Participant Information Sheet and Consent Form

A Post Market Clinical Follow Up (PMCF) Study to Assess the Safety and Efficacy of Use of Perfectha Subskin Lidocaine in the Treatment of Significant loss of volume in the Cheeks, Jawline and/or Chin.

We invite you to take part in a research study

- Before you decide to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take your time to read the following information carefully. Discuss it with friends and/or relatives if you wish.
- You are free to decide whether or not to take part in this trial. If you choose not to take part, this will not in any way affect the care you get from your own doctors.
- Ask us if there is anything that is unclear or if you would like more information.

Information about the trial

Protocol Number:	CS-22-05
Sponsor of the Trial:	Sinclair Pharmaceuticals Ltd, Eden House, Lakeside, Chester Business Park, Chester, CH4 9QT, United Kingdom
Contact Research Organisation:	Aesculape CRO Belseledorp 116, B0101 9111 Belsele, Belgium
Site Name:	<Site Name>
Main Address of the Site:	<Site Address>

Who can I contact in case of questions

Name	Function	In case of	Contact details
Surname, First name	Principal Investigator of the site	Information, problems or concerns	Phone N°, E-mail
	The trial staff	Information, problems, concerns	Phone N°
	Emergency contact	Emergency	Phone N°
	Patient rights ombudsman	Concerns relating to your rights as a participant in a trial	Phone N°
	Insurance Company of the sponsor	In case of disagreement or complaint on a damage claim	Policy N°:
	Data protection officer of the site	Questions relating to the confidentiality of your data	E-mail
Information Commissioner's Office	UK Data Protection Authority	Complaints relating to the confidentiality of your data	dataprotection@ico.org.uk

Table of Contents

The trial at a glance

Madam,
Sir,

You are being asked if you would like to take part in this trial because you are between 25-65 years old and you are interested in receiving treatment for the correction of age-related changes to your face. That is why we are inviting you to take part in this post-market clinical follow-up trial to evaluate the safety and efficacy of Perfectha Subskin Lidocaine as a treatment for significant loss of volume in the cheeks, jawline, and/or chin.

Before you agree to take part in this trial, we want to fully inform you about the trial and its implications in terms of organization, and its possible risks and benefits, so you can decide for yourself if you want to take part. This process is known as giving "**informed consent**".

This section will already give you an idea of what will happen during this trial, but we nevertheless ask you to read all the pages, even if it will take you some time. It is important that you read and understand all the information. If you don't do this, you will take part in the trial without fully understanding what you are signing up for. In addition to the written information, please ask me any questions that you have about the study before making your decision.

In this study, the Perfectha Subskin Lidocaine filler will be tested. This product has a CE Mark and is commercially available within the UK and Europe. It is also important for you to know that these products are approved for the treatments that will be made in this study. As required by regulation, the sponsor, Sinclair Pharmaceuticals Ltd, would like to collect additional safety and clinical performance information about these products. This type of study is called a post-marketing clinical follow-up study or PMCF study.

If you choose to take part in this study, you will receive a treatment with Perfectha Subskin Lidocaine in the area of your face that will be treated (you may also be treated in the other facial areas being assessed for this study if you meet the inclusion criteria and are seeking treatment in these areas). If you do receive treatment in more than one area, a primary treatment area is defined and you will be assigned to this treatment group of the study, but we will assess and ask you about the improvement in all areas you were treated.
The volume of product used will be dependent on the judgment of the Investigator to achieve the best treatment outcome. The maximum treatment volume is 3ml per area (the left and right side of your face are considered separate areas). You will then be followed-up for 18 months. A total of 7 visits is anticipated, starting with the screening and baseline Visit (i.e. including Perfectha Subskin Lidocaine administration). Those visits could be carried out at the same visit or different visits. Then 6 more follow-up visits will follow at month 1, month 3, month 6, month 9, month 12 and month 18. During the follow-up visits, photographs will be taken to check for any improvement (or worsening) of the treated area and a satisfaction questionnaire will need to be completed. At week 2, a phone call will be made between you and me to perform a safety assessment only.

If it agreed to be required by you and I and you are still eligible, an optional touch-up treatment at **month 1** may be performed. If you do receive the optional touch-up treatment at month 1 there will be an additional follow up phone call at 6 weeks to assess safety only.

If you agree to take part in the trial, I will check your suitability to participate in this trial, which includes an assessment against defined inclusion and exclusion criteria.

Your participation in this study is expected to last for 18 months.

It is also very important that you know that the treatment with any dermal filler can cause unwanted **side effects**. Therefore, it is really important that you **report any side effects or any new health problems to me.**

The sponsor of this trial, has taken out public liability insurance for this trial, as required by law.

