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

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Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
	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

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
			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).	,

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
			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.	· · · · · · · · · · · · · · · · · · ·
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.;

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). In the case of other data necessary for the performance of 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 performance of the agreement of the agreement performance of the agreement of the data included in the investigation documentation (e.g. investigators). Taxation documents: 5 years from the termination of individuals: affected in the investigators). Taxation documents: 5 years from the termination of individuals: affected in the investigators). Taxation documents: 5 years from the termination of individuals: affected in the investigators). To the case of other data necessary for the performance of the agreement is entered into with the relevant individual: name and address (address of the workplace/private practice/business); the data included in the service agreement (Section 6:22 of investigators). Taxation documents: 5 years from the termination of individuals: 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 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, address, tax number, bank account in the agreement (Section 6:22 of investigators). Accounting documents: 5 years from the termination of individuals: 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	Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
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Article 6 (1) (b) of the GDPR – performance of the agreement individual: individual: name, address, tax number, registration number, bank account (Sections 168-169 of Accounting Act).				
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Article 6 (1) (f) of the GDPR - The Domestic Sales Director		Autiala ((1) (f) aftha CDDD Tha		Domestic Sales Directorate
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				Trial Manager, Scientific Trial
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5		\mathcal{E}		Directorate, Scientific Trial Unit.
storage of authorizing		, i		Directorate, Scientific Trial Offit.
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investigator's documents necessary		,		
for conducting the NIT in an		•		

Purpose of data processing	Legal basis of data processing	Scope of processed data	Data retention period, access rights, recipients of data transfers
	organised and traceable manner, facilitating and substantiating billing and verification of performance for internal controlling, allowing pharmaceutical regulatory, official tax inspections, documenting the inspection.		