Appendix No. 1.1 to the Request for Bids No. 02/WPD104/2020

Detailed description of the service

Work Package No. 1 Phase Ib/II clinical trials in adult subjects with GBM start up activities		
Lp.	Stage	Tasks*
1.	Investigator and site selection for the purpose of phase Ib/II clinical trials in adult population with GBM, according to ICH GCP and applicable regulatory requirements.	1. Review and verification of Documentation prepared for clinical trial 2. Conduct the Feasibility study with full documentation and Report 3. Site selection visits preparation and conduct with Reports 4. contracting process support 5. Clinical trial set-up support 6. Regulatory documentation preparation and organization support (Regulatory Management Plan, Regulatory Master File, EudraCT Application Form), compilation of regulatory master file 7. EMA regulatory support
2.	Safety management and Pharmaco-vigilance	1. Medical Management Plan preparation 2. Pharmaco-vigilance Plan preparation 3. Regulatory support
3.	Data management	1. Case Report Form (CRF) design, including CRF module plan and CRF completion guideline 2. Develop Data Management Plan 3. Database design and build 4. Develop data validation plan 5. Programming edit checks 6. Validation and Testing of Data Base 7. Review and acceptance of documents related to EDC
4.	Orphan drug designation	1. Document review, compillation including assessment and supplementation the content 2. Document preparation 3. Quality control and review of the application, according to regulatory requirements, overall scientific and program management
Work Package No. 2 Phase I (first-in-human) clinical trial in pediatric population with GBM start up activities		
Lp.	Stage	Tasks*
1.	Investigator and site selection for the purpose of phase I clinical trial in pediatric population with GBM, according to ICH GCP and applicable regulatory requirements.	1. Review and verification of Documentation prepared for clinical trial 2. Conduct the Feasibility study with full documentation and Report 3. Site selection visits preparation and conduct with Reports 4. contracting process support 5. Clinical trial set-up support 6. Regulatory documentation preparation and organization support (Regulatory Management Plan, Regulatory Master File, EudraCT Application Form), compilation of regulatory master file
2.	Safety management and Pharmaco-vigilance	1. Medical Management Plan preparation 2. Pharmaco-vigilance Plan preparation 3. Regulatory suport
3.	Data management	1. Case Report Form (CRF) design, including CRF module plan and CRF completion guideline 2. Develop Data Management Plan 3. Database design and build 4. Develop data validation plan

		5. Programming edit checks 6. Validation and Testing of Data Base 7. Review and acceptance of documents related to EDC
4.	Pediatric Investigation Plan (PIP) process support	1. Document review and compillation 2. Submission preparation and management