Pregnancy during the trial will result in **your exclusion** from the study. I will discuss with you the appropriate methods of contraception.

Sinclair Pharmaceuticals Ltd. has designed this trial and has asked me and the hospital/clinic - together with other investigators and their hospital/clinics - to conduct it, and pays us a fee for it.

This means that all treatments and examinations that you will undergo or receive specifically in the context of the trial will be **free of charge for you**.

Your **personal data** collected during this trial will be **treated confidentially**. The **results** of the study may form the basis of future presentations and publications.

You should also know that to be included in this trial, you will need to consent to photographs being taken of your face at the different visits. However, you will have the option to request that (i) a black box is used to cover your eyes on the photographs (as long as it does not hinder the assessment) when transferred to the sponsor or independent evaluator to prevent identification and (ii) that your photographs are not used for presentations and publications or in promotion materials of Perfectha Subskin Lidocaine products.

Please note that you are in no way obliged to participate in this study. Even if you have already started the trial, you can stop at any time. I will accept your decision and continue to take appropriate care of you in relation to the treatment that you received in the study.

An independent ethics committee has evaluated and approved the design of this trial. However, do not feel obliged to participate in this study because they have approved the trial.

To be able to take part in this trial, you must, for your own safety, **agree that I, the investigator, inform your treating physicians** of your participation in this trial. You **are not allowed to take part in another clinical trial at the same time** without informing me or the trial staff prior to you joining the other clinical trial. We may refuse that participation to other trials for justified reasons. It is also very important that **you cooperate** and follow the instructions that the trial staff and I give you regarding the trial.

If you agree to take part, you will need to sign the informed consent form. I will also sign the form and thereby confirm that you have received the necessary information about the trial. You will receive a signed and dated copy of the form.

Now that you have some idea what this trial is about, please take your time to read the other pages of this document. You do not have to do that all at once. It is important that you understand what you are reading. Feel free to discuss the trial with a trusted person (for example a friend, relatives, your family doctor). My staff and I are also available to help you

if there is anything that is not clear. It is our job to make sure that you understand all the information.

With my best regards,

Your study doctor and investigator

Description of the trial and your rights when participating

1. Why are we doing this trial?

Post-marketing clinical follow-up or PMCF studies are required by regulation to collect additional safety and clinical performance information about medical devices that have a CE-Mark and are commercially available within Europe.

This post-marketing clinical follow-up trial (further on referred to as “trial”) will evaluate the efficacy and safety of the medical device, Perfectha Subskin Lidocaine, an aesthetic treatment for significant volume loss in the cheeks, jawline, and/or chin (see Figure 1). Perfectha Subskin Lidocaine is an injectable cross-linked hyaluronic acid-based dermal filler gel. It is important for you to know that these products are approved by the relevant regulatory bodies for the treatments that will be made in this study.

Hyaluronic acid is a substance that is naturally present in the skin, that gradually decreases with the aging process. With its high-water binding capacity, hyaluronic acid contributes to the hydration of our skin. A filler based on hyaluronic acid is a high-tech product consisting of a gel that is injected into the skin or into the fatty tissue of the face. The body will absorb the gel gradually and completely over time.

There are different types of hyaluronic acid products that are used in aesthetic treatments; some are used to correct volume loss and lift the skin; others are more for smoothing the appearance of fine lines or wrinkles or hydrating the skin.

