

Recommended information sheet template for a compassionate use program in Duchenne muscular dystrophy

For Adult Patients

Program title:	Compassionate Use Program (CUP) for the treatment with givinostat in ambulant patients of 6 years and older with Duchenne muscular dystrophy (DMD) aged 6 years and older and with concomitant corticosteroid treatment.
Manufacturer:	Italfarmaco S.p.A.
Doctor's name:	[insert name]
Doctor's address or affiliation	[insert address]
Where you will go for your visits in this program:	[insert name & address of site]
Doctor's Daytime Telephone Number:	[insert telephone number]

Important information about this compassionate use program

This information sheet and consent form gives you important information that will help you decide if you want to join this compassionate use program.

Take your time, and feel free to talk it over with your family or friends. Please ask the compassionate use program team if you have any questions about anything in this form. If you have questions later, contact your doctor at the phone number listed above.

Treatment in compassionate use programs include only people who choose to take part. It is your choice whether or not you want to take part in this program. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

You may take this information sheet home and an unsigned copy of the consent form with you and discuss with family or friends before making your decision.

1. Background

What is a compassionate use program?

Compassionate use is a potential pathway for a patient with a serious or life-threatening disease or condition to try an investigational medical product for treatment outside of clinical trials when there are no comparable or satisfactory therapies available.

This compassionate use program provides givinostat as an investigational product for the potential treatment of Duchenne muscular dystrophy (DMD) in ambulant patients, aged 6 years and older and with concomitant corticosteroid treatment. Italfarmaco S.p.A. will provide access to givinostat free of charge for patients registered in this compassionate use during the entire program.

During this program, you will be treated and followed-up by a doctor specialised in DMD and will be able to continue their DMD standard care of treatment including corticosteroids. However, you will not be able to participate simultaneously in any other compassionate use program, clinical study or take any DMD investigational drug or any other DMD drug- except of corticosteroids.

Why is this compassionate use program being offered to me ?

You are being asked to take part in this compassionate use program by your treating doctor because you have Duchenne muscular dystrophy, have health care insurance, reside in Belgium and there is no other comparable or satisfactory therapy available *for them*. This means that you are not candidate to participate in any ongoing clinical trial with givinostat or any other ongoing clinical trial and are not a candidate for any licensed or standard-of-care-DMD therapy option, except for corticosteroids available at the time of inclusion to this program.

Your participation in this program is voluntary. If you decide to not take part in this program, you can continue with your current medical care.

Has givinostat been used in clinical studies?

Givinostat is an investigational drug that has been tested in clinical trials and is approved by the Food and Drug Administration (FDA) and by the European Medicines Agency (EMA), this means that the authorization to market such drug in Europe has been granted. Overall, more than 200 patients with DMD have received givinostat within the clinical trial setting.

Compassionate use Program Activities

What will happen if I decide to join the program?

Before any program-related tests and procedures can be done, you will be asked to read this information sheet and sign the consent form. Additionally, if appropriate, you will be asked to provide your assent.

The treating doctor will make some tests and evaluations on you to determine whether you meet the requirements to participate, as well as the standard evaluations as per DMD clinical practice.

The following inclusion criteria must be met:

- Confirmed diagnosis of DMD in ambulant patients aged 6 years and older with concomitant corticosteroid treatment.
- Patient must be willing to use adequate contraception
- Patient is not a candidate for any licensed and reimbursed or standard-of-care pharmacological DMD therapy option -except for Corticosteroids- available at the time of inclusion
- Health Care Insurance and Patient residency in respective country

The following exclusion criteria will apply:

- Patients with a platelet count less than $150 \times 10^9/l$
- Fasting triglycerides > 300 mg/dl
- Concomitant treatment with any DMD drug (investigational or licensed) other than corticosteroids
- Previous exposure to any DMD drug (investigational or licensed) other than corticosteroids without adequate wash out.
- Patient is eligible for any ongoing clinical trial for DMD or Patient is participating in any ongoing clinical trial or another CUP.
- Have any hypersensitivity to the components of the CUP medication.
- Have a sorbitol intolerance or sorbitol malabsorption or have the hereditary form of fructose intolerance. Please ask your doctor for more information, if needed.

If the program doctor evaluates that you do not meet all of the requirements to participate in the program, you will be informed and you can discuss with the program doctor the next steps for you.

