Annex VIIIA

Guideline for correct preparation of a model patient information sheet and informed consent form (PIS/ICF)

Version 27th February 2025

Clarification note: this document should not exceed 15 pages (including the ICF) and must be written in Arial or Times New Roman font with a font size of at least 11 points, minimum line spacing of 1.5, and no decrease in the document margins.

The minimum essential content for each section is indicated in black as a recommendation and proposed text is shown in italics and quotation marks, with unacceptable text in bold.

Patient information sheet

STUDY TITLE	
STUDY CODE	
EudraCT NUMBER	
SPONSOR	
PRINCIPAL INVESTIGATOR	*Leave space blank to be completed by each site*
SITE	*Leave space blank to be completed by each site*

Introduction

(It should contain the following information)

<<We are writing to inform you about a research study in which you are invited to participate. The study has been approved by an Ethics Committee for Investigation with medicinal products (CEIm) and the Spanish Agency for Medicinal Products and Medical Devices in accordance with current legislation, Royal Decree 1090/2015, of 4 December, and European Regulation 536/2014, of 16 April, regulating clinical trials with medicinal products.

Our intention is for you to receive correct and sufficient information so that you can decide whether or not to participate in this study. Please read this information sheet carefully. We will address any question you may have.

In addition, you may consult with anybody you think appropriate>>

Voluntary Participation

(It should contain the following information)

Begin the section informing the patient of the reason he/she is invited to participate in the study. For example: We invite you to participate in the study because you have been diagnosed with...

<<You should know that your participation in this study is voluntary and that you can decide

NOT to participate. If you decide to participate, you can change your decision and withdraw your consent at any time, without this affecting your relationship with your doctor or causing any penalty to your treatment>>

It is not mandatory to record the IC revocation with the signature of a revocation document. In the case that the protocol establishes that the revocation signed by the patient must be included in a document, both in the text of the information sheet document and at the beginning of the revocation consent, it should be stated: <<*You should know that you can decide to stop participating in the study at any time and that you are NOT OBLIGATED to sign this revocation document in order to exercise this right.*>>

Study objective

(It should contain the following information)

Briefly describe why the study is being done.

Define the objective without using technical terms or specifying the mechanism of action of the drug in excessive detail. The description of the main objective of the study should express in simple terms the main question of the trial.

Study description

(It should contain the following information)

An exhaustive list of inclusion and exclusion criteria should not be included, but rather a simple description of the patient to whom the study is directed.

It should indicate the total number of subjects that are planned to be included.

It should state what drug or drugs are proposed to be administered and how many treatment groups there are, indicating what chances the patient has of receiving the study drug or the comparator if there is one.

It should explain that the procedure for assignment to one group or the other is done at random (when appropriate), avoiding any technical terms such as randomisation.

It should state that "neither the doctor nor the patient will know what treatment you will receive", if it is a double-blind study.

It should explain, if appropriate, the existence of placebo and its definition: the dosage form (e.g., tablet or capsule) with the same appearance as drug X, but which does not contain a pharmacologically active substance and therefore is not expected to have an effect.

If the study includes HIV/HBV/HCV testing, add the following:

<<The results of all your blood tests, as well as other analytical results, will be provided to the sponsor. These results are coded so the sponsor does not know to whom these results belong. Positive results for HIV and viral hepatitis will be reported to the local health authorities as required by health legislation.>>

Technical terms such as double blind, randomization, etc., that are to be described later, should not be used. Directly use the non-technical description or explanation.

Study Activities

(It should contain the following information)

It should specify the duration of the study. When applicable, clearly separate the treatment phase from the follow-up phase.

The number or frequency of visits, complementary examinations and other activities to be

performed during the study should be indicated (without going into excessively technical details), clearly reflecting those that are part of the patient's usual treatment and those that will be performed on an extraordinary basis due to his/her participation in the study. Their number should also be reported.

Do not repeat the same explanations for each visit, unnecessarily lengthening the document. Information should be discarded on common routine examinations such as: blood pressure, pulse, electrocardiogram, weight, height, etc.

