**STATEMENT**

**REQUIREMENTS FOR THE TENDERER**

**RFP 024481** **– eCTD DOCUMENTAITON AND SEND DATASET FOR BIOLOGICAL DRUG CANDIDATE**

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| **REQUIREMENTS** | **CONFIRMATION [YES/NO]** |
| The Tenderer must have at least 3 years’ experience in preparation of toxicological report according to requirements of IND/IMPD , as well as BLA/MAA application.  |  |
| The contractor must have at least 3 years’ experience in studies on novel pharmaceuticals in the scope of ADME / PK, toxicology and legal regulations applicable in this scope, including experience in work with biological compounds in the field of oncology. |  |
| The Tenderer should demonstrate that it has all resources to provide services in non-GLP and GLP regulatory toxicology studies. |  |
| The Contractor should use a quality management system and the auditing system to ensure compliance with all required regulatory requirements. |  |
| The Tenderer should demonstrate the experienced personnel involved in preclinical research and development projects of innovative drugs of the principle team members, in particular a Study Director and toxicologist with highlighted experience in the field of formal preclinical development and regulatory expertise on toxicology of at least 3 years, including at least five in GLP studies conducted.  |  |
| The contractor must have at least 3 years’ experience in conducting at least 5 GLP-compliant toxicology studies in selected species – rat and cynomolgus monkey |  |
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**………………………………**

 *(date and signature of Tenderer's authorized representative)*