What will happen during the treatment program?

The frequency and type of assessments beyond the recommended standards of care are under the discretion of the treating doctor and in the best interest for your safety.

If needed, safety assessments may need to be performed at specific timepoints/frequency, as per treating doctor decision. These assessments could also be performed close to your home by a local qualified healthcare professional, under the supervision / advice of the treating doctor.

Usually at a hospital visit the treating doctor conducts the standard evaluations as per DMD clinical practice and can also decide whether to include additional examinations/tests according to your health status. The blood tests need to be performed before starting treatment with givinostat, every two weeks for the first 2 months of treatment, at month 3, and then every 3 months thereafter, to measure the number of blood cells in your body; before starting treatment with givinostat, on the third month, on the sixth month and then every 6 months to measure also the triglycerides, a type of fat in your blood. Standard evaluations include but are not limited to:

- ✓ Physical exam, height, weight, vital signs (blood pressure, pulse rate, temperature)
- ✓ Blood tests, including level of platelets and triglycerides
- ✓ Electrocardiogram (ECG) to measure the electrical activity of your heart
- ✓ Functional movement tests.
- ✓ Ask you questions about how you are feeling.

Not all of these things will happen at all of the visits. The doctor can tell you more about which things happen at each visit. Some of the assessments could happen close to your home by a local doctor or nurse. Transfer of the identifying personal data (such as name and address) will be sent to the local doctor or nurse via the doctor, and that this will not be given to the sponsor or another third party. In any case, the treating doctor will decide on the frequency and type of assessment, in the best interest of your safety.

During the compassionate use program you will be asked to:

- ✓ Attend all visits, as scheduled by the treating doctor.
- ✓ At home, store the bottle(s) of givinostat in the refrigerator. Before use, shake at least 30 seconds by inverting the bottle by 180° for approximately 40 times, and the homogeneity of the suspension should be visually verified. Incorrect shaking may lead to over dosing or under dosing. Administer, as directed, orally twice daily with food.
- ✓ Follow your treating doctor's instructions about whether you may continue to take your regular medications or other prescribed or over-the-counter medicines during the program period.
- ✓ Tell your treating doctor of any changes to your current medications, illnesses or injuries,

unexpected or troublesome side effects, or problems that occur during the program.

- ✓ Tell your treating doctor if you are planning to have an elective surgery or any other medical treatment or procedure.
- ✓ Make sure that givinostat is kept out of the reach of children and people who have a limited capacity to read or understand. You are the only person who should be given givinostat.
- ✓ Contact your treating doctor if you have any question about the program after you sign the consent form.

2. Benefits, Available options, and Costs

What are the benefits of being in this program?

There is no guarantee that you will receive any benefits. However, your treating doctor will explain the possible benefits and risks associated with your participation in the program.

What are the other options available for not being in this program?

Since your participation in this program is voluntary, the alternative would be to not join the program and to continue regular care under the supervision of your usual doctor.

Who is paying for this program?

Italfarmaco S.p.A. will provide access to givinostat free of charge for patients registered in the Compassionate use during the entire program. Please discuss with your treating doctor on any other costs that may be associated with the treatment.

3. Risks and possible discomforts

There may be risks in the compassionate use program that are unforeseeable, but the known risks are listed below.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may have one or more of the following side effects after taking givinostat:

Very common side effects (may affect more than 1 in 10 people):

- belly (abdominal) pain
- decrease in blood platelet count (thrombocytopenia)
- diarrhoea
- elevated levels of blood fats (hypertriglyceridaemia)
- fever (pyrexia)
- vomiting

Common side effects (may affect up to 1 in 10 people):

- anxiety
- constipation
- decreased appetite
- dizziness
- skin redness (erythema)
- tiredness (fatigue)
- diarrhoea and vomiting (gastroenteritis)
- collection of blood under the skin (haematoma)
- increased thyroid stimulating hormone (TSH) levels in blood
- joint pain (arthralgia)
- muscle pain (myalgia)
- muscular weakness
- rash

Givinostat lowers the number of blood cells in your blood, most notably the number of blood platelets responsible for clotting of the blood (a condition known as thrombocytopenia).

Your doctor will check your blood for levels of platelets before treatment and regularly during the entire course of treatment with Givinostat.

Your doctor may reduce your dose to increase your platelet count or stop treatment with Givinostat if thrombocytopenia continues.