It is recommended to include a timetable in the form of a table, preferably as an annex to the document. The activities to be performed should be written, for example, as "blood sample collection" (details of the type "determination of xxx biomarkers" or "quantification of drug levels" are not necessary if it has been explained that in some visits blood will be obtained for these purposes), physical examination, etc.

The same tables that appear in the protocol should not be included, preparing others that are simpler and easier to understand for the patient.

In some clinical trials, patients need to undergo certain tests inherent to the conduct of the trial at a site other than the main site (satellite, collaborating, external, etc.) where the principal investigator is located and where almost the entire study is conducted. This requires the patient to travel to these other sites for these tests or study visits. In these cases, add the following information:

<<"It is possible that in the course of your follow-up in this study some of the scheduled tests may have to be performed at a site other than your usual one. In this case, your doctor will inform you of this".>>

Risks and discomforts resulting from your participation in the study

(It should contain the following information)

It should state whether the drug is or is not authorised/marketed. It should inform about the approved or endorsed indications for use in our setting in the case of "off-label use".

It should briefly explain previous experience with the study drug(s). **Data from animal studies should not be given when sufficient information is available in humans.**

It should list the possible risks of the drug or combination of drugs that are under study (in terms the subject can understand and in a concise manner). **It is recommended to include the most frequent and most serious events.** The idea should be conveyed that there may be possible risks or events unknown at this time and that it cannot be ruled out that they may occur.

In the case of marketed drugs, a statement like the following may be included: "As a drug approved by the competent health authorities, information on the side effects of XXX is available in the package insert. You can consult your study doctor for this information".

The risks and discomforts of the tests that are to performed as a result of the study should be described. Avoid technical terms and long, drawn-out writing with unnecessary details, but make it clear that visits may be lengthened by procedures derived from participation in the study such as, for example, questionnaires, kinetic samples, etc.

If discomforts were previously mentioned when describing the study activities, do not repeat them here.

It should state the responsibilities of the participant with regard to:

- Compliance with visits and study activities
- Reporting any adverse event occurring to him/her or changes in medication, warning that, except in an emergency, they should not modify the medication they are taking or take other medications or "medicinal plants" without first consulting with the study

doctor.

Possible Benefits

(It should contain the following information)

The expected benefits for the subject, if any, and society should be discussed and it should be added that the patient may not obtain any benefit for his/her health from participating in this study.

Free medication, test results, close follow-up, etc., should not be included as a benefit of patient participation in the study.

Contact in case of questions

(It should contain the following information)

<<If during your participation you have any questions or need further information, please contact <<Study doctor, including name, service, how to reach him/her, contact telephone number and hours of operation on that telephone number>> (If exceptionally it is another professional, it should indicate which professional it is)>>.

Patient can also be referred to the point of contact established at the center for questions related to participation in the research. Add contact information (e-mail address, telephone number and consultation/patient attention timetable).

In case of urgency or emergency, refer the patient to his/her usual site.

Inform the patient that if he/she needs medical attention from a team other than the one that has offered to participate in this study, he/she should report his/her participation in this trial and provide as much information as possible regarding the study. For example, indicate the importance of carrying the card provided at the time of inclusion.

Pregnancy warning

In the case of participation of women of childbearing age or male patients with partners of childbearing age, there should be a specific section on pregnancy or breastfeeding.

It should include the known risks of the drug to the foetus, and if not, state that they are unknown.

When necessary, it should mention the need to take contraceptive measures as specified in the protocol.

<<If you become pregnant during your participation in the study, you should inform your doctor immediately to receive appropriate medical care>>

It should indicate that in case of pregnancy, collection of data on the pregnancy and on the baby's health will be requested. It should inform of the period during which information is collected (until delivery, 3 months after delivery, etc.) and guarantee compliance with current legislation on *Personal Data Protection (refer to the corresponding section of the document*).

In case of pregnancy of the partner of a male participant, this information will be requested through a specific consent.

Alternative treatments

(It should contain the following information)

Briefly explain, if any, the other effective alternative treatments currently available for treatment of the patient's disease, which he/she could receive if he/she did not participate in the study (it should even be explained that the patient could receive the same drugs that are offered to him/her in the study, as would be the case, for example, in phase IV clinical trials).

Add that the study doctor will give more information if the patient wishes, but this does not avoid briefly listing the possible alternatives.

