4.10 Data processing related to clinical trials

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
1. Processing the personal data of the principal investigator and sub-investigators required to conduct and authorize a clinical trial.	Items necessary for the submission of an application for authorization under Section 17/A of Government Decree No 235/2009 (X. 20.) on the rules of procedure for the authorization of medical research conducted on humans, the clinical trial of trial medicinal products for human use and the clinical trial of medical devices intended for human use for clinical trial ("**Government Decree No 235/2009**"): professional curriculum vitae of the coordinating principal investigator, letter of intent from the principal investigator or coordinating principal investigator in which he/she undertakes to implement the trial plan known to him/her in accordance with its requirements and the terms of the resolution on its authorization if the trial is authorised. In accordance with the following guideline on "Good Clinical Practice" ("GCP") issued by EMEA (European Medicines	Relevant individuals: (coordinating) principal investigators and sub-investigators. Scope of data: professional curriculum vitae of the coordinating principal investigator and sub-investigators and/or any other appropriate document certifying their qualification; a letter of intent from the principal investigator or coordinating principal investigator in which he/she undertakes to implement the trial plan known to him/her in accordance with its requirements and the terms of the resolution on its authorization if the trial is authorized. The data contained in the investigation protocol - name and contact details of the principal investigator.	25 years after the trial is archived, or 5 years after the product ceases to be marketed, whichever is longer, with a view to verifying the process and results of the trial. **Persons who have access within Egis:** Clinical Pharmacology and Development Department, Marketing Authorisation Department General; Research Quality Assurance Department, management of the Medical Science Department Professional curriculum vitae of the principal investigators and sub-investigators and/or any other appropriate document certifying their qualification are integrated into the application for marketing authorisation which is available to the authorities in the course of marketing authorisation.

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	Agency) under Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (www.ogyei.gov.hu/dynamic/GCP_1.pdf) the professional CVs of the principal investigators and sub-investigators and/or any other relevant document proving their qualifications should be available to document that the persons concerned have the qualification required to conduct the trial and/or provide for the medical supervision of the persons involved in the trial and are competent to carry out such tasks. Article 6 (1) (f) of the General Data Protection Regulation 2016/679 of the European Parliament and of the Council - the legitimate interest of Egis and - if the business is a contracting partner of Egis – the business enter into an agreement with Egis.		

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	Legitimate interest: successfully conducting the official audit and completing the trial.		
2. Verifying the patient monitoring data forms (that contain the anonymized trial data).	Under the GCP: "*2:10 All information related to clinical trials should be should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.*" Article 6 (1) (f) of the – legitimate interest of Egis. Legitimate interest: compliance with the trial rules applicable to Egis and with the GCP.	The name, signature and - as the case may be - the stamp number of the **principal investigator or sub-investigators** on each patient's data form.	25 years after the trial is archived, or 5 years after the product ceases to be marketed, whichever is longer, with a view to verifying the process and results of the trial. **Persons who have access within Egis:** Clinical Pharmacology and Development Department, Marketing Authorisation Department General, Research Quality Assurance Department, management of the Medical Science Department The patient monitoring data forms that contain the anonymized trial data that are verified by the investigators are integrated into the application for marketing authorisation which is submitted to the relevant authority in the course of marketing authorisation.
3. Monitoring clinical trials - on-site audit of trial documents	Under the GCP: "*2:10 All information related to clinical trials should be should be recorded, handled, and*	Health data and other personal data of the subjects (individuals) involved in the trial: name, signature of the individual, his/her data necessary for contacting and	Data processing adjusts to the time required for the on-site audit of the documents. **Persons who have access within**

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
	stored in a way that allows its accurate reporting, interpretation and verification." *"5.1.1. The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)."* *"5. 1. 3. Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly."* Article 6 (1) (f) of the GDPR – legitimate interest of Egis. Legitimate interest: compliance with the trial rules applicable to Egis and with the GCP. In respect of processing health data: under Article 9 (2) (h) of the GDPR – processing is necessary for the purposes of preventive medicine, the provision of healthcare or treatment and under	identifying him/her, health data required for conducting the trial, evaluating the safety of the trial and generating trial results.	**Egis:** monitoring staff during monitoring. Identifiable, non-anonymised data are **not** retained and transferred by the monitors (auditing staff) or at the sponsor.

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	Article 9 (2) (i) of the GDPR processing is necessary for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices (if clinical trial relates to medicinal products and/or medical devices).		