Inform your doctor if you notice any unexpected bleeding.

Givinostat may be associated with increased levels of fats (triglycerides) in your blood.

Your doctor will do blood tests before you start givinostat and regularly during treatment to check your triglyceride levels.

The dose of givinostat may be reduced in case of persistent increase in levels of fats (triglycerides) in your blood.

Your doctor may stop treatment if the levels of fats in your blood (triglycerides) do not decrease despite dietary measures and dose reductions.

You may experience diarrhoea and vomiting while taking givinostat.

Your doctor may adjust the dose of givinostat based on severity of diarrhoea or stop treatment if diarrhoea and vomiting do not improve.

Your doctor might consider the use of medicines to treat vomiting, diarrhoea and to avoid excessive loss of fluids.

High doses of givinostat (5 times higher than the recommended dose) may cause an irregular heartbeat. Your doctor will consider if you can use givinostat when there is an increased risk for abnormal heartbeat, abnormal mineral levels in your body or concomitant use of other medicines.

Your doctor may check your heart function when starting givinostat if you have an underlying heart problem or if you use medicines that can cause irregular heartbeat.

Your doctor may consider to stop treatment with givinostat if your heartbeat is found irregular.

Contact your doctor, who may stop your therapy with givinostat, if any of the above conditions appear.

You may not benefit from participation in this Compassionate use Program and your DMD symptoms may worsen.

There may be risks and side effects that are unknown. All drugs have a possible risk of an allergic reaction.

- **Blood Test Risks:** The blood tests in the program will take few mL of blood. It is possible that you will feel some pain and have some bruising at the needle site. Also, sometimes during blood tests, a vein can become inflamed, or in rare cases, a blood clot may occur.
- **Electrocardiogram (ECG):** ECG patches placed on your skin may cause itching, redness, or mild rash. It may be necessary to shave the area on your chest for placement of the ECG patches directly on your skin.

All participants in the program will be watched carefully for any side effects; however, your treating doctor does not know all the effects that the program drug may have on you. Your treating doctor may give you medicines to help reduce side effects. These side effects may be

mild or serious. In some cases, these side effects might be long-lasting, or permanent, and may even be life-threatening.

In any case you observe side effects go in contact with your treating doctor or report directly to FAMHP (Federal Agency for Medicines and Health products) : www.eenbijwerkingmelden.be / www.notifierunefetindesirable.be

What happens if I have a problem or gets injured while in the program?

If your health is affected or you suffer any damage during or after this treatment, please contact the treating doctor. They will initiate the necessary steps for you.

<Treatment site> will provide you with necessary emergency medical treatment if you suffer a physical reaction or injury as a result of givinostat or a procedure required by this treatment.

You do not give up any of your rights by signing this form.

Pregnancy /birth control methods (if applicable)

If you are able to get pregnant or if you are sexually active with a partner who is able to have children, you and your partner must be willing to use highly effective contraceptive methods of birth control consistently and correctly until 3 months after your last dose of program drug. The treating physician will discuss with you the appropriate methods of birth control that you and your partner must use during this program.

Acceptable methods of birth control include a condom with spermicide in addition to the female partner using an acceptable method of contraception, such as an oral, transdermal, injectable, or implanted steroid based contraceptive, or a diaphragm or a barrier method of contraception in conjunction with spermicidal jelly such as a cervical cap with spermicide jelly.

True abstinence (absence of any sexual intercourse) is also an acceptable method of birth control, when in line with your preferred and usual lifestyle. Periodic abstinence (such as calendar, ovulation, symptothermal [is a natural method of birth control by abstaining from sexual intercourse on days that a women is fertile, or capable of getting pregnant], postovulation methods) and withdrawal are not acceptable methods of contraception.

If you/your partner becomes pregnant or thinks they may be pregnant during the program or within 3 months after your last dose of program drug, you must tell the treating physician immediately. The treating physician may also ask you/your partner questions about pregnancy and baby.

4. Deciding Not to Participate

What happens if I do not agree to be in the program?

Nothing bad will happen to you if you say no. No one will be angry with you or treat you any differently than before you were asked to be in the program.

Being in this program is completely voluntary. Your usual medical care will not change if you decide not to agree to be in the program.

Can I leave the program after it begins?