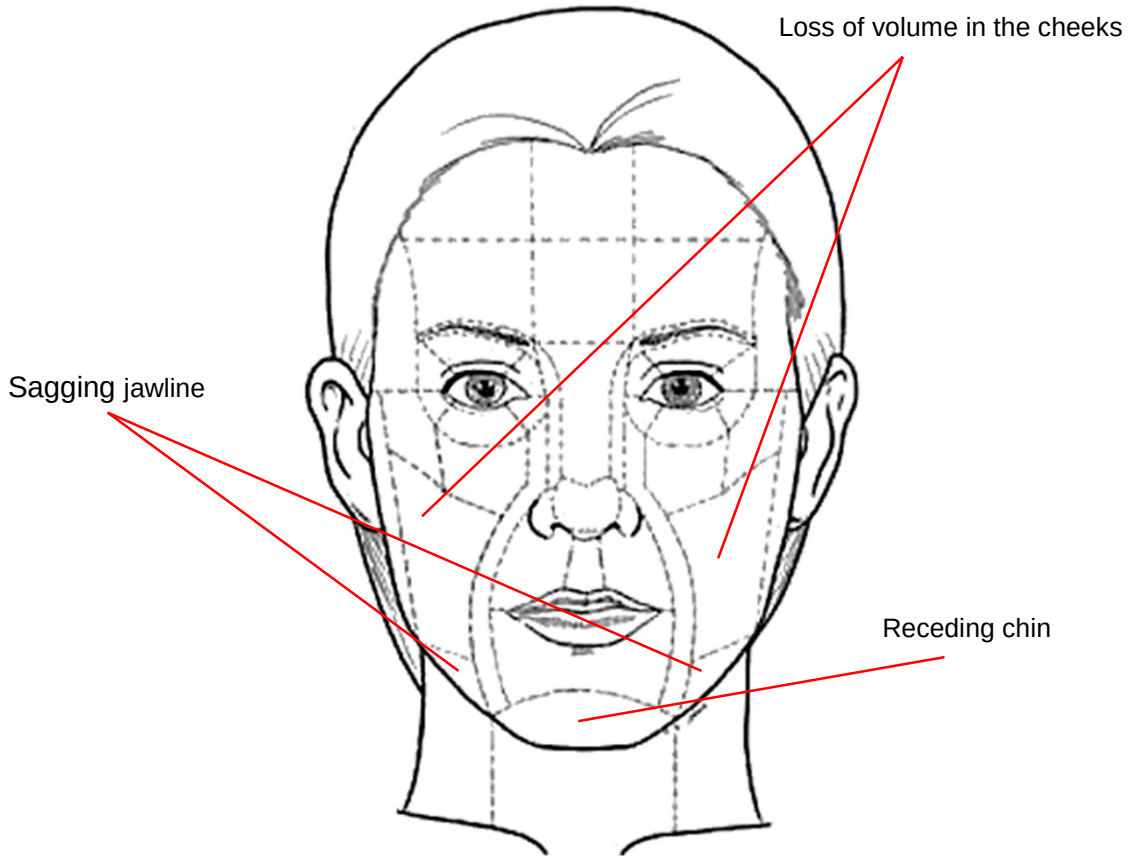

Figure 1. Facial treatment areas of Perfectha Subskin

2. Why am I being asked to take part?

You are being asked to take part of this study because you are between 25-65 years old and you are interested in receiving treatment for the correction of age-related changes to your face (i.e., loss of volume in the cheeks, jawline sagging, and chin retrusion).

The investigator or trial staff will discuss with you the requirements to enter the trial.

3. Do I have to take part in the trial?

Your participation in a trial is voluntary and must remain free of any coercion. This means that you have the right not to take part in the trial or to withdraw at any time without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the study doctor nor will it affect the quality of your future medical care.

There are other similar aesthetic treatments (differ in composition and treatment area(s)) compared to Perfectha Subskin Lidocaine available to restore facial volumes. These treatments can be discussed with the investigator or his/her delegate.

4. What will happen during this trial?

This trial will include about 69 participants, spread over 2 study sites located in the United Kingdom.

The test product in this study is Perfectha Subskin Lidocaine (3 x 1ml syringes) which contains a cross-linked hyaluronic acid (HA) (20mg/mL) + 0.3% lidocaine hydrochloride + phosphate buffer saline (q.s. 1mL).

Lidocaine hydrochloride is a local anaesthetic agent which is included to reduce pain caused by the injection during the treatment.

After you have given your consent to participate in this study, you will be assessed to see if you meet the requirements to participate in the study. If you meet the criteria, you will be assigned to the appropriate treatment in the area where it is needed. In addition, photographs will be taken of your face from different angles. A black box will be put over your eyes on the photographs, if you wish so that you remain anonymous.

At the baseline visit, the injection will be administered slowly into the deep subcutaneous (under the skin) fat tissue or into the supraperiosteal (close to the bone) area in the appropriate zone(s) of the face by the study doctor. The volume of the injection varies according to the desired correction and may be administered in a number of small injections. At each visit, photographs are taken of your face to assess the treatment effect. At 3 months and 18 months, these photographs are reviewed and an assessment made as to whether an improvement can be seen. This assessment is done by an independent evaluator. Table 1 below describes the procedures for each study visit in more detail.

If deemed necessary by the study doctor, an additional treatment can be given at month 1.

In the rare case that significant side effects occur (see Table 2), the investigator may deem it necessary to carry out additional tests, which will then be considered study specific.

