# INFORMATION ON THE PROCESSING OF PERSONAL DATA PURSUANT TO ARTICLE 14 OF EU REGULATION 2016/679

**"Development of a Predictive Model for the Risk of Cytokine Release Syndrome With CD20xCD3 Bispecific Antibodies in Large B-cell Lymphomas: A Multicenter Retrospective Study."**

## 1) Data controller and other subjects participating in the trial

Pursuant to and for the purposes of Article 14 of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we inform you that the **Azienda Socio Sanitaria Territoriale Papa Giovanni XXIII** (hereinafter PG23), as Sponsor and Trial Center of the Clinical Study entitled "Development of a predictive model for the risk of cytokine release syndrome with CD20xCD3 bispecific antibodies in large B-cell lymphomas: a multicenter retrospective study.", is the Data Controller and for this purpose processes the personal data provided by the Data Subject in writing or verbally and freely communicated by the same.

As of today, all information relating to the Data Controller (Art. 14.1, letter a) Reg. 679/2018), together with the updated list of Data Processors and Designated System Administrators, is available at the PG23 headquarters in Piazza OMS 1, 24127 Bergamo, ufficioprotocollo@pec.asst-pg23.it *to the relevant European Regulation*.

PG23 guarantees that the processing of personal data is carried out in compliance with the fundamental rights and freedoms, as well as the dignity of the Data Subject, with particular reference to confidentiality, personal identity and the right to protection of personal data, in compliance with the provisions of Regulation 679/2016/EU, the Italian national legislation harmonizing with the Regulation itself and the provisions of the Guarantor Authority for the protection of personal data in matter. All processing operations will be carried out only by personnel duly trained and authorized by the Data Controller and will take place in compliance with professional secrecy, official secrecy and the principles of correctness, lawfulness and transparency, in accordance with the provisions of current regulations.

The other subjects who take part in the Study and who will process the personal data of the Data Subject are:

| Subject Name | Role within the study/research |
|---|---|
| ASST Papa Giovanni XXIII Bergamo | Promoter and Experimentation Center |
| Bergamo Hospital Research Foundation – Third Sector Entity (FROM) | PG23 Delegate – Data Processor |

The other subjects participating in the Study and who will transmit personal data to PG23, in its capacity as Sponsor, are:

| Subject Name | Role within the study/research |
|---|---|
| Memorial Sloan-kettering Cancer Center | Participating Centre - Independent Holder |
| Peter MacCallum Cancer Institute | Participating Centre - Independent Holder |

## 2) Data Protection Officer (DPO) (Art. 14.1.b Regulation 679/2016/EU)

The Data Protection Officer identified by PG23 is the following subject:

| DPO | VAT number | Street/Square | Zip code | Common | Name of the DPO |
|---|---|---|---|---|---|
| LTA S.r.l. | 14243311009 | Via della Conciliazione, 10 | 00193 | Rome | Luigi Recupero |

The Data Protection Officer can be contacted at PG23's corporate headquarters in Piazza OMS 1, 24127 Bergamo. In the case of written requests/communications to be sent digitally, the Data Protection Officer can be contacted using the institutional contact details of the ufficioprotocollo@pec.asst-pg23.it *to the European Regulation,* also indicated on the Authority's website.

## 3) Categories of data processed (Art. 14.1.d Regulation 679/2016/EU)

Data processed by PG23 in the clinical study entitled "Development of a predictive model for the risk of cytokine release syndrome with CD20xCD3 bispecific antibodies in large B-cell lymphomas: a multicenter retrospective study.", are of a common personal/identifying nature and also belong to special categories *pursuant* to Article 9 of Reg. 679/2016/EU; during the aforementioned study, in fact, personal data relating to the clinical condition and state of health of the Data Subject *will be processed* (Patient characteristics (age, gender, race, etc), disease characteristics, response, outcomes, vitals, clinical lab values, treatment information).

The data of the Data Subject will be processed through a code that will be attributed to each patient. In particular, during the course of the study, the Data Subject will be identified with a code that will not allow his or her identity to be directly traced. Only the doctor and the subjects authorized by the Trial Centers will be able to link this code to the name of the Data Subject.


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The Data Controller adopts all technical and organisational measures to ensure compliance with the principle of minimisation as provided for by art. 89 of Regulation (EU) 2016/679 and by the provisions of the Supervisory Authority approved on the subject.

**4) Purpose of the processing of personal data (Art. 14.1.c Regulation 679/2016)**

The purposes for which the Data Subject's personal data will be processed are listed below:

- Execution, monitoring and development of the study entitled "Development of a predictive model for the risk of cytokine release syndrome with CD20xCD3 bispecific antibodies in large B-cell lymphomas: a multicenter retrospective study.";
- Reporting to entities to which the legislation recognizes powers of monitoring and control over PG23.

By virtue of the provisions of Article 110 of Legislative Decree no. 196 of 30 June 2003, containing the "Code regarding the protection of personal data" ("Privacy Code") and the Provision of the Guarantor for the Protection of Personal Data entitled "Deontological rules for processing for statistical purposes or scientific research pursuant to art. 2-quarter and 106 of the Code" of 9 May 2024, PG23 has prepared the necessary guarantees for the processing in the absence of consent of personal data, including data of a particular nature, contained in the medical records (also in the possession of the Centers participating in the study listed in the tables referred to in paragraph 1 above) of patients who will be enrolled in the Study. It is also announced that the impact assessment pursuant to art. 35 of Regulation 679/2016/EU carried out on the processing of personal data relating to the study is published and can be consulted on the website ~~https://www.asst-pg23.it/amministrazione-trasparente/privacy/studi-retrospettivi~~https://www.asst-pg23.it/modulistica/privacy-studi-clinici.

