Clinical/operative characteristics of "European Myeloproliferative Neoplasms (MPN) Registry" clinical and database transfer

1) Aim of "ERNEST – European Myeloproliferative Neoplasms Registry" study and database transfer

This privacy disclaimer is aimed at those subject affected by myelofibrosis who, in 2013, gave consent to participate in the ERNEST – European Myeloproliferative Neoplasms Registry, started in 2013 (hereinafter, "Ernest Study"),
The Ernest Study, promoted by Fondazione Mario Negri sud, was dedicated to collect information concerning your disease, which, belonging to the general group of classic chronic myeloproliferative diseases with a prevalence on 4-6 cases every 100,000 individuals, is classified as a rare disease.
From February 2013 to November 2014, 1292 patients were included in the Ernest Study, afferent to 13 European centers (Italy, Germany, Spain, Sweden, United Kingdom) and a first analysis of collected data was presented at the American Society of Hematology's (ASH) annual meeting in San Francisco in December 2014. Results of this analysis are publicly available and can be read on FROM's website at the following address:
https://www.fondazionefrom.it/media/1237/posteernest2014_1dic2014.pdf".
Based on the encouraging results, the Ernest Study should have continued both recruiting new patients and updating data on already registered cases, such as yourself. Unfortunately, due to economic difficulties met by the study promoter (Fondazione Mario Negri Sud), the ERNEST Registry has not been updated anymore and further information on patients still under active surveillance has not been available.
The sample data collected in the Ernest Study has great scientific values because of its remarkable numerosity, despite dealing with a rare disease, and therefore represents a formidable source of information useful to understand the evolution of the disease and to evaluate therapeutic options in normal clinical practice.
Under these premises FROM - Fondazione per la Ricerca Ospedale di Bergamo (FROM) (hereinafter, "FROM"), considered the scientific value of the ERNEST study due to the nature of collected information and large sample size, chose to acquire the Ernest Study database from Fondazione Mario Negri Sud in liquidation, of which it is now the data controller.

2) Consequences of the study on the patient

None: it is a collection of data about your disease, that are already present in clinical records.

3) Benefits and risks for the study patient

You are not exposed to any risk. No direct benefits derived from your participation the Ernest Study are expected, nevertheless, your participation contributes to produce new information from which other patients could benefit in the future.

4) Mode of use of study results

Results of the Ernest Study will only be spread in aggregate and therefore anonymous form, through scientific publications, statistics and scientific conventions.

Description of characteristics concerning privacy protection
Privacy disclaimer pursuant to art. 14 of EU regulation 679/2016 GDPR

5) Data controller

Under Article 14 of the EU REGULATION) 2016/679 of the EUROPEAN PARLIAMENT AND COUNSEL of April 27th 2016 (hereinafter, "GDPR"), 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 personal data that are object of the study/research covered by this privacy notice are processed by FROM - Fondazione per la Ricerca Ospedale di Bergamo, with registered office in 24127 Bergamo, piazza OMS – Organizzazione Mondiale della Sanità n. 1 (hereinafter, "FROM") as data controller.

FROM, in particular, informs you that, following transfer of the database by the original promoter of the ERNEST study (Fondazione Mario Negri Sud in General Liquidation) – a research project to which you previously gave consent to participate and to process your personal data - FROM became data controller of collected data in conducting the ERNEST study, with the purpose of continuing the research. FROM's qualification as data controller descends from its role of transferee in the study/research covered by this description.

FROM ensures that personal data processing is performed with respect to the fundamental rights and freedoms as well as dignity of the data subject (hereinafter, "Data Subject"), with a particular focus on privacy, personal identity and right to personal data protection, pursuant to prescription of the EU Regulation 679/2016, to the Italian legislation of harmonization with said regulation and to measures of the supervisory authority.