Table 1: Schedule of assessment and study timepoints

	Screening/ baseline visit	2 Weeks	1 Month	6 Weeks	3 Months	6 Months	9 Months	12 Months	18 Months
Visit ± maximum window	Day 0	D14 ± 3	D30 ± 3	D42 ± 3	D90 ± 3	D180 ± 7	D270 ± 7	D360 ± 14	D540 ± 14
Informed consent	X								
Inclusion/Exclusion criteria	X								
Medical history	X								
Physical examination	X								
Pregnancy test	X								
Prior/Concomitant medications/Treatments	X								
Facial photography (full face, 45° angle left and right, 90° angle left and right)	X		X		X	X	X	X	X
Photographic assessment by blinded remote independent evaluator					X				X
Global Aesthetic Improvement Scale (GAIS) by the subject			X		X	X	X	X	X
Global Aesthetic Improvement Scale (GAIS) by on-site live independent evaluator			X		X	X	X	X	X
Subject self-assessment for overall satisfaction	X		X		X	X	X	X	X
Subject Pain at Injection Assessment (using VAS)	X		(X)						
Investigator self-assessment for injection satisfaction	X		(X)						
Subject diary (provision and collection)	X	X	X	X	X	X	X	X	X
Administer study treatment	X		(X)						
Safety assessment: Identify and Record AEs		X	X	X	X	X	X	X	X
Investigator ISR Evaluation	X	X	X	(X)	X	X	X	X	X

4.1. Day 1 – Screening Visit (Baseline) – about 1-2 hours

During the screening/baseline visit, the following will be done:

Screening/Enrolment activities

- If you are willing to take part in the study, you must sign this Informed consent form.
- You will also be asked to consent to photographs of your face being taken during the course of the study. These photographs will be used for scoring on photographs by an independent evaluator at month 3 and month 18 and for publication of the study data in literature or for presentations. Where possible (in order to not prevent the independent evaluators from making unhindered assessments of treatment areas such as the cheekbones and mid face),

there will be an option to put a black bar over your eyes in the photographs, if you wish so that you remain anonymous or to not use your photographs for publications or presentations purposes or promotion of Perfectha Subskin Lidocaine products.
- You will be screened according the inclusion and exclusion criteria.
- Your medical history will be analysed.
- There will be a physical examination where your vital parameters (e.g. blood pressure, weight and height) will be measured.
- There will be questions about whether you are taking/have taken any medication or are undergoing treatment that may affect the results of the study.
- A urine pregnancy test will be performed on potential childbearing women.

Baseline visit/treatment activities
- Your face will be photographed at different angles (full face, 45°, and 90°).
- You will be given a questionnaire to indicate your overall satisfaction with the appearance of the area(s) of your face that will be treated.
- The treatment will take place. The specialised health practitioner will inject Perfectha Subskin Lidocaine into the specific area(s) of your face.
- The investigator will fill in the injection satisfaction questionnaire.
- You will be given a visual analogue scale (VAS) to rate the pain you experienced during injection.
- The investigator will evaluate any injection site reactions (ISRs) as per the ISR table.
- You will receive a blank diary (Day 1 – Day 30) to record any adverse events that may occur.
- You completed diary will need to be returned at your next scheduled visit.

If necessary, the screening and baseline visits can be performed on different days but you will need to return to the clinic within 14 days of your screening appointment to receive your treatment and complete the baseline assessments (otherwise a repeat screening visit would be required).

4.2. Week 2 phone call – about 10 minutes

- During the phone call at week 2, a safety assessment is performed to record any side effects that may have occurred.

4.3. Month 1 – Follow-up visit and/or optional second treatment – about 30-60 minutes

- Photographs will be taken of your face at different angles (full face, 45°, 90°). A black box will be placed over the eyes in the photograph if you have ticked this option when signing this informed consent form.
- You will be given a questionnaire to indicate your overall satisfaction with the appearance of the treated areas(s) of your face.
- A safety assessment is performed including the recording of any Adverse Events (AEs) and Injection Reactions (ISRs) from your diary (Day 0 –Day 30)/ISR form. The investigator will evaluate any injection site reactions before and after the optional touch-up treatment is administered (if applicable).
- You will return the completed subject diary (Week 0 – Day 30) and will be given a blank diary for the next period (Week 4 – 18 months). If an additional treatment was received, a 30-day diary for recording ISRs will be provided and should be returned at the Month 3 visit.
- You and the on-site independent assessor will be asked to carry out a live evaluation using the GAIS scale and the photographs taken at the screening visit.

- If deemed necessary by the investigator and agreed by yourself, you will receive an optional touch up treatment.
- If you receive the optional touch up treatment the investigator will fill in the injection satisfaction questionnaire and you will be given a visual analogue scale (VAS) to rate the pain you experienced during injection.

4.4. Week 6 phone call – about 10 minutes

- During the phone call at week 6, a safety assessment is performed to record any side effects that may have occurred.