Yes. Even if you agree to agree to join the program, you are still free to leave the program at any time without giving any reason. There will also not be any penalty or loss of benefits to which you are entitled at this site if you decide not to take part or if you decide to leave the program.

If you decide to leave the program, you should contact the treating doctor who will explain the safest way to end your participation.

Can I be taken out of the program even if I want to continue?

Yes. Sometimes the treating doctor may have to end your participation in the program even if you want to stay in it.

This can happen if:

- ✓ Any change in your medical condition that might be harmful to you.
- ✓ Your failure to follow the treating physician's instructions.
- ✓ You no longer meet the program health care insurance eligibility criteria
- ✓ Compassionate use programs enable participants to gain access to a medicine before its approval by the competent health authorities.
 - If the competent health authorities do not grant the approval for givinostat, Italfarmaco SpA reserves the right to revise or discontinue the Compassionate use program.
 - If givinostat is approved and authorized by the health authorities for reimbursement for Duchenne Muscular Dystrophy, the compassionate use program will be phased out, and access to the product will then be under the normal system.

5. Confidentiality and Privacy

How will you protect my privacy?

Information about you will be collected as part of the compassionate use program. The hospital (name is indicated on page 1 of this information sheet) will process and record your personal data, in particular that information regarding your health, exclusively in order to implement the program and for purposes of pharmaceutical vigilance. A full updated list of the organisations that will have access to your data will be available to the treating doctor on request.

The information collected in this program will be handled by qualified people who will follow the local requirements of confidentiality and sensitivity of the data.

Every effort will be made to keep all information about you private. Therefore, all information which is sent/provided outside of the hospital will show only a coded patient identification number instead of your name.

You will find the complete details about the processing of your personal data in the "Information Notice and declaration of consent to the processing of personal data" attached as Addendum A

6. Other Concerns

Will you tell me anything you learn that may change my mind about being in the compassionate use program?

If new findings come up during the program that would affect your safety and/or your willingness to participate in the program, you will be told as soon as possible so you can decide whether to continue or leave the program.

What if I have a question or concern?

You should feel free to ask questions about the program and your rights as a patient before, during, and after the program.

Whom can I call?

If you have any questions about this program or your rights, or if at any time you believe that you have a treatment-related injury or a reaction to the program medication, you should contact the treating doctor whose details are indicated on page 1 of this information sheet.

In any case you observe side effects go in contact with your treating doctor or report directly to FAMHP (Federal Agency for Medicines and Health products) :
www.eenbijwerkingmelden.be / www.notifierunefetindesirable.be

Important

Do not sign the consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Signing your name to the consent form means that you voluntarily agree to take part in this program.

This agreement can be withdrawn at any time.

Adult Patient Consent Form for givinostat Compassionate use Program

[insert physician name]

[insert physician address or affiliation]

[insert physician telephone number]

Program Title: Compassionate use Program (CUP) for the treatment with givinostat in ambulant patients of 6 years and older with Duchenne Muscular Dystrophy (DMD) aged 6 years and older and with concomitant corticosteroid treatment.

- I have been given ample time to read and understand the information sheet and this consent form. I have been given the opportunity to ask any questions I had about the program, and all the questions I asked were answered to my satisfaction. I understand the potential risks and benefits of my participation as described in the information sheet. By signing this consent form, I freely consent to be treated with givinostat under the treating doctor's direction. I also certify that, to the best of my knowledge, all information I have given about my medical history is true and correct.
- I understand that I am free to withdraw from the program at any time for any reason. I will notify the treating doctor if I decide to withdraw so that my participation may be ended in an orderly manner and future care can be discussed.
- I understand that I will be informed of any information that might relate to my willingness to continue in the program.
- If I have any physical or mental health symptoms or problems, I will tell the treating physician.
- I understand that I will receive a signed and dated copy of this consent form for my records.
- My consent to participate in this program does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved with this program. Nothing in the information sheet and this consent form is intended to change any applicable local laws regarding informed consent.

First and Last Names of Patient (Print)

Signature of Patient

Date

Where an adult patient has signed this assent form, a signed Parent/Guardian Informed Consent Form must also be completed.

First and Last Names of Parent/Guardian (Print)

Signature of Parent/Guardian Date

First and Last Names of Program Doctor or Person Administering the Consent (Print)

Signature of Program Doctor
or Person Administering Consent

Date

Impartial Witness (if needed)

I am an impartial witness and was present during the entire informed consent discussion. I attest that the information in this consent form was accurately explained to, and apparently understood by, _____, and that he/she freely gave consent to participate.

