CONFIRMED
Chairman of the Management Board

Hmelnickis J.Hmeļnickis

Olaine, 15.09, 2026

Description of procurement subject ID No. 2026/09/2

1. General information about the customer:

Name of customer:	JSC „Olpha"
Commercial registration No.:	40003007246
Address:	Rupnicu street 5, Olaine, Olaines district, LV-2114, Latvia
Contact person:	Vladimirs Medvedevs, Director of Procurement and projects department Phone: +371 22055387 E-mail: vladimirs.medvedevs@olpha.eu

2. Procurement subject technical specification:

Full-service bioequivalence study.
Additional information about the procurement subject is available from the customer, by writing to the above-indicated e-mail.

1.	Study design and key requirements	Type of study: Pivotal Design: An open label, balanced, randomized, single-dose, two-treatment, two-period, crossover Condition: Fast Participants: Healthy adult volunteers (males and females). The final number of participants will be based on a sample size calculation, including an appropriate drop-out reserve, to ensure that a sufficient number of participants complete both study periods (a formal power-based sample size calculation shall be provided by the applicant). The same participants shall participate in both study periods, with an adequate washout. Investigational products (Test/Reference): tablets. Therapeutic area: Nervous system PK sampling: 20 sampling time points up to 24 hours post-dose × two administration periods per participant Number of analytes to measure: 1 (parent in plasma)

2.	Scope of work	Full scope bioequivalence study as detailed above, including following activities: 1. Preparation of study documentation and obtaining permits, including: – Study documentation development (Protocol, Informed consent Form (including translations), Case report form etc.); – Insurance; – Obtaining the required study permits. 2. Clinical phase of the study, including healthy volunteers' recruitment and enrolment in the study, clinical phase conduct and execution, blood sample collection, safety analysis, medical coordination and supervision. 3. Clinical trial supply services - receipt, accountability and storage of investigational products (IPs), preparation for dispensing and distribution to the volunteers, reconciliation and destruction of unused IPs. 4. Bioanalytical phase services, including: – Bioanalytical method development and validation fully compliant with relevant EMA guidelines; – Procurement or synthesis of a suitable internal standard (note: the reference standard will be provided by Customer); – Long term sample stability studies; – PK sample retention for at least 12 months; – Bioanalytical study plan preparation, analysis of biosamples, incurred sample reanalysis (ISR), preparation of a Bioanalytical report. 5. Data management and statistics services, including formal sample size calculation, generation of randomization list, statistical analysis, and preparation of a Statistical report. 6. Preparation of Final Clinical study report and CTD 2.7.1 module. 7. Project management. 8. Study document archiving in compliance with applicable regulatory requirements.
3.	Financial proposal requirements	The proposal must include all costs associated with the performance of the services, including costs for regulatory charges, estimated costs of internal standard, analytical columns and consumables, study-related insurance and approximate costs of one (1) SAE handling etc. The proposal shall provide a clear breakdown of total project costs (service costs and pass-through costs).

3. Requirements for Applicant:

1.	Applicant´s experience	1. Applicant has sufficient experience in conducting bioequivalence studies, including the bioanalytical phase (bioanalytical method development and validation, and analysis of biological samples). 2. Applicant is able to demonstrate proven experience in conducting bioequivalence studies, supported by relevant study examples and regulatory submissions. 3. Applicant is eligible to conduct above mentioned study in compliance with GCP, GLP, European Medicines Agency (EMA) and any other applicable regulations. 4. The Applicant shall hold valid regulatory approvals and/or certifications required to conduct bioequivalence studies in the proposed country.
2.	Applicant´s resources	1. Applicant has qualified scientific personnel. Key team members are trained in GCP principles. 2. Applicant has access to the suitable study population to ensure conduct of proposed study. 3. Applicant has the necessary technical facilities and equipment to conduct the study in accordance with technical specification. 4. The Applicant shall confirm readiness to initiate the study without undue delay upon contract award.
3.	Date of completion	The date of completion refers to mutually accepted (final) Clinical trial report. This date will be confirmed with the selected applicant and set in service agreement.
4.	Amount of work	For the purpose of this procurement, applicant shall apply for all activities presented in the technical specification.
5.	Compliance	In case of possible equivalent for requirements listed in the description of procurement subject, unforeseen by the customer, the applicant can submit equivalent offer in conformity with requirements. The applicant can also submit the offer, which corresponds to higher (better) requirements.
6.	Price	The financial proposal shall include the total contract amount (including pass-through costs), indicated in EUR (excluding VAT), and a detailed cost breakdown per activity in accordance with Section 2. "Procurement subject technical specification" Subsections 2. "Scope of work" and 3. "Financial proposal requirements".
7.	Schedule of payment	The applicant agrees that the payment conditions will be set in the contract. The applicant can indicate the desired payment schedule in the application. The applicant agrees that the invoice payment term is 45 days.