Expenses and financial compensation

(It should contain the following information)

When appropriate, it should state that the investigator/site receives financial compensation for the conduct of the study. The following text is proposed for those documents that do not include it:

<<The study sponsor is responsible for managing study funding. For the conduct of the study, the sponsor of the study has signed a contract with the study doctor and the site where it will be performed.

You will not have to pay for the study drugs or the specific tests of the study. Your participation in the study will have no additional cost for you to the one you would have had in normal clinical practice and you will be reimbursed for extra expenses (e.g., meals, trips) generated by your participation in the study>>.

Exceptionally, if not applicable due to the characteristics of the study, it will be suppressed, but it will be explained in the cover letter to the CEIm.

In the cases where it is planned, due to the characteristics of the study (with no therapeutic benefit), to compensate the patients for the time spent in the study or for the inconvenience caused to them, the amount foreseen should be included in this section. It should also indicate that this compensation will be proportional to the participation in the study.

Regarding these economic compensations, the following indication for the patient must also be included:

<<These compensations are treated by the tax authorities as income, so they will have an impact on your income tax return. If you decide not to accept this payment, please inform your study doctor of this fact>>>.

What treatment will I receive when the clinical trial is ended?

It should be explained if the patient will be able to continue receiving the study medication and under what conditions.

For example:

<<When your participation ends, you will receive the best available treatment that your doctor considers most appropriate for your disease, but you may not be able to continue receiving the study medication. Therefore, neither the investigator nor the sponsor takes on any commitment to maintain such treatment outside of this study>>.

Or in the case of serious diseases without available treatment:

<<If the study is suspended or terminated while you are under treatment with <<name of drug>>, your disease remains controlled, the study data indicate that <<name of drug>> shows a benefit in the management of your disease, and adequate stock of the drug is available, the sponsor will ensure an adequate and free supply of <<name of drug>>, until it is available, so that you may continue your treatment for as long as your disease remains controlled>>.

Insurance

(When required, it should contain the following information)

<<The sponsor of the study has an insurance policy that complies with current legislation (Royal Decree 1090/2015) and will provide compensation and indemnity in case of harm to

your health or injuries that could occur in relation to your participation in the study, provided they are not a consequence of the disease being studied or of the progression of your disease as a consequence of the ineffectiveness of the treatment.

If you would like more information about this section, consult the principal investigator of the study at your site, or with the contact points set up at each site.

We inform you that it is possible that your participation in this clinical trial may modify the general and particular conditions (coverage) of your insurance policies (life, health, accident, etc.). Therefore, we recommend that you contact your insurer to determine whether your participation in this study will affect your existing insurance policy>>.

Personal data protection

<<Both the sponsor and the site shall ensure that the principles of data protection regulations, both national and European, are complied with>>>.

For more information on confidentiality and personal data protection, please refer to Appendix 1.

What will my data be used for?

(It should contain the following information, as appropriate)

<<Your data are necessary for the sponsor to develop the medicine, obtain authorization to introduce and maintain it on the market, monitor its safety, and cover it by health insurance, i.e., for the duration of the drug development programme. Therefore, they will be used as planned in this study, as well as within the related research activities necessary for this drug development programme in order to:

- *understand how the study drug and similar medicines work in the body (i.e., to assess the mode of action of the study drug),*
- *better understand the disease being studied and the associated health problems,*
- *[unless you are sure that this may never be done, add also: develop diagnostic tests for the disease]*
- *learn from previous studies in order to plan new studies or improve methods of scientific analysis,*
- *publish research results in scientific journals or use them for educational purposes,*
- *[*where other purposes of use are necessary for the drug development programme and are not optional (i.e., without separate consent), add them here].>>

For future uses not limited to the above (i.e., future uses for purposes beyond the drug development programme or for unrelated diseases/areas), a separate consent from the patient would be required explaining in a general way the type of studies for which consent is sought. For this purpose, it will be possible to add a **"yes/no"** box on the general IC form for the participant to express his/her willingness.

