ANNEX 2 – CHECKLIST FOR THE BIDDER (with a list of required attachments)

Instruction: This form must be submitted together with the offer. In addition to marking YES/NO responses, please attach the required annexes. The absence of any annex may result in rejection of the offer at the stage of formal assessment. If a given item is not applicable, please provide a brief justification in the 'Comments' column.

0. Basic information of the Bidder

Full company name:	
Registered office address:	
VAT / REGON / KRS:	
Authorized contact person:	
Position of the contact person:	
Phone / e-mail:	
Website (if applicable):	

I. Compliance with legal requirements and guidelines

Criterion / Statement	YES/NO	Comments
The Bidder declares that the study will be conducted in compliance with: ICH E6(R3) GCP, Declaration of Helsinki (2013), Directive 2001/83/EC, Directive 2005/28/EC, Regulation (EU) 536/2014 (if applicable), BE Guideline CPMP/EWP/QWP/1401/98 Rev.1/Corr (2010), GLP principles (EMA/INS/GCP/532137/2010), ICH M10 (EMA/CHMP/ICH/172948/2019, 2022).	☐ YES ☐ NO	

Documentation and the final report will be prepared in accordance with ICH E3 (CPMP/ICH/137/95).	☐ YES ☐ NO	

II. Study participants and regulatory approvals

Criterion / Statement	YES/NO	Comments
The Bidder has the capability to recruit healthy participants of both sexes, in accordance with the protocol criteria.	☐ YES ☐ NO	
The Bidder has experience in obtaining Ethics Committee opinions and Competent Authority approvals.	☐ YES ☐ NO	

III. Participant safety

Criterion / Statement	YES/NO	Comments
The Bidder has infrastructure and procedures in place to provide immediate treatment to participants (emergency preparedness).	☐ YES ☐ NO	
The Bidder has AE/SAE reporting procedures compliant with GCP (SAEs reported to the Sponsor within 24h).	☐ YES ☐ NO	

IV. Certificates, inspections, and audits

Criterion / Statement	YES/NO	Comments
The Bidder holds valid GCP/GLP certificates or has a positive inspection history.	☐ YES ☐ NO	
In the last 4 years, the Bidder has not received critical findings during inspections by European authorities.	☐ YES ☐ NO	
The Bidder has been audited by sponsors in the last 2 years.	☐ YES ☐ NO	

V. Experience and personnel

Criterion / Statement	YES/NO	Comments
The Bidder has conducted ≥3 bioavailability/bioequivalence studies in the last 3 years, including ≥1 resulting in EU registration.	☐ YES ☐ NO	
The Bidder employs competent personnel (clinical, bioanalysis, PK/statistics).	☐ YES ☐ NO	
The Principal Investigator holds valid GCP training (statement; evidence available upon request).	☐ YES ☐ NO	
The Bidder employs a pharmacokinetics/statistics specialist with relevant experience.	☐ YES ☐ NO	
The Bidder employs staff competent to prepare integrated clinical study reports (CSR) compliant with ICH E3.	☐ YES ☐ NO	

VI. Organizational and technical facilities

Criterion / Statement	YES/NO	Comments
The Bidder has the infrastructure and technical capability to perform services (clinical, bioanalytical, PK, statistical parts).	☐ YES ☐ NO	

VII. Bioanalytical methods (ICH M10)

Criterion / Statement	YES/NO	Comments
The Bidder has or can validate bioanalytical methods in compliance with ICH M10 before the study initiation.	☐ YES ☐ NO	
The Bidder has infrastructure, equipment, and experience to conduct analysis of biological samples (determination of analyte concentrations in blood/plasma).	☐ YES ☐ NO	

VIII. Liability insurance

Criterion / Statement	YES/NO	Comments
The Bidder has valid liability insurance covering participants and the entire study period; declares continuity of coverage under the same terms.	☐ YES ☐ NO	
The insurance policy covers responsibility for payment of compensations (no-fault compensation).	☐ YES ☐ NO	

IX. Quality system and SOPs

Criterion / Statement	YES/NO	Comments
The Bidder has a quality system compliant with GCP and maintains up-to-date SOPs.	☐ YES ☐ NO	
The Bidder has a quality system compliant with GLP and maintains up-to-date SOPs.	☐ YES ☐ NO	

X. Audit readiness

Criterion / Statement	YES/NO	Comments
The Bidder declares readiness for audit of the site and laboratory by the Sponsor/Contracting Authority.	☐ YES ☐ NO	

XI. Subcontractors

Criterion / Statement	YES/NO	Comments
The Bidder may use subcontractors and declares that they comply with the requirements of this RFP and hold GCP/GLP certificates or positive inspection history.	☐ YES ☐ NO	
The Bidder undertakes to conclude relevant agreements with subcontractors ensuring compliance with GCP/GLP.	☐ YES ☐ NO	

The Sponsor will be informed of and must approve all subcontractors before the start of the study.	☐ YES ☐ NO	

A. Required annexes (to be attached to the offer)

No.	Annex name	Scope/What it must contain	Required	Attached	File name / Comments
1	GCP/GLP Certificates	Valid certificates; for PI – valid GCP training certificate.	YES	☐	
2	List of regulatory inspections	Completed table in Section B.	YES	☐	
3	List of BE/BA studies (last 3 years)	Completed table in Section C.	YES	☐	
4	List of SOPs	Summary of current SOPs (Section E) – title, code, version, date.	YES	☐	
6	Subcontractors	List of subcontractors + their GCP/GLP certificates/inspection history (if applicable).	If applicable	☐	
8	Participant safety	Description of infrastructure and procedures (emergency, AE/SAE, referral hospital).	YES	☐	
9	Bioanalysis – list of methods	Section D: scope of validation (LLOQ–ULOQ, stability, ISR), laboratory, date.	YES	☐	

B. Table of regulatory inspections (last 4 years)

Authority/Agency	Country	Type (GCP/GLP)	Date	Scope (clinical/bioanalytical)	Result/Status	Remarks (Critical/Major/Minor)	Related to BE/BA?

C. List of BE/BA studies in the last 3 years

Product/API	N	Analyte(s)	Bioanalytical lab	CSR date	Submitted in EU?	Registration status	Key remarks

D. Bioanalysis – list of methods and validation status (ICH M10)

Method ID	Analyte	Matrix	Range (LLOQ–ULOQ)	Calibration model	ISR – plan/status	Stability	Validation date	Laboratory	Report/Reference

E. List of current SOPs (Quality System)

Code/ID	SOP title	Version	Effective date	Area (clinical/bioanalytical/QA)	Status

F. Key personnel

Role	Name	Experience in BE/BA (years)	GCP – training date	Remarks

G. Final declaration

I declare that all information provided in this form and the attached annexes is true and complete. I undertake to provide source documents confirming the above data at the Sponsor's request.

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Place, date

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Signature and stamp of the Bidder