8.	Documents / information to be submitted	1. Details of the bioequivalence study design, bioanalytical method development and validation, biosamples analysis. 2. Copy of documents verifying the applicant's legal status and certification.
9.	Requirements for offer preparation	1. Offer shall be prepared on the form "Offer" in Annex no. 1 to the Description of procurement subject with all details completed. 2. Offer shall be written in English or Latvian language. 3. The signed and scanned offer should be sent to: Vladimirs Medvedevs, Director of Procurement and projects department, e-mail: vladimirs.medvedevs@olpha.eu

Annex no.1: Technical offer form on 4 (four) pages.

This procurement is organized within the framework of project No. 5.1.1.2.i.0/2/24/A/CFLA/005

Annex no.1
to the Description of procurement subject

[Applicant name]
Registration number: [ ]
Legal address: [ ]

[Place], [Date]
No._____

Offer

1.	**Customer**	JSC "Olpha"	
2.	**Customer address**	Rupnicu street 5, Olaine, Olaines district, LV-2114, Latvia	
3.	**Procurement subject**	Full-service bioequivalence study	
4.	**Place of study conduct**	[*Applicant address*]	
5.	**Information about applicant**	[*Short description of the applicant*]	
6.	**Description of procurement subject**		
		Requirements	Offer
6.1	Scope of work:	Full scope bioequivalence study as detailed above, including following activities: 1. Preparation of study documentation and obtaining permits, including: – Study documentation development (Protocol, Informed consent Form (including translations), Case report form etc.); – Insurance; – Obtaining the required study permits. 2. Clinical phase of the study, including healthy volunteers' recruitment and enrolment in the study, clinical phase conduct and execution, blood sample collection, safety analysis, medical coordination and supervision. 3. Clinical trial supply services - receipt, accountability and storage of investigational products (IPs), preparation for dispensing and distribution to the volunteers, reconciliation and destruction of unused IPs. 4. Bioanalytical phase services, including:	

		– Bioanalytical method development and validation fully compliant with relevant EMA guidelines; – Procurement or synthesis of a suitable internal standard (note: the reference standard will be provided by Customer); – Long term sample stability studies; – PK sample retention for at least 12 months; – Bioanalytical study plan preparation, analysis of biosamples, incurred sample reanalysis (ISR), preparation of a Bioanalytical report. 5. Data management and statistics services, including formal sample size calculation, generation of randomization list, statistical analysis, and preparation of a Statistical report. 6. Preparation of Final Clinical study report and CTD 2.7.1 module. 7. Project management. 8. Study document archiving in compliance with applicable regulatory requirements.	
6.2.	Financial proposal requirements	The proposal must include all costs associated with the performance of the services, including costs for regulatory charges, estimated costs of internal standard, analytical columns and consumables, study-related insurance and approximate costs of one (1) SAE handling etc. The proposal shall provide a clear breakdown of total project costs (service costs and pass-through costs).	
7.			
7.1.	Applicant´s experience	1. Applicant has sufficient experience in conducting bioequivalence studies, including the bioanalytical phase (bioanalytical method development and validation, and analysis of biological samples). 2. Applicant is able to demonstrate proven experience in conducting bioequivalence studies, supported by	

		relevant study examples and regulatory submissions. 3. Applicant is eligible to conduct above mentioned study in compliance with GCP, GLP, European Medicines Agency (EMA) and any other applicable regulations. 4. The Applicant shall hold valid regulatory approvals and/or certifications required to conduct bioequivalence studies in the proposed country.	
7.2.	Applicant's resources	1. Applicant has qualified scientific personnel. Key team members are trained in GCP principles. 2. Applicant has access to the suitable study population to ensure conduct of proposed study. 3. Applicant has the necessary technical facilities and equipment to conduct the study in accordance with technical specification. 4. The Applicant shall confirm readiness to initiate the study without undue delay upon contract award.	
7.3.	Date of completion	The date of completion refers to mutually accepted (final) Clinical trial report. This date will be confirmed with the selected applicant and set in service agreement.	
7.4.	Amount of work	For the purpose of this procurement, applicant shall apply for all activities presented in the technical specification.	
7.5.	Compliance	In case of possible equivalent for requirements listed in the description of procurement subject, unforeseen by the customer, the applicant can submit equivalent offer in conformity with requirements. The applicant can also submit the offer, which corresponds to higher (better) requirements.	
7.6.	Price	The total contract amount (including pass-through costs) and a detailed cost breakdown per activity in accordance with Section 2. "Procurement subject technical	

		specification" Subsections 2. "Scope of work" and 3. "Financial proposal requirements", indicated in EUR (excluding VAT).	
7.7.	Schedule of payment	The applicant agrees that the payment conditions will be set in the contract. The applicant can indicate the desired payment schedule in the application. The applicant agrees that the invoice payment term is 45 days.	
7.8.	Documents/ information to be submitted	1. Details of the bioequivalence study design, bioanalytical method development and validation, biosamples analysis. 2. Copy of documents verifying the applicant's legal status and certification.	

[Company Name]

[Position] _____ [Signature, Name, Surname]