In this case, the following information must be included:

<< An IRB/CEIm shall have issued a favourable opinion prior to the processing of your data. Failing this, the entity responsible for the research shall require the prior report of a data protection officer or an expert in European data protection law for such future use of your data.>>

Other relevant information

(It should contain the following information)

<<A description of this clinical trial will be available at http://reec.aemps.es, as required by Spanish law>>.
If the sponsor also uses other open access databases to publicise the study, they can be added in this section.

<<Any new information regarding the medicines used in the study that may affect your willingness to participate in the study that is discovered during your participation will be communicated to you by the investigators as soon as possible.

You should be aware that you may be excluded from the study if the study sponsor or the investigators deem it appropriate, either for safety reasons (your disease is not responding adequately, any adverse events occurring from the study medication, etc.) or because they feel that you are not complying with the established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.

By signing the attached consent form, you agree to comply with the outlined study procedures.>>

In cases where the sponsor wishes to follow up patients who drop out without withdrawing consent (i.e., they no longer attend visits), this should be clearly stated in this section.

Patient should be informed of the data processing of all trial activities that the sponsor outsources to third service providers. This information will be included in **Appendix 1**. In the section reserved for this purpose, contracted services (processing purpose) will be listed: courier, payments or reimbursements, hiring of personnel to carry out activities at home... And the patient will be assured that the company (which would act as data processor) will only use his or her data for this purpose, will not transfer the patient's personal data to the sponsor and that the data will be deleted at the end of the study.

It will not be necessary to list the names of the companies.

<<You should be aware that your primary care physician may be aware of your participation in this study.>>

Clinical studies in minors

(When applicable)

For studies conducted in the paediatric population, the document prepared by KIDS Barcelona ("Young Persons' Advisory Group of Hospital Sant Joan de Déu") is provided as a recommendation and as an aid or guide in its preparation".

When the study includes minors or is a study in paediatrics, the following information should be added to the PIS/ICF of the parents/guardians:

<<We inform you that your child will be given an information sheet and an informed consent adapted to his/her capacity of understanding which he/she must sign>>.

Taking into account the provisions in the new RD, consent should comply with the provisions of Article 156 of the Civil Code, where it is specified that "The informed consent document of the parents shall be valid provided that it is signed by one of them with the express or tacit consent of the other which should be adequately documented". It is recommended to add the following:

☐ The parents (both)

In the event that only one of the parents is authorised, the authorising parent must declare

one of the following:

☐ I hereby confirm that the other parent does not object to our child's participation in the study.
☐ The signatory is the sole legal guardian.

Collection and use of biological samples

In the case of storage of clinical trial samples, once the trial is completed, the ethical and legal requirements provided in RD 1716/2011 must be complied with for their subsequent use in research. This document will mention this regulation and inform the patient of the points that are applicable. See additional instructions in **Annex VIIIB** for the paragraphs to be included in the informed consent for the collection and use of biological samples in clinical trials.

When a substudy is performed in the main study:

One of two scenarios are possible:

1.- ALL participants in the general study may be offered the possibility of participating in a substudy such as obtaining pharmacokinetic samples, imaging tests, etc.

In this case, it is not necessary to create a separate document for the substudy. It is sufficient to indicate it clearly in the general document in a separate section <<SUBSTUDY XXXX>>. This section will clearly explain what participating in this substudy involves, describing any special considerations for the patient's participation, explaining the risk and benefit/absence of benefit and giving the patient the option to agree or NOT to this. For example:

☐ YES, I agree to participate in this XXX substudy (kinetics, imaging tests, etc.).

☐ NO, I do not wish to participate in this XXX substudy (kinetics, imaging tests, etc.).

2. - When the SUBSTUDY is directed to a specific subpopulation (e.g., the first 20 patients, only sites having the test, only sites agreeing to participate, etc.), an information document should be written for the specific patient of the substudy, separate from the general study.

<<Do not sign this consent form until you have had the opportunity to ask any questions you have deemed appropriate and you have obtained satisfactory answers to them.>>

Acknowledgment:

<<Whatever is your decision, the sponsor and the research team would like to thank you for your time and attention. >>

INFORMED CONSENT

(It should contain the following information)

It is not acceptable for the consent form to repeat the same information that was already provided.

Study title	*<<Title>>*
EudraCT number	*<<EudraCT number>>*
Protocol code	*<<Code (version X, date)>>*

I, *<<first and last name of the participant>>*

☐ I have read the information sheet and appendix 1 provided to me about the study.

