4.11 Data processing related to tests of medical devices conducted for the evaluation of performance

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
1. Obtaining official permit (National Institute of Pharmacy and Nutrition - OGYÉI) and ethics committee ruling (Health Scientific Council - Scientific Research Ethics Committee - ETT-TUKEB) necessary for the evaluation tests of the clinical performance of medical devices.	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: principal investigators, sub-investigators and coordinating investigator of trial sites. Scope of data: professional curriculum vitae of the coordinating principal investigator and investigators of the trial sites 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 trial 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 the obligation to retain documentation and assure and control the quality of medical devices under Section 6 (9) and point 3 of Schedule 8 of MosFA Decree No 8/2003. **Persons who have access within Egis:** Sales Directorate, Research Directorate, Research Quality Assurance Department, Biological and Business Development Technology Department, Preparation Documentation Department, in-house legal counsel. The name, address of the workplace and professional curriculum vitae of the coordinating principal investigator and the principal investigators of trial sites are transferred to OGYÉI and the ETT-TUKEB in the course of authorization procedure of clinical trials of medical devices.

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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. In the course of authorisation specified in Annex 8 of Decree No 8/2003 (III. 13.) of the Minister of Social and Family Affairs ("**MoSFA Decree 8/2003**") the trial plan (protocol) shall be attached. Article 6 (1) (f) of the General Data Protection Regulation		Professional curriculum vitae of the principal investigators and sub-investigators and/or any other appropriate document certifying their qualification are integrated into the technical documentation which is available to the authorities in the course of registration procedure.

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	2016/679 of the European Parliament and of the Council - the legitimate interest of Egis. Legitimate interest: compliance with the trial rules applicable to Egis and with the GCP.		
2. Processing the personal data of the clinical trial staff (principal investigator, sub-investigator, clinical trial coordinator, clinical trial nurse) **required for the agreements entered into to conduct the trials to evaluate the clinical performance of medical devices**.	Depending on whether the agreement is entered into with the relevant individual or any other business: Article 6 (1) (b) of the GDPR - for the performance of a contract to which the data subject is directly party / Article 6 (1) (f) of the GDPR – legitimate interest of Egis and the business entering into an agreement with Egis: Legitimate interest: successfully conducting the official audit and completing the trial.	Data included in the service agreement entered into with the trial staff (principal investigator, sub-investigator, clinical trial coordinator, clinical trial nurse) or the business represented by the individual for the performance of the investigator's tasks of the evaluation test of the **clinical performance of medical devices**: name, address, tax number/tax identification number, registration number, bank account number of the investigator or, in the case of an agreement with a business, the contact details of the representative and the corporate and billing information of the business.	**5 years** from the termination of the agreement entered into with the individual/business represented by him/her in accordance with Section 6:22 of Act V of 2013 on the Civil Code (in general civil law claims lapse in 5 years). **Taxation documents: 5 years** from the last day of the calendar year in which the tax or data concerned should have been declared or reported or, in the absence of such declaration or report, the tax should have been paid (Sections 78 (3) and 202 (1) of Act CL of 2017 on the Rules of Taxation). **Accounting documents: 8 years** (Sections 168-169 of Act C of 2000 on Accounting. **Persons who have access within Egis:** Sales Directorate, Research Directorate, Biological and Business

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
			Development Technology Department (BÜTO), Preparation Documentation Department, Finance, in-house legal counsel.
3. Collecting electronic patient monitoring data forms (CRF, *Case Report Form*) containing pseudonymized 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 GDPR – legitimate interest of Egis. Legitimate interest: efficient processing of patient monitoring data forms, reducing the burden imposed by paper-based administration and document management, ensuring more efficient trial procedure and communication with investigators. 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	Pseudonymized health data of the subjects undergoing the trial (individuals) and other personal data related to the trial required to conduct the trial that is needed to complete the trial and assess the safety of the trial and generate trial results (including without limitation demographic data, comorbidities, medications, laboratory results, adverse drug reactions).	25 years after the trial is archived, or 5 years after the product ceases to be marketed, whichever is longer, with a view to the obligation to retain documentation and assure and control the quality of medical devices and conduct the trial and verify its process and result under Section 6 (9) and point 3 of Schedule 8 of MosFA Decree No 8/2003. **Persons who have access within Egis:** Sales Directorate, Research Directorate, Biological and Business Development Technology Department (BÜTO), Preparation Documentation Department. Patient monitoring data forms may undergo internal controlling. **Data is transferred to** the organization engaged by EGIS to conduct and monitor trials (Clinical Research Organization) and