4.5. Month 3 till Month 18 Visits – about 30-60 minutes

For visits occurring during month 3 to month 18 of the study period, the following will be carried out:

- Photographs will be taken of your face at different angles (full face, 45°, 90°). A black box will be placed over the eyes in the photograph if you have ticked this option when signing this informed consent form.
- You will be given a questionnaire to indicate your overall satisfaction with the appearance of the treated areas(s) of your face.
- Subject will return the (in)complete filled in subject diary (Week 4 – Month 18) and will be given a blank diary (Week 4 – Month 18).
- A safety assessment is performed including the recording of any Adverse Events (AEs) from the diary (Week 4 – Month 18) and assessment/review of injection site reactions (ISRs). If the patient diary is not brought to the visit or is lost, any AEs should be recorded at the next follow-up visit.
- You and the on-site independent assessor will be asked to carry out a live evaluation using the GAIS scale and the photographs taken at the screening visit.

In addition on month 3 and 18:

- A blinded remote independent assessor will evaluate the photographs taken for any improvement in your face using an appropriate rating scale for the area(s) treated (here: blinded means the assessor does not know at what time in the study period the photos were taken). You will not be present for this assessment.

(Optional) on month 3:

- If you have received the touch-up treatment at month 1, you will return the 30-day diary, next to the (in)complete filled in subject diary (Week 4 – Month 18), to perform a safety assessment and record any AEs and/or ISRs

4.6. End of Study Visit/ Premature Discontinuation

Procedures described for month 18 visit will be applicable:

- You will come to the Investigator's office.
- If applicable, you will return your completed patient diary.
- Eventual adverse events and concomitant treatments will be collected.

4.7. Unscheduled/Rescue treatment Visit

If an unscheduled visit is required due to any side effects occurring, you should receive immediate medical attention. An evaluation by an appropriate specialist physician will be performed in case of the occurrence of an intravascular injection.

In case of side effects of the device affecting your well-being, the investigator is authorised to prescribe rescue treatment. The adverse event (side effect) will be recorded in the electronic Case Report Form (eCRF) and your medical record, including details of the rescue medication.

5. Will I benefit from the trial?

The information obtained during a trial may contribute to a better understanding of the use of the Perfectha medical devices in daily practice or to the development of new medical devices for the treatment of yourself or future subjects.

The Perfectha Subskin Lidocaine medical devices may or may not be beneficial in treating your facial volume loss or improving your appearance. Even if it is beneficial to you in the first instance, a potential return to your pre-treatment appearance over time is still possible.

6. What are the possible risks and discomforts of taking part in this trial?

6.1 What are the possible side effects of Perfectha Subskin Lidocaine?

Participation in a trial involves some risk.

The use of hyaluronic filler such as Perfectha Subskin Lidocaine can have side effects. Some of these side effects are already known, and some are not known. Even if previous studies have shown that Perfectha Subskin Lidocaine is normally well tolerated, you may still experience side effects.

The information in the table (Table 2) is extracted from the Clinical Investigation Report (Ref 1). All adverse events recorded in Perfectha studies performed to date were counted and divided by adverse event type. In a total number of 1,963 subjects, 403 Adverse events were recorded during Perfectha clinical trials.

Table 2. Frequence of Adverse Events during Perfectha Trials

Frequent AE (≥10%)	**Less frequent AE (<10%)**
• Localised injection related reactions (bleeding, swelling (oedema), bruising (haematoma), itching (ecchymosis), redness (erythema), pain)	• Foreign Body Granulomas • Nodule • Allergic Reaction • Failed Implant • Prolonged Oedema & Erythema (90 days) • Palpable Fibrous Cord • Ectropion • Cellulitis • Herpes reactivation

If you have ever suffered from herpes infection, the risk of herpes reactivation following dermal filler injection is rare (about 1.5%) (Ref.2). If you have an herpes episode in the treatment area at the time of study visit, you can miss the visit (or attend for a safety assessment without an efficacy assessment/photographs) and attend the next study visit when the herpes has resolved.

Other currently unknown risks and discomforts could occur. **Therefore, it is very important that you report any new or worsened health problems immediately to the investigator, regardless of whether or not you think it has to do with the trial (or to Perfectha Subskin**

Lidocaine), and even when it is already described in this document. If you need to use other medication, discuss this with the investigator before taking it. If, for any reason, you consult another treating physician during the trial you must inform him/her that you are taking part in a trial. This could be important in determining a diagnosis and giving you the correct treatment if needed.

Most symptoms usually disappear within 1 -2 weeks after the injection. The investigator will perform a safety assessment by phone call at 2 weeks, if side effects still remain at 2 weeks, you should report this and the Investigator will decide if treatment is required. Side effects will be monitored in your patient diary for 30 days following injection and if these effects continue to persist l, you should report this to your Investigator as soon as possible. The investigator should treat these side effects with the appropriate treatment.