**5) Any recipients or categories of recipients of personal data (Art. 14.1, letter e) Reg. 679/2016)**

The personal data of the Data Subject, in cases where necessary, may be communicated (this term means making it known to one or more specific subjects), as well as to the subjects indicated in point 1:

- to subjects whose right to access data is recognized by provisions of law, secondary legislation, community legislation, as well as collective bargaining;
- the Ethics Committee (EC) or the independent EC supervising this study;
- to any suppliers of services closely related and functional to the activities necessary for the performance of the study (such as, for example, external consultants, analysis laboratories, IT service providers for the management of the technological infrastructure, information systems and telecommunications networks, etc.), duly appointed as data processors pursuant to art. 28 of Reg. 679/2016/EU.

Personal data relating to health, sex life, genetic data and biometric data are not disseminated under any circumstances (this term means making them known in any way to a plurality of undetermined subjects).

**6) Data transfer to non-EU countries (Art. 14.1, letter f) Reg. 679/2016/EU)**

The personal data collected during the trial will not be communicated to countries outside the European Union.

**7) Criteria used to determine the retention period (Art. 14.2, letter a) Reg. 679/2016)**

The Data Controller declares that the personal data will be kept for a period of 5 (five) years from the conclusion of the study, except for the need to comply with legal obligations, comply with regulatory requirements, or resolve disputes or disputes.

**8) Processing methods**

The data, processed also by electronic means, will be disseminated in a strictly anonymous form, for example through scientific publications, statistics and scientific conferences. Participation in the study implies that the staff of the Sponsor or of the external companies that carry out the monitoring and verification of the study on its behalf, the Ethics Committee and the Italian and foreign health authorities will be able to know the data concerning the data subject, also contained in the original clinical documentation, in such a way as to guarantee the confidentiality of the identity of the data subject.

The Data Subject may at any time and without providing any justification interrupt his/her participation in the study: in this case any biological samples related to the person will be destroyed. Furthermore, no further data concerning the Data Subject will be collected, without prejudice to the use of any data already collected to determine, without altering them, the results of the research.

If the Data Subject decides not to participate in the Study, he/she may contact and freely express his/her will to PG23, using the contact details indicated in this policy; In this case:

- the Data Subject will no longer be able to participate in the study;
- no new information will be collected from the study staff;
- your personal information, including your encrypted Information, that has already been collected up to the time of your withdrawal will be retained and used by the Sponsor to ensure the integrity of the study, determine the safety effects of any medication received, meet legal or regulatory requirements and/or for other purposes permitted by applicable data protection and privacy laws;
- Your Personal Information (including your Encrypted Information) will not be used for further scientific research.

**9) Rights of the data subject (Art. 14.2, letters c) and d) Reg. 679/2016)**

We inform you that, at any time, the Data Subject may exercise:


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- Right to withdraw consent at any time without prejudice to the lawfulness of the processing based on the consent given before the withdrawal, pursuant to Art. 7, par. 3 of Regulation 679/2016/EU;
- The right to ask the Data Controller, pursuant to Article 15 of Regulation 679/2016/EU, to be able to access your personal data;
- The right to ask the Data Controller, pursuant to Article 16 of Regulation 679/2016/EU, to be able to rectify their personal data, where the latter does not conflict with the current legislation on the storage of the data and with the need to protect the healthcare professionals who have processed them in the event of legal disputes;
- The right to ask the Data Controller, pursuant to Article 17 of Regulation 679/2016/EU, to be able to delete their personal data, where the latter does not conflict with the current legislation on the storage of the data and with the need to protect the healthcare professionals who have processed them in the event of legal disputes;
- The right to ask the Data Controller, pursuant to Article 18 of Regulation 679/2016/EU, to be able to limit the processing of your personal data;
- Right to ask the Data Controller, only in the cases provided for in art. 20 of Regulation 679/2016/EU, that the transmission of personal data to another healthcare professional in a readable format is carried out.

The Data Subject may exercise the above rights by making an informal request to the Data Controller by hand delivery, traditional mail, registered letter, fax or e-mail to the following addresses: ufficioprotocollo@pec.asst-pg23.it *to the relevant European Regulation.* To facilitate the exercise of these rights, the Italian Data Protection Authority has prepared a specific form that can be downloaded from the www.garanteprivacy.it website.

Also through the aforementioned e-mail address, the Data Subject may request the Data Controller to access the information contained in the research project.

**10) Right to lodge a complaint (Art. 14.2, letter e) Reg. 679/2016)**

The Data Subject always has the right to lodge a complaint with the Data Protection Authority for the exercise of his rights or for any other matter relating to the processing of his or her personal data.

**11) Source from which the data originated (Art. 14.2, letter f) Reg. 679/2016)**

PG23 informs that the personal data that have not been obtained from the Data Subject, are acquired at the Participating Center that has previously collected them or are acquired from the archives of the departments of the Data Controller's health facility where they were originally collected for the purposes of care and assistance of the


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