☐ I have been able to ask questions about the study.

☐ I have received enough information about the study.

☐ I have talked with *<<name of investigator>>*

☐ I understand that my participation is voluntary.

☐ I understand that I may withdraw from the study:

- Whenever I wish.
- Without giving any reason.
- Without this affecting my medical care.

I will receive a signed and dated copy of this information sheet and informed consent form.
I freely consent to participate in the study, confirm that I have read **Appendix 1** and agree with its contents.

Signature of participant
Date: ____/____/____
(Name, signature and date in handwriting by participant)

Signature of investigator
Date: ____/____/____

When the IC is obtained from persons with modified capacity to give their IC

Signature of legal representative, family member or related person
Date: ____/____/____
(Name, signature and date in handwriting by legal representative, family member or related person)

Signature of investigator
Date: ____/____/____

I would like to be informed of any information arising from this research that may be relevant to my health:

☐ YES

☐ NO

Signature of participant
Date: ____/____/____
(Name, signature and date in handwriting by participant)

Signature of investigator
Date: ____/____/____

I would like to be informed of any information arising from the genetic tests performed (only those studies including this type of tests, provided they are validated and may be relevant to the participant's health). If they are part of the study objective, information about them should be given in the information sheet.

☐ YES

☐ NO

Signature of participant
Date: ____/____/____
(Name, signature and date in handwriting by participant)

Signature of investigator
Date: ____/____/____

INFORMED CONSENT before witnesses

(It should contain the following information)

It is not acceptable for the consent form to repeat the same information that was already provided.

Study title	*<<Title>>*
EudraCT number	*EudraCT number*
Protocol code	*<<Code (version X, date)>>*

I, *<<name and last name of witness>>*, as a witness, affirm that in my presence Mr/Ms *<<name and last name of participant>>* has been informed and it has been read the information sheet which was given to him/her about the study, and that:

☐ He/she has been able to ask questions about the study.
☐ He/she has received enough information about the study.
☐ He/she has talked with *<<name of investigator>>*
☐ He/she understands that his/her participation is voluntary.
☐ He/she understands that he/she can withdraw from the study:
- Whenever he/she wishes.
- Without giving any reason.
- Without this affecting his/her medical care.

The patient will receive a signed and dated copy of this information sheet and informed consent document.

The participant freely agrees to participate in the study and confirms that he/she has read **Appendix 1** and agrees with its contents.

Signature of witness
Date: ____/____/____
(Name, signature and date in handwriting by witness)

Signature of investigator
Date: ____/____/____

The patient would like to be informed of any information arising from this research that may be relevant to his/her health:

☐ YES

☐ NO

Signature of witness
Date: ____/____/____
(Name, signature and date in handwriting by witness)

Signature of investigator
Date: ____/____/____

The participant would like to be informed of any information arising from the genetic tests performed (only those studies including this type of tests, provided they are validated and may be relevant to the participant's health). If they are part of the study objective, information about them should be given in the information sheet.

☐ YES

☐ NO

Signature of witness
Date: ____/____/____
(Name, signature and date in handwriting by witness)

Signature of investigator
Date: ____/____/____

The study participant has indicated that he/she is unable to read.

A member of the study staff has read the Information Sheet, reviewed and discussed it with the participant, and the participant was given the opportunity to ask questions or consult with other people.

The witness must be an impartial person, unrelated to the study.

Annex VIIIA. Appendix 1

Guidance for the correct preparation of a sample APPENDIX to the Personal Data Protection section.

Version 30th November 2023
English Version Publication: 30th November 2023

Clarification note: this document should not exceed 2 pages and must be written in Arial or Times New Roman font with a font size of at least 11 points, minimum line spacing of 1,5, and no decrease in the document margins.
This first page includes the minimum information to be included in the appendix. For each section of the appendix, the proposed text is indicated in italics, with unacceptable text in bold. In some sections, black text is added as a clarification/recommendation.

Appendix 1. PROTECTION OF PERSONAL DATA RELATING TO THE STUDY PATIENT INFORMATION SHEET AND INFORMED CONSENT

STUDY TITLE	
STUDY CODE	
SPONSOR	
PRINCIPAL INVESTIGATOR	*Leave space blank to be completed by each site*
SITE*	*Leave space blank to be completed by each site*

Who is responsible?