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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 medical devices.		the following provider of the system that records electronic patient monitoring data forms (providing hosting services as a data processor) also have access to the data within the scope indispensable for the provision of the service: Infosector Kft. (address: 1024 Budapest, Rómer Flóris u. 4., telephone: 06-1-800-8115, email address: helpdesk@infosector.hu, website: www.infosector.hu The patient monitoring data forms that contain the pseudonymized trial data that are verified by the investigators are integrated into the technical documentation which is submitted to the relevant authority in the course of official registration procedure.
4. Granting access to the program that processes electronic patient monitoring data forms in the case of a clinical trial for the evaluation of performance of medical devices requiring electronic data input.	Article 6 (1) (f) of the GDPR – legitimate interest of Egis. Legitimate interest: efficient processing of patient monitoring data forms, reducing the burden imposed by paper-based administration and document management, ensuring more efficient trial procedure and communication with	Name and email address of the clinical trial physician or person authorized by the principal investigator.	Data are stored by Egis for **10 years** with respect to official inspections and internal controlling (certification of payment). **Persons who have access within Egis:** Sales Directorate, Research Directorate, Biological and Business Development Technology Department (BÜTO), Preparation

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	investigators.		Documentation Department.
5. Monitoring clinical trials of medical devices - on-site audit of trial documents	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.*" *"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.	Health data and other personal data of the subjects (individuals) involved in the trial: name of the individual, his/her signature on the information leaflet and consent form, his/her data necessary for contacting and identifying him/her, health data required for conducting the trial, evaluating the safety of the trial and generating trial results.	Data processing adjusts to the time required for the on-site audit of the documents. **Persons who have access within Egis:** Monitoring staff assigned by Egis and doing the on-site monitoring. Identifiable, not anonymized data are **not** transferred by the monitors (staff doing the monitoring) or kept at the sponsor.

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	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 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 medical devices.		
6. Preparing a clinical trial report on medical devices.	Under Section 17/B (5) of Government Decree 235/2009 a report shall be made after the completion of the trial. Thus the trial documentation includes the following: a trial summary: title of the research, data of the medical device used, data of the sponsor, initial statement which the trial seeks to evidence, initial set-up, description of the procedure, start and end date of the test, results,	The health data of the subjects (individuals) involved in the trial and collected in the electronic patient monitoring data forms for the purpose of conducting the trial.	25 years after the trial is archived, or 5 years after the product ceases to be marketed, whichever is longer, with a view to the obligation to retain documentation and assure and control the quality of medical devices and conduct the trial and verify its process and result under Section 6 (9) and point 3 of Schedule 8 of MosFA Decree No 8/2003. **Persons who have access within Egis:** Sales Directorate, Research

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	conclusions, signature of the person compiling the summary, date, summary of the clinical trial plan, together with the reasons for the modifications (if any) in the course of the trial, the results of the trial, evaluation of the fulfilment of the endpoints specified in the trial plan, records of adverse events Article 6 (1) (f) of the GDPR – legitimate interest of Egis. Legitimate interest: compliance with the trial rules applicable to Egis.		Directorate, Biological and Business Development Technology Department (BÜTO), Preparation Documentation Department. The trial documentation is submitted to OGYÉI and the authorizing authority provides a copy thereof to ETT TUKEB for scientific, medical-professional and ethic evaluation. ETT TUKEB notifies the authorizing authority of the outcome of evaluation.