented that the recognition of the possibility of exercising the rights regarding the protection of personal data (articles 15-22, of the Regulation) by part of the subjects listed in art. 2-terdecies, paragraph 1, of the Code, entails - as a natural consequence and necessary logical-legal presupposition - that the safeguards provided for by the regulations on the protection of personal data continue to apply to personal data concerning deceased persons (see ex multis opinion 7 February 2019, n.27, web doc. n.9090308).

The Lazio Region in the aforementioned response to the Office's request for information stated that "if the complainant had exercised the right of rectification within the terms set out in the brief form contained in the letter of invitation to the screening program, she would have had a more immediate and timely protection ". In this regard, it is confirmed what has already been noted in the act of dispute or that the failure to indicate the data controller in the aforementioned invitation did not allow the complainant to know the subject to which he / she can contact to exercise the rights recognized by the Regulation, including includes that of rectification (Article 16 of the Regulation).

Taking into account what was declared by the Region regarding the qualification of the fact as "exceptional" and that "all the other personal data present in the SIPSOWeb platform were checked, in order to minimize the risk of further similar episodes", with reference to the need that for this purpose "the possibility of using the National Resident Population Registry (ANPR) by the Regions can no longer be postponed", it should be noted that the Guarantor has recently adopted its opinion on the draft decree of the President of the Council of Ministers on the National Register of Patients (ANA). The ANA will take over from the registries and lists of patients held by the individual local health companies, which will retain ownership of the data within their competence and will ensure its updating (Article 62 ter, paragraph 2, of Legislative Decree No. 82 / 2005). Therefore, once the aforementioned decree is adopted, the Lazio Region, like any other Region or Autonomous Province, will be required to adapt to the envisaged "Plan for the gradual takeover of the ANA to the registries and lists of clients held by the individual local health authorities and the ministry of health and for the alignment of regional databases "(annex A to the draft decree).

### 3. Conclusions.

In light of the aforementioned assessments, taking into account the statements made by the data controller during the investigation ☐ and considering that, unless the fact constitutes a more serious crime, anyone, in a proceeding before the Guarantor, falsely declares or certifies information or circumstances or produces false deeds or documents is liable pursuant to art. 168 of the Code "False statements to the Guarantor and interruption of the execution of the tasks or the exercise of the powers of the Guarantor" it is stated that the elements provided by the data controller in the defense briefs relating to the aforementioned proceedings do not allow to overcome the findings notified by the 'Office with the acts of initiation of proceedings for the adoption of corrective and sanctioning measures, however, none of the cases provided for by art. 11 of the Guarantor Regulation n. 1/2019.

For these reasons, the unlawfulness of the processing of personal data carried out by the Lazio Region with reference to the procedure initiated following the complaint is noted, in the terms set out in the motivation, in particular, for having processed personal data in violation of the principles of lawfulness, correctness and transparency and accuracy of the data (Article 5, paragraph 1 letter a), and d) of the Regulation) and of the provisions concerning: the responsibility of the data controller (Article 24 of the Regulation), the legal bases of the processing ( articles 6 and 9 of the Regulation), the information to be provided to the interested parties and the exercise of rights by the interested parties (articles 12, 13 and 14 of the Regulation).

In this context, considering the provisions of the Region in the aforementioned resolution of 23 March 2022, it is deemed

necessary to order the aforementioned Region, pursuant to art. 58, par. 2, lett. d) of the Regulations, the following corrective measures to be adopted within 90 days of the adoption of this provision:

- carry out a correct identification of the roles, the purposes of the processing and the legal bases of the same as indicated in paragraphs 2.1 and 2.2 of this provision, consequently also revising the aforementioned determination of 23.3.2022;
- modify and integrate the information to be made to the interested parties involved in the regional screening campaigns as indicated in par. 2.3 of this provision, providing, also in relation to this aspect, to uniformly modify the aforementioned resolution dated 23.3.2022 and the related annexes.

4. Adoption of the injunction order for the application of the pecuniary administrative sanction and ancillary sanctions (articles 58, par. 2, lett. l and 83 of the Regulation; art. 166, paragraph 7, of the Code).

The violation of articles 5, par. 2, lett. a) and d), 6, 9, 12, 13, 14 and 24 of the Regulations, caused by the conduct of the Lazio Region is subject to the application of the pecuniary administrative sanction pursuant to art. 83, paragraphs 4 and 5, of the Regulation.

It should be considered that the Guarantor, pursuant to art. 58, par. 2, lett. i) and 83 of the Regulations, as well as art. 166 of the Code, has the power to "inflict an administrative pecuniary sanction pursuant to Article 83, in addition to the [other] [corrective] measures referred to in this paragraph, or instead of such measures, depending on the circumstances of each single case "and, in this context," the College [of the Guarantor] adopts the injunction order, with which it also disposes with regard to the application of the ancillary administrative sanction of its publication, in whole or in excerpt, on the website of the Guarantor pursuant to Article 166, paragraph 7, of the Code "(Article 16, paragraph 1, of the Guarantor Regulation no. 1/2019).