First and Last Names of Witness (Print)

Signature of Witness

Date

ADDENDUM A
PERSONAL DATA PROTECTION INFORMATION SHEET AND CONSENT FORM
for the processing of personal data

for Adult Patients

FOR COMPASSIONATE ACCESS PROGRAM (CUP) OF AN UNAUTHORISED DRUG (GIVINOSTAT)
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Dear,

<Treatment site> provides you with the information below relating to the processing of personal data as a result of the entry into force of new Regulation (EU) 2016/67 on 25 May 2018. This is information about you that will be collected by the <Treatment site> if you agree to the participation in the Compassionate use Program (CUP) of an unauthorised Drug (Givinostat) about which you have been informed through the dedicated Information Sheet and Consent Form that you have signed.

Please note that “personal data” means any information that may be used to identify you and therefore relates to you.

1. Why should you read this Information Sheet?

The <Treatment site> will use the information concerning you, and you have the right to be informed about what this information is, for what purposes it will be used, to whom it may be disclosed etc. After being informed of the consequences related to your refusal to consent, you will be free to choose whether to authorize or not authorize the <Treatment site> to process your personal data.

2. Who is the Controller of your personal data?

The Controller of your personal data is <Treatment site>

3. Other entities participating in the Compassionate use Program (CUP)

The other entities participating in the Compassionate use Program (CUP), who will deal with personal data processing, are as follows:

Entity name	Role in the Program

The contact person for your personal data processing, acting on behalf of, is <Treatment site>. His/her contact details are the following: <contact details>.

<Treatment site> guarantees that personal data processing is carried out while observing the fundamental rights and freedoms, and the dignity of the person involved, with special reference to confidentiality, personal identity and the right to personal data protection in compliance with the provisions of Regulation 679/2016/EU, the Italian national legislation of harmonization with such Regulation and the measures taken by the [relevant Data Protection Authority] on the subject.

The coded patient identification number for you, your weight and age will be sent to Italfarmaco S.p.A. and third parties (individuals and/or companies) that act on its behalf for the delivery of the drug.

4. Who is the Data Protection Officer (DPO) according to Art. 13.1b of Regulation 679/2016/EU?

DPO acting on behalf of <Treatment site>

To exercise your rights, you may contact the Data Protection Officer, <name> appointed by the <Treatment site>, who can be contacted at the following e-mail address: <email address>

5. What data do we need from you?

The data processed by <Treatment site> conducting the Compassionate use Program are ordinary personal, identifying data, as well as data belonging to special categories:

- genetic data
- biometric data
- data concerning health
- data on ethnic and racial origin
- data on lifestyle or sexual orientation

Please be informed that the provision of personal and special data which are the subject of this Compassionate use Program is necessary in order to process your data for the conduct of the above program. If you do not provide the data correctly, your participation in the Compassionate use Program will not be guaranteed.

Your data will be processed using a code that will be assigned to each patient.

The Data Controller will adopt all technical and organizational measures to ensure the observance of the data minimization principle as provided for by art. 89 of (EU) Regulation 2016/679.

6. Purposes for processing your personal data (Art. 13.1.c Regulation 679/2016)

All personal and sensitive data you provide will be processed by the Data Controller, based on one or more of the following legitimate reasons:

- Consent given by the person involved (Art. 6.1, letter a) and Art. 9.2, letter a) Regulation 679/2016);
- Protection of the vital interests of the person involved and/or the community (Art. 6.1, letter d) Regulation 679/2016);
- The processing is necessary to safeguard a vital interest of the person involved or of another natural person if the person involved is physically or legally unable to give his/her consent (Art. 9.2, letter a) Regulation 679/2016;
- The processing is necessary for reasons of public interest in the public health sector, such as protection from serious cross-border threats to health or to ensure high quality and safety levels in healthcare, medicinal products and medical devices, based on the European Union or Members States right that requires appropriate and specific measures to protect the rights and freedoms of the person involved, in particular professional secrecy (Art. 9.2, letter i) Regulation 679/2016;

Listed below are the purposes for which your personal data will be processed:

- Inclusion in company computer databases;
- Execution, monitoring and progress of the Compassionate use Program;
- Response to specific requests of the person involved.