6.2 Can I take other medicines during this trial?

During the 14 days before and following the injection, you cannot receive a COVID-19 vaccination. Other vaccinations (e.g. flu or travel vaccinations) may be scheduled.

Aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), antiplatelet agents, thrombolytics or anticoagulants should not be taken within one week prior to injection visit and 1 month after treatment.

Do not hesitate to ask your study doctor for more explanation about the use of other medicines.

6.3 Will my participation in this trial have an impact on my daily activities?

It is advised to avoid exposure to the sun, UV-rays and temperatures below 0°C, sauna or hammam sessions during the two weeks following the injection procedure. Also, you should avoid any cosmetic products (e.g. make-up, skin care products) during the 12 hours following the injection procedure. Finally, you should not apply intense pressure or massage the treatment site for a few days after the injection.

6.4 Can I get pregnant or breastfeed during the trial?

This section is intended solely for participants with a potential to get pregnant.

Female participant: Because the effects of Perfectha Subskin Lidocaine on an unborn child or infant is not known, you will not be allowed to take part in this trial if:

- you are pregnant,
- wish to become pregnant during the course of the trial,
- if you are breastfeeding.

If you take part in the trial, you must use one effective medically recognised method of contraception, 12 weeks prior to study entry and during the entire study (18 months). Please discuss this point with your investigator if this applies to you. Please inform the investigator in case you would decide during the trial to change your method of contraception.

You will be required to have a pregnancy test (urine) at trial start before the administration of Perfectha Subskin Lidocaine. A repeated pregnancy test must be done if you miss any periods or your menstrual cycle becomes irregular.

Nevertheless, if you become pregnant during the trial, you should inform immediately the investigator and your treating physician. (S)he will ask you to sign a specific informed consent (for the pregnant participant) to follow up your pregnancy and its outcome.

7. What if something goes wrong within the trial?

Even if there is no fault, the sponsor is liable for harm caused to you whether directly or indirectly related to your participation in the trial. The sponsor has taken an appropriate insurance (a so called “NO FAULT INSURANCE”) for this liability (Ref. 3). A copy of the insurance certificate can be obtained from the investigator or trial staff.

If you (or in the event of death, your rightful claimants) seek compensation for a harm to your health as a direct or indirect result of participating in the trial, you must inform your investigator or trial staff promptly.

If the investigator believes that a link between the new or worsened health problem(s) and the trial is possible, he/she will inform the trial sponsor. The sponsor will then immediately initiate the declaration procedure to its insurance company. If the insurance company considers it necessary, it will appoint an expert to assess whether there is a link between your reported health problem(s) and the trial. The insurance does not cover the natural progression of your facial volume deficit or the known side effects of the treatment you would have received without taking part to the trial (that is your standard treatment).

Whenever you feel it is appropriate or if you or your rightful claimants disagree either with the investigator or with the expert appointed by the insurance company, you may contact the insurance company or proceedings may be brought against the insurance company. You will find the contact details on the front page of this form.

8. What if other treatment options or new information on the Perfectha Subskin Lidocaine filler becomes available during the course of the trial?

During the course of the trial, important new information might become available, possibly affecting your decision to (further) participate. It is the duty of the investigator to discuss this new information with you and to give you the opportunity to re-consider your participation in the trial.

If you decide to stop taking part in the trial or if you are no longer able to participate, your investigator will see to it that you continue to receive the best possible medical care for the treatment of any side effects arising from the study treatment.

9. Can my participation end prematurely?

As explained in detail below, your trial participation may end prematurely when

- you decide to withdraw your consent,
- the investigator decides to end your trial participation, or
- other entities interrupt or end the trial.

In any case, if your trial participation ends prematurely, the investigator will discuss your future medical care with you. The sponsor can continue to retain and use any data that have already been collected before the end of your participation. This is to avoid skewing / biasing results of the trial.

If you experience a side effect at the moment of stopping the trial, the investigator may contact you in the future, if you consent so, to see if it has resolved or not after the end of the trial participation.

If you experience a new side effect after the end of your trial participation you may contact the investigator to ask for a follow-up.

9.1 You decide to withdraw your consent

You are entitled to withdraw your consent for any reason, at any time, without having to justify your decision. However, for your safety, you should inform the investigator of your decision. Although it is not mandatory, it may be useful for the investigator and for the sponsor to know the reason of your decision (for example side effects, frequency of clinical visits,…).

If you withdraw your consent, this means you decide to stop:

- the treatment with Perfectha Subskin Lidocaine filler (if withdrawal occurred prior to filler administration), and
- all trial-related visits and examinations.

Please discuss with your investigator to evaluate the practical modalities of your withdrawal (in light of your situation), including any follow up-visits or procedures.

In any case, no new data will be sent to the sponsor.

