

## 1. Purpose and Use

1.1 The web application StudiesPortal is an electronic data collection system. It provides input forms for the documentation of collected data. The data is encrypted and sent via the internet (see Privacy Policy). The use of StudiesPortal for this purpose is contractually agreed between the sponsor of the trial and the centre performing the trial or between the sponsor of the trial and the physician performing the trial and is used to conduct the data collection.

## 2. Access

2.1 Each user receives personal access to the web application StudiesPortal consisting of a user name and password. Contact data (first name, last name, company address, e-mail address) is collected and stored for this purpose.

2.2 By registering on StudiesPortal and accepting these Terms of Use of StudiesPortal, the user also agrees to the collection, storage and processing of their contact details according to section 2.1 above for granting access in accordance with our Privacy Policy.

2.3 Depending on their function in the respective trial, each user receives specific access rights which apply for their access. As a rule, the default user only has access to the data collected and documented on their own centre, as well as to their own contact information and this is all they can retrieve. In addition to the users themselves, people employed by the trial sponsor for data administration and contractually authorised persons have access to the data.

2.4 In the event of the user being inactive in StudiesPortal for over 6 months, or in the case of improper use (e.g. disclosure of the password), the sponsor of the trial reserves the right to block the user's access to StudiesPortal.

## 3. Confidentiality

3.1 The user agrees to keep secret the personal access data and the details of StudiesPortal and its design as well as to treat such information confidentially and to not pass such information on to any other person or institution. Not respecting this rule shall lead to access being blocked immediately.

3.2 All people employed by the trial sponsor for data administration and contractually authorised persons are obliged to maintain confidentiality.

## 4. Responsibilities

4.1 The physician performing the trial must inform every patient of the collection and documentation of data. They are obliged to obtain the patient's written declaration of consent for data processing BEFORE the data is collected. Consent must be obtained using the form provided by the sponsor of the trial. Without a signed declaration of consent, inputting data into StudiesPortal is expressly prohibited and illegal. In the event of any violation, data protection legislation stipulates appropriate sanctions. The sponsor of the trial reserves the right to verify the existence of the declaration of consent.

4.2 The physician performing the trial shall inform their competent Ethics Commission before beginning with the respective trial and before the first recording of a patient in the trial documentation.

## 5. Data Protection

5.1 The Privacy Policy is an integral part of these Terms of Use. All anonymised personal data and personal data collected for registration on StudiesPortal is subject to this Privacy Policy. You can access this and print it off at any time on StudiesPortal.

5.2 All data documented in StudiesPortal is subject to the statutory provisions on data protection, including the EU General Data Protection Regulation. By using StudiesPortal, the user agrees to act in accordance with the provisions of medical secrecy and the statutory provisions on data protection.

Should individual provisions of these Terms of Use be or become invalid or unenforceable, the validity of the remaining terms is unaffected. In this case, the statutory provisions apply in place of the ineffective or unenforceable provision.

5.3 Patient data collected is anonymised; i.e. the data is encrypted and stored under a patient number. Only the physician performing the trial can match this patient number to a person.

5.4 The system offers the option of uploading files. The user is obliged to check the content of the file they have uploaded and, as necessary, to correct and anonymise it, i.e. remove information on name, date of birth, place of residence, contact information, etc.

5.5 StudiesPortal is a validated EDC (Electronic Data Capture) system and has an audit trail. This means that every record, i.e. every entry or modification of data by a user, is logged. This log can be called up at any time and captures the user (user name) of the person entering the information, the time of the activity and the entries/changes made. The audit trail is used to ensure data integrity and data consistency and is therefore an integral part of StudiesPortal.

## **6. Disclaimer**

To the extent permitted by law, the sponsor assumes no liability for loss or damage caused to the user through the use of StudiesPortal.

## **7. General**

These Terms of Use and the use of StudiesPortal are subject to the law of the Federal Republic of Germany.