CONFIRMED
Chairman of the Management Board

Hmelnickis J.Hmeļņickis

Olaine, 16.04, 2026

Description of procurement subject ID No. 2026/04/1

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:	Vadims Ķīsis, Head of Medicine & Clinical Research Department, E-mail: Vadims.Kisis@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	Design: A single-dose, randomized, two-treatment, two-period, two-sequence, two-stage crossover study under fasting conditions in healthy adult male and female participants. A two-stage design with a pre-specified interim analysis after Stage 1, allowing early termination or continuation to Stage 2 with sample size re-estimation, based on a pre-defined statistical methodology ensuring control of Type I error, in accordance with regulatory guidance. Participants: Healthy adult volunteers (~80% male, 20% female). Washout: at least 3 days. Sample size: Stage 1: ~ 40 participants; maximum sample size (Nmax): ~ 60 participants (a formal power-based sample size calculation shall be provided by the applicant). Investigational products (Test/Reference): film-coated tablets. Therapeutic area: Cardiology. Safety assessments: cardiac monitoring under physician oversight i.e. blood pressure monitoring and 12-lead ECG recording. ECGs shall be performed pre-dose and at least three (3) times post-dose per study period. PK sampling: 20 sampling time points up to 36.0 h post-dose × two administration periods per participant.

		Number of analytes to measure: 1
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, conduct of Stage 1 and, if required, continuation of the study with additional participants under Stage 2, blood sample collection, safety analysis, medical coordination and supervision. 3. Clinical trial supply services - receipt (incl. custom clearance), 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 generation of randomization list, statistical analysis, and preparation of a Statistical report(s). Stage 1 statistics must be performed by independent statistician. 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), and specify: 1. costs for Stage 1; 2. costs for Stage 2, based on maximal number of additional participants; the costs related to Stage 2 should be presented both as total sum and as per-patient cost.

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 two-stage design 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. 5. The Applicant shall ensure the independent statistical expertise for Interim analysis.
3.	Date of completion	Final study report must be submitted to Customer no later than November 29, 2026.
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, bioanalytical method development and validation, biosamples analysis. 2. Copy of documents verifying the applicant's legal status and certification. 3. Confirmation of outsourced independent statistical expertise, indicating provider's details.
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: Vadims Ķīsis, Head of Medicine & Clinical Research Department, e-mail: Vadims.Kisis@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, conduct of Stage 1 and, if required, continuation of the study with additional participants under Stage 2, blood sample collection, safety analysis, medical coordination and supervision. 3. Clinical trial supply services - receipt (incl. custom clearance), 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 generation of randomization list, statistical analysis, and preparation of a Statistical report(s). Stage 1 statistics must be performed by independent statistician. 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), and specify: 1. costs for Stage 1;	

		2. costs for Stage 2, based on maximal number of additional participants; the costs related to Stage 2 should be presented both as total sum and as per-patient cost.	
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 two-stage design 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. 5. The Applicant shall ensure the independent statistical expertise for Interim analysis.	

7.3.	Date of completion	Final study report must be submitted to Customer no later than November 29, 2026.	
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, bioanalytical method development and validation, biosamples analysis. 2. Copy of documents verifying the applicant's legal status and certification. 3. Confirmation of outsourced independent statistical expertise, indicating provider's details.	

[Company Name]

[Position] _____ [Signature, Name, Surname]