9.2 The investigator decides to end your participation

The investigator may end your trial participation because

- you become pregnant during the trial,
- it is better for your health,
- he/she determines that you are not following the instructions given to participants, or
- any other reason that will be explained.

9.3 Other entities may interrupt or end the trial

The sponsor, the competent UK health authorities or the Ethics Committee may interrupt or end the trial because

- the information gathered shows that Perfectha Subskin Lidocaine fillers are not effective (does not deliver a sufficient level of improvement in the facial appearance of the trial participants),
- the Perfectha Subskin Lidocaine fillers cause more (serious) side effects than anticipated, or
- any other reason that will be duly motivated by such party.

10. Will my participation in the trial involve extra costs for me?

10.1 Examinations and treatments paid by the sponsor

The sponsor has arranged to compensate the hospital or site for

- the time devoted to the trial by the investigator and the trial staff,
- the visits/consultations and all scheduled examinations specific to the trial,
- the investigational treatment

The treatments and examinations that are trial specific will be paid by the sponsor and will not be charged to you.

10.2 Other expenses paid by the sponsor

You will receive up to £240 upon completion of the study to compensate you for any expenses incurred during the study (this is calculated as a standard amount of £30 per visit to the clinic and £15 for each telephone visit).

For any unscheduled visits, you will be compensated an additional £30 per visit.

Please contact the study staff for the practical arrangements of your clinic visit.

11. Which data are collected about me during the trial and what will happen with them?

11.1 Which data are collected and processed during the trial?

The collected and processed personal data concern information about your health and facial volume deficit. This includes your medical history, some of your background information (for example your age, sex, and ethnic origin) and the results of examinations required by the trial.

11.2 How will the investigator treat my personal data?

The investigator is bound by professional secrecy about the data collected.

This means that he/she will never reveal your identity, including in a scientific publication or a lecture and that he/she will pseudonymize your data (that is by replacing your identity by an identification code in the trial) before sending them to the sponsor.

Therefore, the investigator and the trial staff under the responsibility of the investigator, will be the only ones able to establish a link between your identity and the data transmitted during the trial, with the exceptions listed under section 11.6.

The data transmitted to the sponsor will not allow the sponsor to identify you.

11.3 What will happen to information about me collected during the trial?

Your participation in the trial means that your personal data

- are collected by the investigator, and
- are used in an encoded form by the trial sponsor.

The investigator and the sponsor can only use the encoded personal data for research purposes in connection with presentations and scientific publications within the context of the trial that you participate in, or for a broader use of the encoded data if described below.

If wider use of the encrypted data is planned, it will be mentioned below.

In addition, the sponsor may provide access to the encoded data to external researchers (that are not involved in this trial). In the event an external researcher wants to use the data in a project not yet described in this document, this project will have to be approved by an Ethics Committee. If your encoded trial data are sold, you will not benefit from this.

11.4 How will my data be handled?

Your trial data will be processed in accordance with the General Data Protection Act (GDPR, Ref. 4) and in line with the GDPR guidance for research in the NHS/HSC (Ref 3.). The sponsor is responsible for this processing.

Processing your personal data in this trial is allowed because we are conducting scientific research and you have given your consent.

11.5 Do I have access to my data collected and processed during the trial and can I rectify them?

You are entitled to ask the investigator what data are being collected about you and how those data will be used in connection with the trial.

You have the right:

- to inspect and access these data
- to have all your data erased
- to ask for correction if they are incorrect,
- to restrict the processing of your data.
- to object to the processing of your personal data
- to withdraw your consent for the processing of personal data. However personal data collected before withdrawal will be kept to avoid skewing of results in the trial.

11.6 Who, other than the Investigator and his staff, has access to my personal data?

To verify the quality of the trial, it is possible that your personal uncoded data or information in your medical records relevant for the trial, will be examined by people outside the trial staff but under the responsibility of the investigator. These persons must be subject to professional secrecy or a confidentiality agreement. The following might be considered:

- the personnel designated by the sponsor of the trial (MONITORS and AUDITORS), and people or organisations providing services for or collaborating with the sponsor. They will however never transfer your name and contact details to the sponsor.
- inspectors of competent health authorities worldwide
- an independent audit group
- people designated by the Ethics Committee

For the needs of the trial, the encoded trial data may be sent to other EU and non-EU countries and may be reviewed by

- personnel (other than the inspectors) of competent health authorities (The United Kingdom Health Research Authority NHS) and other EU and non-EU countries,
- the evaluating Ethics Committee(s),
- external researchers,
- the sponsor of the trial, personnel designated by the sponsor, and people or organisations providing services for or collaborating with the sponsor, and/or
- group companies of the sponsor in the UK, and in other EU and non-EU countries.