<<XXXX is the sponsor of this study. It is based in XXXXX.
Both the site and the sponsor are responsible for their respective processing, and each of them is responsible for the obligations derived from their activity. The site is responsible for all the data included in the medical record that may identify you, and the sponsor for those that are collected in this study in coded form (pseudonymised).

The role of the data controller is to ensure that your information is used correctly, in particular by implementing appropriate technical and organisational measures to ensure that the data are processed in accordance with the applicable regulations.

The sponsor and the site shall comply with data protection regulations:
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (GDPR) on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- The Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights (LOPDPGDD) and any other implementing legislation.>>

In case that, for study management needs, personal patient information is made available to third parties, the contract between the sponsor and each company will contain the personal data processor clauses, in accordance with RGPD, article 28. This should be reported in this section and add the purposes for which the companies have been contracted for (for example: travel

management, patient location...).

What is the legal basis for processing your data?

The legal basis for processing your data is compliance with the legal obligations set out in the regulation of medicines and medical devices, regarding to:

- *the general interest in scientific research*
- *the improvement and guarantee of the quality and safety levels of the medicinal product, in order to commercialize it in the future.*

When applicable, additional ones could be contemplated.

What about confidentiality?

<<At all times, the confidentiality of your data will be maintained. During your participation in the study, you will be identified by a code and neither the investigator nor the hospital will transfer any information that could directly identify you to the sponsor.

The list linking the identification code with the data that identifies you (name, surname, medical record number, etc.) is kept confidentially at your health site.

Access to your personally identifiable information will be restricted to the study doctor/collaborators, health authorities (Spanish Agency of Medicines and Health Products, foreign health authorities), the Ethics Committee for Research involving medicinal products (CEIm) and personnel authorised by the sponsor (study monitors or auditors), when required to check the data, study procedures, and compliance with standards of good clinical practice; but always maintaining the confidentiality of the same. Your identity may be disclosed in exceptional cases, such as situations of medical urgency for your health or as required by law. The processing, communication and transfer of the personal data of all participants will comply with the provisions of the applicable regulations.*

Likewise, in the event of an adverse reaction, your identification data may be communicated by the Center to the competent health authorities and to the insurance companies which the insurance has been contracted with, in order to carry out the necessary steps>>>.

Lists with other possible accesses do not need to be added.

If there is any special situation where the identity of the subject is needed to fulfil a requirement of the study, it should be explained in this section.

How long will your data be stored for?

<<All the information we request from you is necessary to participate in this study and it is mandatory to provide it in order to guarantee the correct development of the study.

The site, the investigator and the sponsor are obliged to keep the data collected for the study according to the legal deadlines established in the regulations. The sponsor and the investigator for at least 25 years after the end of the study (according to clinical trial regulations) and the site for the time necessary to provide adequate care (according to regulations governing clinical records). >> >>

If the sponsor plans to keep the patient's data for longer than the established period (25 years), it should be mentioned in this section, explaining the reason. The CEIm will assess the adequacy of the sponsor's plan in relation to data protection regulations.

What rights do I have?

<<With respect to your data, you have the following rights that you may exercise with the principal investigator and/or site:

You can ask at any time what data is being stored (right of access), who is using it and for what purpose; you can request a copy of your personal data for your own use.

You may request to receive a copy of the personal data provided by you in order to transmit it to other persons (portability).

You can correct personal data provided by you and limit the use of data that is incorrect (right of correction and deletion).

You can object to or restrict the use of your personal data (right of objection).>>

<<With regard to your rights over your personal data, we remind you that there are some limitations in order to ensure the validity of the research and to comply with the legal duties of the sponsor and drug authorisation requirements. If you decide to stop participating in the trial or withdraw your consent to the processing of your data, the data collected up to that point may not be deleted. You should be aware that withdrawing consent to the processing of your data may result in your termination of participation in the trial. >>

Explain other limitations to the right of access (e.g., until the end of the study, biomarker data that are considered exploratory...).