The aforementioned administrative fine imposed, depending on the circumstances of each individual case, must be determined in the amount taking into account the principles of effectiveness, proportionality and dissuasiveness, indicated in art. 83, par. 1, of the Regulation, in light of the elements provided for in art. 85, par. 2, of the Regulation in relation to which for both proceedings it is noted that:

- the Authority became aware of the event following a complaint (Article 83, paragraph 2, letter h) of the Regulations);
- the unlawful treatment concerns a deceased minor patient and, for some aspects, data on the health of over 5 million patients affected by regional screening programs (Article 83, paragraph 2, letters a) and g) of the Regulation);
- the Lazio Region during the investigation proceeded to delete the data of the complainant's daughter and checked the other

personal data present on the SIPSOWeb platform, in order to minimize the risk of further similar episodes (Article 83, paragraph 2, letters c) and f) of the Regulation);

- there are no previous specific and pertinent violations committed by the Lazio Region similar to the one subject to dispute (Article 83, paragraph 2, letter e), of the Regulation);

- the Lazio Region adopted the resolution of March 22, 2022 during the investigation with the intention of overcoming the findings made by the Office which however remain as indicated in paragraph 2 of this provision (Article 83, paragraph 2, lett. . c) and f) of the Regulations);

- regarding the incorrect identification of the roles of processing by the Lazio Region, the Authority has already intervened with the sanctioning provision of January 14, 2021, no. 9 (Article 83, paragraph 2, letters d) and i) of the Regulations);

Due to the aforementioned elements, assessed as a whole, it is believed to determine the amount of the pecuniary sanction provided for by art. 83, par. 5, lett. a) of the Regulations, for the violation of articles 5, par. 2, lett. a) and d), 6, 9, 12, 13, 14 and 24 of the Regulation to the extent of 100,000 euros (one hundred thousand) as an administrative fine, pursuant to art. 83, par. 1, of the Regulation, effective, proportionate and dissuasive.

It is also believed that the ancillary sanction of the publication on the website of the Guarantor of this provision, provided for by art. 166, paragraph 7 of the Code and art. 16 of the Guarantor Regulation n. 1/2019, also in consideration of the type of personal data subject to unlawful processing.

Finally, it is noted that the conditions set out in art. 17 of Regulation no. 1/2019 concerning internal procedures with external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor.

WHEREAS, THE GUARANTOR

declares the unlawfulness of the processing of personal data carried out, in both the procedures described, by the Lazio region, for the violation of articles 5, par. 2, lett. a) and d), 6, 9, 12, 13, 14 and 24 of the Regulation in the terms set out in the motivation.

INJUNCES

pursuant to art. 58, par. 2, lett. d), of the Regulation, to the Lazio Region within 90 days from the notification of this provision, of:

- carry out a correct identification of the roles, the purposes of the processing and the legal bases of the same as indicated in



paragraphs 2.1 and 2.2 of this provision, also reviewing the aforementioned decision of 23.3.2022;

- modify and integrate the information to be made to the interested parties involved in the regional screening campaigns as indicated in par. 2.3 of this provision, also modifying the aforementioned decision of 23.3.2022 in a uniform sense and the related annexes.

In this regard, the Region is requested to communicate which initiatives have been undertaken in order to implement the aforementioned provisions with this provision and in any case to provide adequately documented feedback, pursuant to art. 157 of the Code, within 20 days from the expiry of the term indicated above; any non-response may result in the application of the pecuniary administrative sanction provided for by art. 83, paragraph 5, of the Regulation.

#### ORDER

pursuant to art. 58, par. 2, lett. i) and 83 of the Regulations, as well as art. 166 of the Code, to the Lazio Region, with registered office in Rome, Via R. Raimondi Garibaldi 7- C.F./P. IVA 80143490581, in the person of the pro-tempore legal representative, to pay the sum of 100,000 euros (one hundred thousand) as a pecuniary administrative sanction for the violations indicated in this provision according to the methods indicated in the annex, within 30 days from the notification of motivation; it is represented that the offender, pursuant to art. 166, paragraph 8, of the Code, has the right to settle the dispute by paying, within 30 days, an amount equal to half of the sanctions imposed.

#### INJUNCES

to the aforementioned Region, in the event of failure to settle the dispute pursuant to art. 166, paragraph 8, of the Code, to pay the sum of 100,000 euros (one hundred thousand) according to the methods indicated in the annex, within 30 days of notification of this provision, under penalty of the adoption of the consequent executive acts pursuant to art. 27 of the law n. 689/1981.

#### HAS

pursuant to art. 166, paragraph 7, of the Code, the full publication of this provision on the website of the Guarantor and believes that the conditions set out in art. 17 of Regulation no. 1/2019 concerning internal procedures with external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor.

Pursuant to art. 78 of the Regulation, of art. 152 of the Code and 10 of Legislative Decree no. 150/2011, against this provision, it is possible to appeal before the ordinary judicial authority, under penalty of inadmissibility, within thirty days from the date of

communication of the provision itself or within sixty days if the applicant resides abroad.

Rome, September 15, 2022

PRESIDENT

Stanzione

THE RAPPORTEUR

Cerrina Feroni

THE SECRETARY GENERAL

Mattei