



Project No. Nr. 5.1.1.2.i.0/2/24/A/CFLA/004
Research Project No. 30

CONFIRM:
JSC „Grindeks”
Chairman of the Board Ph.D. Juris Hmelnickis

Riga, SEE DATE IN THE TIME STAMP

Riga, SEE DATE IN THE TIME STAMP

Description of Procurement Subject

1. General information on Beneficiary of funding:

Name of company: JSC „Grindeks”
Registration number: 40003034935
Address: 53 Krustpils Street, Riga, LV-1057, Latvia
Contact person: Indra Jonāne-Oša, phone: +371 67083503,
e-mail: indra.jonane@grindeks.com

2. Description of procurement subject:

Clinical study – 1 (in the group of central nervous system diseases)

a) Technical specification:		
1.	The Scope of work:	It should be a full service bioavailability (<i>in vivo</i> biological equivalence) pivotal study, including set-up (study design, protocol writing, writing of CRF, ICF and written information to study subjects, preparing and submission documents to Regulatory Authority and Ethics Committee), implementation of the clinical part, bioanalytical services, data management, pharmacovigilance, pharmacokinetic calculation, statistical planning, data processing and statistical analysis, preparation of the final report.
2.	The methods used:	Applicant should use validated analytical method for active pharmaceutical ingredient and it's metabolites, if applicable, detection in human plasma.

b) Additional requirements:		
1.	Conditions:	• Applicant should carry out the study in accordance with

		regulations of the European Medicines Agency (EMA) and local Authorities, International Conference on Harmonization Guidelines like “Structure and content of clinical study reports” (E3), “Guideline for Good Clinical Practice” (E6), and “Statistical Principles for Clinical Trials” (E9); • Applicant should have at least 3-year experience in conducting bioavailability and bioequivalence studies in last 5 years; • Applicant should be inspected by the European Medicines Agency (EMA) and/or by any European Union member state regulatory authority and by the US Food and Drug Administration (US FDA) in last 5 years with no critical findings; • The CRO should be approved by the Gulf Cooperation Council (GCC); • Principal investigator should have experience in conducting at least 3 bioavailability and bioequivalence studies; • Applicant’s staff should be trained on basic principles of Good Clinical Practice (GCP); • Applicant should conduct the study in accordance with Good Laboratory Practice (GLP) principles. • If it will be required applicant has a valid license that permits the undertaking of studies involving substances listed in the control substances list.
2.	Terms of execution:	Applicant should carry out the study by September 30, 2025 (approved clinical study report).
3.	Tender offer is valid:	At least till February 28, 2025.
4.	Terms of payment:	The applicant confirms that the payment terms will be agreed in the contract. Advance payment is not greater than 40% of the contract amount. Final payment is not less than 10% of the contract amount.
5.	Price:	Should be specified in EUR (without VAT).
6.	Conformity:	If the technical specification can be fulfilled by equivalent means, unforeseen by the Beneficiary of funding, then a corresponding offer may be submitted. The applicant could submit the offer, which corresponds to higher (better) requirements.
7.	Requirements for the offer preparation:	1. Tender offer should be completed according to the Technical offer form attached in Appendix 1; 2. Additionally to the Technical Offer the following documents should be submitted: 2.1. Acknowledgement on the conducted bioavailability and bioequivalence studies by the Applicant in last 5 years, 2.2. The list of inspections performed by the EMA and/or by any European Union member state regulatory authority and by the US FDA at Applicant’s facilities in last 5 years, 2.3. CV of Principal Investigator and GCP certificate or equal document,

		2.4.Short study plan with substantiation on number of volunteers required to achieve reliable study results (including supporting documents, which were used for calculation of the proposed number of subjects). 3. 1 (one) signed original tender offer (with annexes) typed either in the Latvian or English language should be submitted; 4. Till the end date of tender 1 (one) scanned copy of signed tender offer with annexes should be submitted by e-mail to Indra Jonane-Osa to the e-mail address indra.jonane@grindeks.com OR via post to the following address: JSC “Grindeks”, 53 Krustpils Street, Riga, LV-1057, Latvia in the closed envelope with reference – “Clinical study – 1”, to deliver personally to Indra Jonane-Osa”. 5. The applicant should indicate the date and the place of preparation of the offer, registration number of the offer, as well as the signature and deciphering of signature of applicant’s representative. 6. The applicant should print the first page of the offer on a company letterhead (if applicable).
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Appendix: Technical offer form on 5 (five) pages.

