process No. 9753/ 2018 1

Authorization No. 7105/2018

Novartis Pharma A.G , NIPC NA, representing Novartis Farma

Produtos Farmacêuticos, SA, notified the National Data Protection Commission

(CNPD) a processing of personal data for the purpose of carrying out a Study

Clinical Intervention, called a randomized, double-blind, phase III study

blinding chemotherapy with daunorubicin or idarubicin and cytarabine for

induction and intermediate dose of cytarabine for consolidation plus midostaurin

(PKC412) or chemotherapy plus placebo in patients newly diagnosed with

FLT3 mutation-negative acute myeloid leukemia (AML) with Protocol No.

CPKC412E2301.

Research is multicentric, taking place in Portugal at research centers

identified in the notification.

There are external data processing services

information properly

identified.

The study results in the creation of a biobank, complying with the requirements of article

19 of Law no. 12/2005, of 26 January.

There is specific justification, validated by the Competent Ethics Commission (CEC),

for the processing of personal data race/ethnicity.

The participant is identified by a code specifically created for this study,

constituted in such a way as not to allow the immediate identification of the data subject;

in particular, no codes are used that match the serial numbers.

identification, name initials, date of birth, telephone number, or result

of a simple composition of this type of data. The encryption key is only

known to the investigator(s).

The express consent of the participant or his/her legal representative is collected.

The information is collected directly from the holder and indirectly from the clinical file.

Any transmission of information is carried out by reference to the code of the

participant and, to that extent, anonymous to the recipient.

process No. 9753/2018 2

The CNPD has already commented in Deliberation No. 1704/2015 on the legal framework,

the grounds of legitimacy, the applicable principles for the correct fulfillment

of Law No. 67/98, of October 26, amended by Law No. 103/2015, of August 24,

hereinafter LPD, as well as on the conditions and limits applicable to the treatment of

data carried out for the purpose of clinical investigation.

In the present case, the treatment that is the subject of the notification falls within the scope of

of that decision and the person in charge expressly declares that he complies with the limits and

conditions applicable under the LPD and Law No. 21/2014, of 16 April, as amended

by Law no. 73/2015, of June 27 – Clinical Research Law –, explained in the

Resolution No. 1704/2015.

The basis of legitimacy is the consent of the holder.

The information processed is collected in a lawful way, for a specific purpose, explicit

and legitimate and not excessive – cf. lines a), b) and c) of no. 1 of article 5 of the LPD.

Thus, under the combined provisions of paragraph 2 of article 7, paragraph a) of the

paragraph 1 of article 28 and article 30 of the LPD, as well as paragraph 3 of article 1 and paragraph 9

of article 16.º both of the Clinical Investigation Law, with the conditions and limits

explained in CNPD Deliberation No. 1704/2015, which are hereby given as

reproduced, the present processing of personal data is authorized in the following

terms:

Responsible – Novartis Pharma A.G

Purpose - Clinical Study with Intervention, called Phase III Study

randomised, double-blind chemotherapy with daunorubicin or

idarubicin and cytarabine for induction and intermediate dose of cytarabine for

consolidation plus midostaurin (PKC412) or chemotherapy plus placebo in patients

newly diagnosed acute myeloid leukemia (AML) with FLT3 mutation

negative, with Protocol No. CPKC412E2301

Category of personal data processed – Participant code; age/date of

birth; genre; race/ethnicity; anthropometric data; Vital signs; history data

clinic; exam data data

physicist; data from supplementary means of

process No. 9753/2018 3

diagnosis; concomitant prior medication; pharmacokinetics; genetics; relating to

sex life; quality of life data/psychological effects; Adverse events

Exercise of the right of access – Through the researchers, in writing/other

communications,

interconnections and

flows

cross-border personal data

identifiable in the recipient – There are no

Maximum data retention period – The key that produced the code that

allows the indirect identification of the data subject must be deleted 5 years after the

end of the study.

LPD and the Clinical Investigation Law, under the terms and conditions set forth herein

Authorization and developed in CNPD Deliberation No. 1704/2015, result

obligations that the person responsible has to fulfill. These must be made known to all

those involved in the processing of personal data.

Lisbon, 24-05-2018

The president

Filipa Calvão