FROM - Fondazione per la Ricerca Ospedale di Bergamo Piazza OMS n. 1 24127 Bergamo **Tel.** 035-2675134 **Fax** 035-2674926 **P.IVA** 03978490161 **CF** 95169260163 segreteria@fondazionefrom.it **fondazionefrom.it**

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

The Data Protection Officer identified by FROM is the following person:

DPO	Vat number	Street/Square	Zip code	City	DPO's point of contact
LTA S.r.l.	14243311009	Via della Conciliazione, 10	00193	Roma	Recupero Luigi

The Data Protection Officer is available at the corporate headquarters of FROM - Fondazione per la Ricerca Ospedale di Bergamo in Piazza OMS - Organizzazione Mondiale della Sanità, 1 - 24127 Bergamo (BG). In case of communication to be sent digitally, the Data Protection officer can be reached using the institutional contacts (segreteria@fondazionefrom.it) reported on the institution's website.

7) Nature of processed data

The data processed by the data controller in the Ernest Study are of a personal/identifiable nature and also belonging to special categories of personal data such as:

- health related data

The Data Subject's personal data will be processed through a code attributed to each patient. The data controller adopts all of the technical/organizational measures required to ensure respect of the minimization principle as indicated by art. 89 of European Regulation 2016/679 and by approved provisions of the supervisory authority on the matter.

8) Purpose of personal data processing (Art. 14.1.c EU Regulation 679/2016)

All personal and sensitive data of the Data Subject are processed by the data controller based on consent previously provided for the purposes of the Ernest Study.

The personal data will be processed only for the execution of the Ernest study as described in the first part of the present disclaimer. To pursue this aim data can be object of the following operations:

- entry of data in corporate database;
- execution, monitoring and development of clinical experimentation/study;
- reporting to institutions to whom legislation grants power of monitoring and control towards the data controller;
- comply to specific requests of the Data Subject.

9) Any recipients or any categories of recipients of the personal data (Art. 14.1, lett. e) EU Reg. 679/2016)

The personal data of the Data Subject, when necessary, may be communicated (meaning the disclosure to one or more specific subjects), other than to police bodies, judicial authorities and persons who may have access to them under the provisions of law or secondary or European legislation:

- between the trial centers participating in the Ernest Study and FROM pursuant to the Authorization issued by the supervisory authority through its provision no. 146 of 5 June 2019, Attachment no. 1, paragraph 5.5.

Health data are in no case disclosed (with this term meaning giving them knowledge in any way to a plurality of indeterminate subjects).

10) Criteria used to determine the data retentiuon period (Art. 14.2, lett. a) EU Reg. 679/2016)

FROM declares that the data contained in the Ernest Study will be kept for a period of 5 years from the conclusion of the updating of the aforementioned study, an activity for which FROM will request your specific and distinct consent.

For From, this term may be extended in order to comply with the conservation terms established in the Health Record Retention periods approved by the Lombardy Region currently in force and subsequent amendments, in any case not exceeding those necessary for the management of possible appeals / disputes.

11) Means of the processing

The data, also processed 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 promoter, 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 interested himself.

Furthermore, no further data concerning the interested party will be collected, without prejudice to the use of any data already collected to determine, without altering them, the search results.

12) Rights of the Data Subject (Art. 14.2, lett. c) EU Reg. 679/2016)

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

- 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 Regulation 679/2016 / EU;
- Right to ask the Data Controller, pursuant to Article 15 of Regulation 679/2016 / EU, to be able to access their personal data;
- Right to ask the Data Controller, pursuant to Article 16 of Regulation 679/2016 / EU, to be able to rectify their personal data, if the latter does not conflict with the current legislation on data retention and with the need to protect the health professionals who treated them in case of judicial litigation;
- Right to ask the Data Controller, pursuant to Article 17 of Regulation 679/2016 / EU, to be able to delete their personal data, if the latter does not conflict with the current legislation on data retention and with the need to protect the health professionals who treated them in case of judicial litigation;
- Right to ask the Data Controller, pursuant to Article 18 of Regulation 679/2016 / EU, to be able to limit the processing of their personal data.

13) Right to lodge a complaint (Art. 14.2, lett. e) Reg.679/2016)

The Data Subject always has the right to lodge a complaint with the supervisory authority for the exercise of his/her rights or for any other matter related to the processing of his personal data.