JSC „Grindeks”

Head of Drug Research and Intellectual Property Group*

Indra Jonāne-Oša

*THE DOCUMENT IS SIGNED WITH A SECURE ELECTRONIC SIGNATURE

to Description of Procurement Subject “Clinical study – 1”
(in the group of central nervous system diseases)

[Place], _____._____.2024.
No.

1.	Beneficiary of funding:	JSC „Grindeks”
2.	Address of Beneficiary of funding:	53 Krustpils Street, Riga, LV-1057, Latvia
3.	Procurement subject:	Clinical study – 1” (in the group of central nervous system diseases)
4.	Place of study conduct:	[]
5.	Date of contract execution:	30.09.2025
6.	Information about Applicant:	[Short description of the Applicant]
7.	<u>Description of Procurement subject:</u>	
	a) Technical specification:	
		Requirements
1.	The Scope of work:	It should be a full service bioavailability (<i>in vivo</i> biological equivalence) pivotal study, including set-up (study design, protocol writing, writing of CRF, ICF and written information to study subjects, preparing and submission documents to Regulatory Authority and Ethics Committee), implementation of the clinical part, bioanalytical services, data management, pharmacovigilance, pharmacokinetic calculation, statistical planning, data processing and statistical analysis, preparation of the final report.
2.	The methods used:	Applicant should use validated analytical method for active

		pharmaceutical ingredient and it's metabolites, if applicable, detection in human plasma.	
	b) Additional requirements:		
		Requirements	Bid
1.	Conditions:	• Applicant should carry out the study in accordance with regulations of the European Medicines Agency (EMA) and local Authorities, International Conference on Harmonization Guidelines like “Structure and content of clinical study reports” (E3), “Guideline for Good Clinical Practice” (E6), and “Statistical Principles for Clinical Trials” (E9); • Applicant should have at least 3-year experience in conducting bioavailability and bioequivalence studies in last 5 years; • Applicant should be inspected by the European Medicines Agency (EMA) and/or by any European Union member state regulatory authority and by the US Food and Drug Administration (US FDA) in last 5 years with no critical findings; • The CRO should be approved by the Gulf Cooperation Council (GCC); • Principal investigator should have experience in conducting at least 3 bioavailability and bioequivalence studies; • Applicant's staff should be trained on basic principles of Good Clinical Practice (GCP); • Applicant should conduct the study in accordance with Good Laboratory Practice (GLP) principles. • If it will be required applicant has a valid license that permits	

		the undertaking of studies involving substances listed in the control substances list.	
2.	Terms of execution:	Applicant should carry out the study by 30.09.2025 (approved clinical study report).	
3.	Tender offer is valid:	At least till February 28, 2025.	
4.	Terms of payment:	The applicant confirms that the payment terms will be agreed in the contract. Advance payment is not greater than 40% of the contract amount. Final payment is not less than 10% of the contract amount.	
5.	Price:	Should be specified in EUR (without VAT).	

Annexes: ...

[Company name]

_____ [Name, Surname]

Annex 1 to Technical offer

**Acknowledgement on the conducted bioavailability and bioequivalence studies by
[Applicant`s name] in last 5 years (2019 – 2023)**

We confirm that [Company name] has had at least 3-year experience in conducting bioavailability and bioequivalence studies in last 5 years. We agree to provide the list of the bioavailability and bioequivalence studies conducted in last 5 years upon request of JSC “Grindeks”.

[Name, Surname]

[Position]

Annex 2 to Technical offer

The list of inspections performed by the EMA and/or by any European Union member state regulatory authority and by the US FDA at [Applicant`s name] facilities in last 5 years (2019 – 2023)

Name of the regulatory authority	Area of inspection*	Date(s) of inspection	Critical findings**

*Verification of compliance with Good Clinical Practice (GCP) and/or Good Laboratory Practice requirements. Please enter “GCP” and/or “GLP”

**Please enter “yes” or “no”

Applicant is ☐ / is not ☐ approved by the Gulf Cooperation Council (GCC)

Approval date: