

Collective information note

This notice is intended for patients meeting the inclusion criteria for the SOPRANO study. It provides information on why your health data may be collected and used.

Your data can help your doctor treat you. When you visit your GP, and pick up your medication from the pharmacy with a prescription, some of your health information is recorded. This information is used so that health professionals are reimbursed for the care they provided to you.

Your data can also be used for research, to find solutions that improve everyone's health. Your data, and that of other people, are studied together to improve knowledge of diseases, and treat them better.

That's why **Atnahs Pharma UK Ltd (Pharmanovia)** is conducting this study.

The purpose of this notice is to provide you with all the information you need to know about this study : its objectives, the people who manage it, the data it contains and your rights.

1. What is the « SOPRANO study - Study of the real-life use of SUNOSI® and its impact on compliance with continuous positive airway pressure (CPAP) in patients with Obstructive Sleep Apnea-Hypopnea Syndrome (OSAHS) »?

Your health data is used to carry out a research called the « **SOPRANO Study - Study of the real-life use of SUNOSI® and its impact on compliance with continuous positive airway pressure (CPAP) in patients suffering from Obstructive Sleep Apnea-Hypopnea Syndrome (OSAHS)** ». The aim of this research is to describe the real-life evolution of the CPAP reimbursement package between the period 6 months before and the first 6 months after the initiation of treatment with SUNOSI®.

The use of your data for this research will be carried out in a very secure environment. Access to your data will take place :

- on a secure technological platform, appraised by the Cnil and compliant with the requirements of the SNDS security guidelines ;
- through CEMKA, recognized for its high level of expertise, confidentiality and independence.

Therefore, Atnahs Pharma UK Ltd (Pharmanovia) will never have direct access to your personal data.

2. Who carries out the research?

Atnahs Pharma UK Ltd (Pharmanovia), a private company based in the United Kingdom (Sovereign House, Miles Gray Road, Basildon, SS14 3FR, UK), has decided to carry out this research.

The conduct of this scientific study falls within the legitimate interests of Atnahs Pharma UK Ltd (Pharmanovia) as it is responding to the request of the Transparency Commission of June 24, 2020 with this study.

3. What data is made available for this study ?

Your health data that made available for research purposes comes from the main database of the Système national des données de santé (SNDS). This database mainly includes information on Health Insurance reimbursements, hospital activity data, medical causes of death and data on covid-19 vaccinations and screening. More specifically, the data required for the research are as follows: **SNDS data from January 1, 2006 to December 31, 2023.**

4. Can I be identified?

This study **does not contain any administrative data enabling you to be directly identified**, such as surnames, first names, postal, e-mail, telephone and bank details.

5. How long will my data be kept?

The data will be made available for research purposes for a **period of 4 years** (*this period may not exceed five years from the date on which the data was last made available*). In exceptional cases, this period may be extended by two years. At the end of this period, the data will be removed from the computing environment on which the researchers work. They will therefore no longer be accessible to CEMKA.

6. Am I obliged to participate in this research?

La fourniture des données vous concernant pour la recherche n'est pas une obligation. Par ailleurs, vous disposez de plusieurs droits sur ces données :

- Le droit d'opposition vous permet, si vous ne souhaitez pas que les données de santé vous concernant soient utilisées pour cette recherche, de vous opposer à leur utilisation. L'exercice du droit d'opposition ne remettra pas en cause vos soins ni la relation avec l'équipe médicale dans votre établissement de santé ;
- Le droit d'accès vous permet de demander à consulter les données vous concernant et à en obtenir une copie ;
- Le droit de rectification vous permet de demander de faire corriger les données vous concernant si vous constatez qu'elles contiennent une erreur ;
- Le droit à l'effacement vous permet de demander que les données vous concernant

soient effacées ;

- Le droit à limiter l'utilisation des données vous concernant, ce qui empêche temporairement leur inclusion dans la recherche.

You are under no obligation to provide your personal data for research purposes. In addition, you have several rights with regard to this data:

- If you do not want your health data to be used for this research, you have the right to object to their use. Exercising your right to object will not jeopardize your care or your relationship with the medical team at your healthcare establishment;
- The right of access allows you to consult your personal data and obtain a copy;
- The right of rectification enables you to ask for your personal data to be corrected if you find that it contains an error;
- The right to erasure allows you to request that your personal data be deleted;
- The right to limit the use of your data, which temporarily prevents its use in the context of this study.

Pour exercer ces droits, il faut contacter le délégué à la protection des données d'Atnahs Pharma UK Ltd (Pharmanovia). Voici les coordonnées dont vous avez besoin :

To exercise these rights, please contact the Data Protection Officer at Atnahs Pharma UK Ltd (Pharmanovia). Here are the necessary contact details:

Organism	Mailing adress	Postal adress
Atnahs Pharma UK Ltd (Pharmanovia)	info@pharmanovia.com	Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR, UK (Royaume-Uni)

If you feel that your rights regarding the use of your data have not been respected, you can **contact the Commission Nationale de l'Informatique et des Libertés (CNIL)** to make a complaint (<https://www.cnil.fr/plaintes> or CNIL - Service des Plaintes - 3 Place de Fontenoy - TSA 80715 - 75334 PARIS CEDEX 07). The CNIL is the supervisory authority responsible for overseeing the application of data protection rules, in order to protect the fundamental rights and freedoms of individuals with regard to data processing.