ANAPHYLAXIE.net

Participation Agreement

Anaphylaxis register

between the

anaphylaxis register,
represented by Prof. Dr. med. Margitta Worm (head of the anaphylaxis register)

and the

participating partner: (clinic/medical practice, etc.)
SPAIC - SOCIEDADE PORTUGUESA de ALERGOLOGIA e IMUNOLOGIA clínica

Address/tel. no.: RUA MANUEL RODRIGUES da SILVA, 7C ESCRITÓRIO 1 - 1600-503 LISBOA - PORTUGAL

Contact: +351 969665090
+351 914767661

Names of the employees responsible for making the entries in the anaphylaxis register:

First name and surname: E-mail address:

_____ _____

_____ _____

_____ _____

Names of the employees to receive the 'Anaphylaxis' newsletter:

First name and surname: E-mail address:

_____ _____

_____ _____

_____ _____

§ 1

The anaphylaxis register is used to keep a record of anaphylactic reactions in German speaking and other countries in Europe. The objective of the register is to analyse the current state of care and develop measures to improve patient diagnosis, treatment and prevention.

§ 2

(1) The primary partners participating in the anaphylaxis register are doctors/surgeries/clinics that specialise in allergies. This may include specialist areas of medicine such dermatology, paediatrics, ENT or pulmonology. A controlled expansion of the reporting institutions is planned in future (emergency doctors, GPs, etc.). Participation is voluntary.

(2) The application to participate shall be made in writing using the standard form provided. If the application is successful, the applicant shall be given a username and password for the online questionnaire. The access information (username and password) is only intended for the participating partner and may not be disclosed to third parties.

(3) Participation in the anaphylaxis register is free of charge.

(4) Participation may be terminated in writing at any time by either party with a notice period of 4 weeks to the end of the month. Once participation has ended, access rights to the register shall be terminated. The data transferred until then shall remain in the register.

§ 3

(1) Upon acceptance, the participating partners undertake to record anaphylactic reactions experienced by patients in the anaphylaxis register. To do this, the data collected shall be transferred in anonymised form via an online questionnaire. In individual cases, subject to prior approval, it may be transferred using a hard copy of the questionnaire.

§ 4

(1) The participating centres have the right to access the data in the register. At the request of one of the partners, an individual assessment of the data entered or the entire data may be carried out. This must be coordinated by the head of the anaphylaxis register. If a centre makes a specific request to process data on a topic or hopes to carry out a special assessment with an option to publish, this project shall first be communicated to all participating centres by the main centre so that these centres have the opportunity to respond and cooperate.

(2) Only the head of the anaphylaxis register has access to all the data. The head of the anaphylaxis register shall provide the participating partners with quarterly updates on the status of the anaphylaxis register.

§ 5

The participating partners agree to handle the data acquired carefully and in strict accordance with data protection regulations, the recommendations of the Declaration of Helsinki and the ICH GCP guidelines and to enter it into the anaphylaxis register on the basis of these principles. The person making the entry is responsible for ensuring the correctness and accuracy of the data, the patient information and the patient explanation. The patient information and the consent form shall be provided

by the head of the anaphylaxis register. These documents have been created according to the recommendations of the Declaration of Helsinki and the ICH GCP guidelines.

(2) The parties to the agreement also undertake to keep confidential and refrain from disclosing to third parties any knowledge and information acquired during the performance of the agreement, even after the agreement has ended.

§ 6

If the data concerned is the subject of publication, all participating partners shall be mentioned in the acknowledgement. The participating partners undertake to consult the head of the anaphylaxis register before any work is published. However, if the Board objects, the work may not be published. In addition to the main authors, at least one employee from the main centre shall be mentioned in the list of authors.
In addition to this, the list of authors shall include the name of at least one person from each participating centre that supplied at least ten per cent of the published data. This person shall be nominated by the head of the relevant centre. Publication shall be by mutual consent of all the authors and shall be coordinated by the head of the anaphylaxis register. The authors shall be given the opportunity to read through the article before publication.

§ 7

(1) No ancillary agreements may be made to this agreement.
Any amendments or addenda must be made in written form in order to be valid. This also applies to the removal of this written form requirement.

(2) Should individual provisions of this agreement be or become invalid, this shall be without prejudice to the effectiveness of the remaining provisions of this agreement. Invalid clauses shall be replaced by legally valid provisions which reflect as closely as

possible the intended purposes of the invalid clauses. The same shall apply to any loopholes.

(3) This agreement is subject solely to German law. The place of jurisdiction shall be Berlin.

Berlin, 02nd August 2018 (date)
(date)

Prof. Dr. med M. Worm
Head of the anaphylaxis register

Lisbon, 30th July 2018

Participating partner

Appendix A

Data protection for participating partners

The administrators of the anaphylaxis register take the protection of personal data extremely seriously. We consider it essential that, as a voluntary participant, you are informed of when, why and what type of data we save, and how long we retain it. The provisions of the Berlin Data Protection Act prevail. We have taken all the necessary technical and organisational measures to ensure that these data protection requirements are met. Every register participant is also obliged to take the necessary measures within his or her scope of responsibility to guarantee data protection and ensure that the patient/physician confidentiality requirement is upheld.

When you consent to participate in the register, we save your personal data to ensure that the data to be entered into the register originates from a legitimate, authorised participant. We save your details on an extremely secure server. It can only be accessed by a very limited number of authorised people who are responsible for providing technical or content support for the register. In connection with your access to our register server, your data is saved for technical and security purposes in such a way that you can be identified (name of registering doctor or clinic and contact details, date of entry). This is necessary so that you can be contacted in an emergency and so that the legitimacy of the saved data can be verified. We store this data for a period of 10 years. It is not made accessible to any third party. Statistical analyses are only carried out using anonymous data.

By consenting to take part, you agree to your personal data being saved for specific purposes. You are entitled to withdraw your consent. For the purposes of legal security, the data sets collected until that point still need to be assigned to you as the registering person in case of doubt by the responsible register administrator.