The European regulation and the United Kingdom legislation on data protection have requirements for transferring data to non-EU countries. The sponsor must ensure equivalent guarantees regarding personal data protection standards before transferring the encoded data to non-EU countries. If for this purpose, there is a data protection agreement, a copy of this agreement may be obtained via the investigator. You can always contact your investigator to obtain more information about any such transfers.

11.7 What will happen to the results of the trial?

After trial closure, a description and the results of this clinical trial may be published in specialised scientific journals. A copy of the scientific publication or a summary for laypersons can be obtained from the investigator or the trial staff.

A description of the trial will also be available on ISRCTN database (https://www.isrctn.com/). You can search this website at any time using the trial number given on the front page of the informed consent form. The website will include a summary of the results within 1 year after the end of the trial.

This website or publications will not include information that can identify you.

11.8 Will my data be used for other purposes than for the trial in which I take part?

The results of the trial will be used to answer the scientific questions of the trial. In addition, and if you consent so, your photographs could be used for presentations and publications concerning the trial and in promotional materials for Perfectha Subskin Lidocaine products.

11.9 How long will my data be kept?

After the end of the trial your encoded data will be retained for at least 25 years (Ref. 5) to ensure the validity of the research. This will also be the case if you stopped trial participation prematurely.

12. Who has reviewed and approved the trial documents?

The documents of the trial have been reviewed by an independent Ethics Committee within the United Kingdom.

It is the task of the Ethics Committees to protect people who take part in a trial.

You should not under any circumstances take their approval as an incentive to take part in the trial.

(Form to be on headed paper)

IRAS ID: _____

Centre Number: _____

Study Number: CS-22-05

Participant Identification Number for this trial: __ __ __ __ __

CONSENT FORM

Title of Project: A Post Market Clinical Follow Up (PMCF) Study to Assess the Safety and Efficacy of Use of Perfectha Subskin Lidocaine in the Treatment of Significant Loss of Volume in the Cheeks, Jawline and/or Chin

Name of Researcher:

1. I confirm that I have read the information sheet dated __ __ / __ __ / __ __ __ __ (version __ . __) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the data management company Adware, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐

1. I understand that the information held and maintained by _____ [*(enter name of organisation(s) that will be providing you with data, including any NHS/HSC organisations)*] may be used to help contact me or provide information about my health status. ☐

2. I agree to take part in the above study. ☐

3. Optional for participating in this trial

• The sponsor wants to take photographs of your face during the course of the study to check for any improvement of the treated area. All of these photographs will be used for scoring by an independent evaluator at month 6 and month 18 and for publication of study data or for presentations.

Do you want a black bar to put over your eyes to remain anonymous?

(Tick as appropriate. If you leave this question open, we assume the answer is 'I want to remain anonymous')

☐ **Yes, <u>I want to</u> remain anonymous**	☐ **No, <u>I don't want to</u> remain anonymous**

• The sponsor would also ask you whether your photographs might be for presentations and publications concerning the trial and in promotional materials of Perfectha products.

Do you agree that your photographs can be used for presentations and publications concerning the trial and in promotional materials?

(Tick as appropriate. If you leave this question open, we assume the answer is 'I do not agree for my photos to be used for this purpose'.)

☐ **Yes, <u>I agree</u> for my photos to be used for this purpose**	☐ **No, <u>I do not agree</u> for my photos to be used for this purpose**

Name of Participant	Date	Signature

Name of Person seeking consent	Date	Signature

Glossary

DPA: The Data Protection Authority ensures that personal data are handled with care and thoroughly protected, and that your future privacy also remains guaranteed.

NO FAULT INSURANCE:

The sponsor is liable for any injury or any damage that the participant has suffered, and which is directly or indirectly related to the clinical trial. You do not have to prove any mistake in this respect.

MONITOR and AUDITOR

Both the monitor and auditor work for, or on behalf of, the sponsor.

The monitor takes care of a continuous quality check during the course of a trial. The auditor performs a quality check after the trial. They verify if the trial is being/was conducted according to the protocol, if the reported data are liable and if the clinical trial was conducted according the applicable rules.

References

[1] Farmer P. Clinical Evaluation Report PERFECTHA LIDOCAINE.; 2020.

[2] King M. Prophylaxis and Treatment of Herpetic Infections. J Clin Aesthet Dermatol. 10 January 2017:E5-E7.)

[3] This is in accordance with the The Medicines for Human Use (Clinical Trials) Regulations 2004 related to experiments on humans.

[4] General Data Protection Regulation No 2016/679 of the European Parliament and of the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

[5] The British Data protection Act of 2018 on the protection of natural persons with regard to the processing of personal data.