7. Possible recipients or categories of recipients of the personal data (Art. 13.1, letter e) Regulation 679/2016)

Your personal data, when necessary, may be shared with/transmitted to (i.e. disclosed to one or more specified subjects), in addition to the subjects listed under point 7:

- subjects whose right to access the data is granted by the law, secondary or EU legislation, and collective bargaining.

Personal data regarding the state of health, lifestyle or sexual orientation, ethnic or racial origin, genetic data and biometric data are not in any case divulged (i.e. disclosed in any way to different unspecified subjects).

8. Transfer of data to non-EU countries (Art. 13.1, letter f) Regulation 679/2016/EU)
(complete or delete the following sections as applicable)

Personal data that are the subject of the Compassionate use Program will not be disclosed to third parties who do not operate on the EU territory.

Or, in case of an external Data Controller

Personal data which are the subject of the Program may be disclosed to third parties who do not operate on the EU territory.

Countries that guarantee an adequate level of protection and confidentiality

The following countries guarantee an adequate level of protection and confidentiality of personal data pursuant to articles 45, 46, 47 of Regulation 679/2016/EU.

Country	Adequacy decision	Appropriate/Suitable guarantees

For the Countries listed in this paragraph, which do not guarantee an adequate level of data protection and security, transfer is only possible when the person involved gives his/her consent (art. 49, paragraph 1, letter a). **These Countries are: ...**

The personal data which are the subject of the Compassionate use Program will be transmitted using the generated code and not the name.

9. Criteria used to determine the storage period (Art. 13.2, letter a) Regulation 679/2016)

<Treatment Site> declares that it will keep the Compassionate use Program documentation containing your personal data for XXXX (____) years or

Your personal data and medical findings will be archived in accordance with local law after the completion or premature termination of the Compassionate use Program but could be retained for longer if required by regulatory requirements.

10. Data processing modalities

The data, which may also be processed using electronic equipment, will be disseminated in a strictly anonymous way, for example in scientific and statistical publications and scientific conferences.

You can, at any time and without giving any justification, interrupt your participation in the Compassionate use Program; in this case no further data concerning him will be collected.

11. Your rights (Art. 13.2, letter b) Regulation 679/2016)

Please be informed that, at any time, you can exercise the following rights:

- Right to revoke your consent at any time, without prejudice to the lawfulness of the processing, based on the consent given prior to revocation, as per Art. 7.3 Regulation 679/2016;
- Right to ask the Data Controller, as per Art. 15 Regulation 679/2016, to access the personal data;
- Right to ask the Data Controller, as per Art. 16 Regulation 679/2016, to amend the personal data, if this is not in contrast with current regulations on data storage and the need to protect, in case of legal dispute, the health professionals who processed them;
- Right to ask the Data Controller, as per Art. 17 Regulation 679/2016, to cancel the personal data, if this is not in contrast with current regulations on data storage and the need to protect, in case of legal dispute, the health professionals who processed them;
- Right to ask the Data Controller, as per Art. 18 Regulation 679/2016, to limit the processing of the personal data;
- Right to oppose the data processing, as per Art. 21 Regulation 679/2016;

- Right to ask the Data Controller, only in the cases provided for by art. 20 of Regulation 679/2016, that the personal data be transmitted to another health operator in a legible format

12. Right to file a complaint (Art. 13.2, letter d) Regulation 679/2016

You will always have the right to file a complaint with the [*relevant Data Protection Authority*] in order to exercise your rights or for any other issue connected with the personal data processing.

2. STATEMENT OF CONSENT

I, the undersigned (first and last name) _____

born in _____ on _____

Taxpayer's Code _____

place of residence (Municipality, Province, State) _____

address _____

YES, I agree or **NO, I don't** agree that my personal data will be collected and processed during the program by the program treating physician or his/her staff and the person authorized by health and legal authorities as described and in accordance with the procedure defined in this document.

YES, I agree or **NO, I don't** agree that my personal data (as listed in section 3) will be sent to Italfarmaco S.p.A., and third parties (individuals and/or companies) that act on its behalf for the delivery of the drug.

YES, I agree or **NO, I don't** agree that my personal data will be to the transfer out of the EU for the purposes discussed in this document. I am aware that laws in these countries might not provide the same level of data protection as in my country. I agree to the processing and storage of my encoded personal data in these third-party countries.