CONFIRMED
Chairman of the Management Board

Hmelnickis J.Hmeļņickis

Olaine, 06.11., 2026

Description of procurement subject ID No. 2026//11/6

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:	Agnese Reitupe, Director of Resources and Development Projects Phone: +371 2940 9499 E-mail: agnese.reitupe@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, two-sequence crossover. Condition: Fed. Participants: Healthy adult volunteers (males and females). Sample size: The customer proposes 52 evaluable participants. The applicant shall determine an appropriate dropout allowance based on its experience and standard practice to establish the total number of participants to be enrolled, ensuring that a sufficient number of participants complete both study periods (a formal power-based sample size calculation shall be provided by the applicant). The applicant is invited to propose an alternative sample size, with justification, if its experience with investigational product or comparable products suggests different assumptions. Any alternative should be quoted in addition to, not instead of, the base case. Investigational products (Test/Reference): capsules. Therapeutic area: Nervous system.

		PK sampling: up to twenty two (22) sampling time points up to forty eight (48) hours post-dose × two administration periods per participant. Wash out period: at least seven (7) days. 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, preparation of Method Validation Report; – 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 as per applicable regulatory requirements and destruction after retention period; – 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, Data management plan preparation, 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), including fixed study costs and the cost per randomized participant.

3. <u>Requirements for Applicant:</u>

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 the final Clinical Trial Report mutually accepted by both parties - this must be done **no later than 30 September 2027.**
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.
8.	Documents / information to be submitted	1. Details of the bioequivalence study design, including sample size calculation and rationale for the proposed number of participants, bioanalytical method development and validation, biosamples analysis. 2. Preliminary project timeline outlining key study activities and the estimated time from contract signing to the Final Clinical study report. 3. Information on the proposed clinical site, bioanalytical laboratory. 4. Copies of documents verifying the applicant's legal status and relevant certifications.
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: Agnese Reitupe, Director of Resources and Development Projects, e-mail: agnese.reitupe@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, including: 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, preparation of Method Validation Report; – 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 as per applicable regulatory requirements and destruction after retention period; – 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, Data management plan preparation, 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), including fixed study costs and the cost per randomized participant.	
7.	**Criteria for selection of offers**		
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 the final Clinical Trial Report mutually accepted by both parties - this must be done **no later than 30 September 2027.**	
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 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".	
7.7.	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.	
7.8.	Documents/ information to be submitted	1. Details of the bioequivalence study design, including sample size calculation and rationale for the proposed number of participants, bioanalytical method development and validation, biosamples analysis. 2. Preliminary project timeline outlining key study activities and the estimated time from contract signing to the Final Clinical study report. 3. Information on the proposed clinical site, bioanalytical laboratory. 4. Copies of documents verifying the applicant's legal status and relevant certifications.	

[Company Name]

[Position] _____ [Signature, Name, Surname]