

process No. 9430/2018 1

Authorization No. 7077/2018

AbbVie, Lda, NIPC 510229050, notified the National Commission for the Protection of

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

Clinical Study with Intervention, called a multicenter induction study, in

double-blind, randomized, placebo-controlled trial to assess efficacy and

safety of Risankizumab in patients with moderately to severely active ulcerative colitis

who have failed prior biological therapy, with Protocol No. M16-067.

Research is multicentric, taking place in Portugal at research centers

identified in the notification.

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.

Exists

specific justification for the

processing of behavioral data,

psychological or volitional, which are directly related to inquiry.

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.

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, process No. 9430/2018 2

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 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 – AbbVie, Lda

Purpose - Clinical Study with Intervention, called Induction Study

multicentre, double-blind, randomized, placebo-controlled

efficacy and safety of Risankizumab in patients with active ulcerative colitis

moderate to severe who have failed prior biological therapy, with Protocol no.

M16-067

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

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

sex life; data on caregivers/companions (only those related to the

participant needs); quality of life data/psychological effects;

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relating to the professional activity in connection with the Investigation; behavioral,

psychological or volitional in connection with the Investigation; Adverse events

Exercise of the right of access – Through the researchers, another

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 the 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