<<To protect your rights, we will use as little information as possible. We also inform you of your right to lodge a complaint with the Data Protection Agency about any action by the sponsor or the site that you consider to be in breach of your data protection rights.>>

For sponsors adhered to the Farmaindustria Code of Conduct, the following sentence is suggested*: <<You may also file a complaint with the Governing Body of the Code of Conduct regulating the processing of personal data in the field of clinical trials, other clinical research and pharmacovigilance approved by Farmaindustria.>>*

Whom do I contact?

<<You can contact the data protection officer of your site, or contact the data protection officer of the sponsor.

Contact details of the principal investigator or the data protection officer (DPO) of the site or institution:

Contact details of the DPO of the sponsor:

To exercise these rights you may also contact the Principal Investigator of the study whose contact information appears on the first page of this document. >>

How will the results be communicated?

«Accoring the spanish regulation, the description and results of the study will be availavle in the Spanish Clinical Trials Register (ReEC): https://reec.aemps.es>>

This section will include any other public site the sponsor also uses to publish the study.

Inform of these obligations:

The sponsor is required to publish the results, whether positive and negative, of authorised clinical

trials, preferably, in scientific journals before being disclosed to the non-healthcare public, irrespective of the obligations to publish the report of the results in the Spanish Register of Clinical Studies (REec) and the provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 in this regard.

When studies and research work on medicinal products are made public to the scientific community, the funds obtained by the author, by or for their execution, and the source of financing shall be stated.

The anonymity of the subjects participating in the trial will be maintained at all times.

Will my data be shared and transferred? (Include if applicable)

<<The Sponsor may transfer or share your data with its delegates, partners and/or to other researchers within or outside the European Economic Area (EEA) applying the necessary security measures for the protection of your information.>>

<<In any case, the recipients of the data will not have access to the code that allows your data to be linked to you; only your doctor or the hospital staff have access to this code.>>

<<The legislation in some of these countries may not be as strict as in your country. Therefore, to ensure an appropriate level of protection of your personal data, the Sponsor will ensure that data transfers respect your rights and confidentiality in accordance with data protection regulations. This provision will only apply in the case of transfers outside the EEA, otherwise the GDPR will apply and the regime is identical.>>

<<All data recipients will sign/agree to a Data Transfer Agreement or equivalent terms of use agreement in which they agree not to attempt to re-identify research participants.>>

Model for processing and transfer outside the EU (countries with a non-equivalent level of protection).

In this case the patient should be informed that his/her encrypted data may be transmitted to third parties and other countries by specifying the following:

- to whom it would be transferred: e.g., to entities of our group, to service providers or to scientific researchers collaborating with us,
- for what purposes: for the same purposes as the study described, not for additional purposes.
- what safeguards the data will be protected with: In the event of transfer of the encrypted data outside the EEA to the sponsor's group entities, service providers or scientific researchers collaborating with the sponsor/investigator, your data will be protected with safeguards or other mechanisms put in place by data protection authorities. Examples (Leave only the one(s) that apply):
    - the country to which the data is to be transferred(specify) has been declared adequate by the European Commission
    - in accordance with the sponsor's binding corporate rules (the procedures put in place by the sponsor), which can be found on the sponsor's website (include web address)
    - standard contractual data protection clauses: e.g., The sponsor shall sign with the recipient the standard contractual data protection clauses as laid down by the European Commission.
    - codes of conduct.
    - certification mechanisms.
    - other: exceptions stated in the GDPR (specify, bearing in mind that they are **exceptions**).

Safeguards for the protection of your personal data

<<Appropriate protective measures shall be taken to protect the encrypted data during and after the trial, including:

- *Access to encrypted data will be limited to persons subject to confidentiality obligations (including the obligation not to attempt to re-identify patients or decode clinical data).*
- *Encrypted data shall be protected by security measures to prevent alteration, loss and unauthorised access and additional measures may be applied to prevent identification.*
- *A data protection impact assessment will be applied to identify and mitigate potential privacy risks, if any, associated with each scientific research.*
- *Encrypted data will not be shared for direct marketing purposes or for other purposes that are not legal obligations or are not considered scientific research in accordance with current data protection legislation. In particular, it will not be used to make decisions about future services that may be offered to you, such as insurance. >>*