4.4 Data processing Related to non-interventional trials (NIT)

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
1. Processing personal data of the principal investigator required to conduct and officially authorize non-interventional trials ("NIT").	Items necessary for the submission of an application 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 clinical trial for human use. ("**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 respect of other data** - 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	Relevant individuals: (coordinating) principal investigators. Scope of data: **Under Government Decree No 235/2009:** professional curriculum vitae of the coordinating principal investigator, 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 authorised. Data included in the service agreement entered into **with the principal investigator who is a private individual** for the performance of the tasks of the NIT principal investigator: investigator's name, address, tax number, registration number, bank account number.	**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 the Civil Code. **Taxation documents: 5 years** from the last day of the calendar year in which the tax 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 the Taxation Act). **Accounting documents: 8 years** (Sections 168-169 of the Accounting Act). **Persons who have access within Egis:** Domestic Sales Directorate, Scientific Trial Unit, Scientific Trial Manager, Scientific Trial Assistant, in-house legal counsel, Domestic Sales Directorate, Scientific Trial Unit. The investigator's name, address of his/her workplace, and curriculum vitae will be transferred to the National Institute of Pharmacy and

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	directly party / Article 6 (1) (f) of the GDPR – legitimate interest of Egis and the business entering into an agreement with Egis: successfully conducting the official inspection and completion of the trial.		Nutrition (OGYÉI) during the NIT authorization process.
2. Processing personal data of the investigator required to conduct and officially authorize non-interventional trials (NIT).	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: successfully conducting the official inspection and completion of the trial.	Data included in the investigator's service agreement entered into with the **investigator who is a private individual** for the performance of the tasks of the NIT investigator: investigator's name, address, tax number, registration number, bank account number.	**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 the Civil Code. **Taxation documents: 5 years** from the last day of the calendar year in which the tax 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 the Taxation Act). **Accounting documents: 8 years** (Sections 168-169 of the Accounting Act). **Persons who have access within Egis:** Domestic Sales Directorate, Scientific Trial Unit, Scientific Trial Manager, Scientific Trial Assistant, in-house legal counsel, in the course of the logistic activity

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			competent medical sales representatives, regional managers, CNS NOKO BU regional representatives, regional managers, Domestic Sales Directorate, Scientific Trial Unit. The names of physicians participating in the trial and the addresses of their workplaces/businesses/places of private practice will be transferred to the National Institute of Pharmacy and Nutrition (OGYÉI) during the NIT authorization process.
3. Obtaining a ruling from the OGYÉI-ETT-TUKEB (Healthcare Scientific Council-Scientific Research Ethics Committee) for NIT authorization.	Section 3, Section 7 of **Government Decree No 235/2009** - obtaining a ruling from the OGYÉI-ETT-TUKEB (Healthcare Scientific Council-Scientific Research Ethics Committee) for the authorisation of research.	Relevant individuals: investigators Scope of data: **Name and address of the investigators** (address of workplace/private practice/business).	For the time necessary to conduct the trial. **Persons who have access within Egis:** Domestic Sales Directorate, Scientific Trial Unit, Scientific Trial Manager, Scientific Trial Assistant, Domestic Sales Directorate, Scientific Trial Unit. The names of physicians participating in the trial and the addresses of their workplaces/businesses/places of private practice will be transferred to the National Institute of

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			Pharmacy and Nutrition (OGYÉI).
4. Medical verification of the patient monitoring data forms (that contain the anonymized trial data).	In accordance with the following guideline on Good Clinical Practice ("GCP") issued by EMEA (European Medicines Agency) under Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use: "*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.*" www.ogyei.gov.hu/dynamic/GCP_1.pdf	Name and stamp number of the **trial physician** in the data form of each patient involved by the investigator in the trial.	Data forms are stored for **5 years** with respect to official inspections and internal controlling (certification of payment). **Persons who have access within Egis:** Domestic Sales Directorate, Scientific Trial Unit, Scientific Trial Manager, Scientific Trial Assistant, statistical data processing company, Domestic Sales Directorate, Scientific Trial Unit. A **WeB2 Research Kft.** (1139 Budapest, Váci út 95.; istvan.janosi@planimeter.net) provides hosting services as a data processor.
5. Providing access to the program that manages electronic patient data forms (eCRF) for NIT with electronic data input.	Article 6 (1) (f) of the GDPR – legitimate interest of Egis. Legitimate interest: efficient processing of patient data forms, reducing the burden imposed by paper-based administration and document management, ensuring	Name, email address and stamp number of the **trial physician**.	After the completion of the trial, the data are deleted. **Persons who have access within Egis:** Scientific Trial Unit. **WeB2 Research Kft.** (1139 Budapest, Váci út 95.;

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	more efficient trial procedure and communication with physicians.		istvan.janosi@planimeter.net provides hosting services as a data processor.
6. NIT Master File: storing main investigator's documents necessary for the trial (trial site report from, signature page of the trial plan, verification of performance of the investigator's service agreement, invoice) (in a lockable cabinet).	**Under Section 12 of Government Decree No 235/2009 allowing and ensuring the inspection of the research during the term of research which Egis is authorised to conduct.** **In the case of other data necessary for the performance of the agreement, but not for the inspection of the trial** - depending on whether the agreement is entered into with the relevant individual or the business represented by it. Article 6 (1) (b) of the GDPR – performance of the agreement entered into directly with the relevant individual. Article 6 (1) (f) of the GDPR - The legitimate interest of Egis and the business entering into an agreement with Egis: more efficient documentation of contractual data, storage of authorizing documentation of the NIT, investigator's documents necessary for conducting the NIT in an	Relevant individuals: data of individuals affected in the investigation documentation (e.g. investigators). Scope of data: On the trial site report form, the investigator who is a private individual: name and address (address of the workplace/private practice/business); the data included in the service agreement of the investigator who is a private individual: name, address, tax number, registration number, bank account number.	**5 years** from the termination of the agreement (Section 6:22 of the Civil Code). **Taxation documents: 5 years** from the last day of the calendar year in which the tax 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 the Taxation Act). **Accounting documents: 8 years** (Sections 168-169 of the Accounting Act). **Persons who have access within Egis:** Domestic Sales Directorate, Scientific Trial Unit, Scientific Trial Manager, Scientific Trial Assistant, Domestic Sales Directorate, Scientific Trial Unit.

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	organised and traceable manner, facilitating and substantiating billing and verification of performance for internal controlling, allowing pharmaceutical regulatory, official tax inspections, documenting the inspection.		