**Name of CRO:**

**Date:**

1. **What type of CRO do you represent? Please mark as X**

**Yes No**

|  |  |  |
| --- | --- | --- |
| **Medical Device** |  |  |
| **IVD** |  |  |
| **Medicinal Products** |  |  |

1. **What kind of services do you / can you provide? Please mark.**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Type of service** | **Yes** | **No** |
| **1.**  **Medical writing** | Study documents preparation |  |  |
| Summary of technical documentation (STED) |  |  |
| General safety and performance requirements (GSPRs) |  |  |
| Labelling development |  |  |
| IFU development and technical writing |  |  |
| Risk planning and reporting (ISO14971) |  |  |
| Summary of safety and performance (SSP) |  |  |
| **2.** | Regulatory and EC/IRB |  |  |
| **3.** | Study set-up and initiation (incl. site selection and qualification, site contracting and payments); |  |  |
| **4.** | Project management; |  |  |
| **5.** | Monitoring; |  |  |
| **6.** | QA, auditing; |  |  |
| **7.** | Safety reporting; |  |  |
| **8.** | eCRF |  |  |
| **9.** | Data management |  |  |
| **10.** | Biostatistics |  |  |
| **11.**  **Laboratory** | Central laboratory for CA19-9 (optional) |  |  |
| Laboratory for Panuri testing - contracting and supervision (We will be analyzing biomarkers in human **urine)** |  |  |
| **12.** | Samples shipment |  |  |
| **13.** | Patients materials logistics (e.g. urine collection containers / tubes) |  |  |
| **14.** | Sites equipment if needed (freezers at -20oC); |  |  |
| **15.** | Investigator meeting |  |  |
| **16.** | Clinical strategy |  |  |
| **17.** | QMS gap analysis |  |  |
| **18.**  **IVDR performance evaluation** | Scientific validity |  |  |
| Analytical performance (plan and report) |  |  |
| Clinical Performance (plan and report – Clinical Performance Study Report - CPSR) |  |  |
| Performance evaluation report (PER) |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **19.**  **PMS planning and writing** | Strategy, PMS procedures |  |  |
| Integration across the business |  |  |
| PMPF planning and writing |  |  |
| Complaint management Strategy |  |  |
| **20.**  **Regulatory submission** | Notified body (NB) application |  |  |
| NB findings support & remediation |  |  |
| **21.** | Other………………………………………….. |  |  |

1. **Which kind and how many numbers of CT have you ever performed for:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of CT** | **No. of projects** | **Number of sites per study** | **Therapeutic areas** | **Intended purposes** | **Your role in these projects** |
| **Medical devices** |  |  | Infectious diseases  Physiological markers  Cancer diagnosis  Transfusion Medicine  Genetic testing  Hematology  Hemostasis  Clinical Chemistry  Microbiology  Others………. |  | Full service  Operational activities  Monitoring  DM  Safety  Medical writing only  Supervision  Coordination  Other….. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of CT** | **No. of projects** | **Number of sites per study** | **Therapeutic areas** | **Intended purposes** | **Your role in these projects** |
| **IVD medical devices** |  |  | Infectious diseases  Physiological markers  Cancer diagnosis  Transfusion Medicine  Genetic testing  Hematology  Hemostasis  Clinical Chemistry  Microbiology  Others………. |  | Full service  Operational activities  Monitoring  DM  Safety  Medical writing only  Supervision  Coordination  Other….. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of CT** | **No. of projects** | **Number of sites per study** | **Therapeutic areas** | **Intended purposes** | **Your role in these projects** |
| **Medicinal products** |  |  | Infectious diseases  Physiological markers  Cancer diagnosis  Transfusion Medicine  Genetic testing  Hematology  Hemostasis  Clinical Chemistry  Microbiology  Others………. |  | Full service  Operational activities  Monitoring  DM  Safety  Medical writing only  Supervision  Coordination  Other….. |

1. **If you have experience in performing CT for IVD medical devices, please provide details:**

|  |  |
| --- | --- |
| **Applications** | **YES** |
| Professional use |  |
| Point of care |  |
| Self-Test |  |
| Companion Diagnostics |  |
| All IVDR classes |  |

|  |  |
| --- | --- |
| **Technology** | **YES** |
| Immunoassays |  |
| NGS |  |
| Multiplex |  |
| Molecular |  |
| Lateral Flow |  |
| Microfluidic |  |
| Chemical chemistry |  |
| Other …………………………. |  |

|  |  |
| --- | --- |
| **Type** | **YES** |
| Laboratory developed tests |  |
| In-house developed tests |  |

|  |  |
| --- | --- |
| **Does the CRO have standard operating procedures for IVDs?** | **YES** |
| For clinical operations following GCPs |  |
| For clinical operations following GCPs, IVDR, and ISO 20916 |  |

|  |  |
| --- | --- |
| **Is the CRO an expert in the following regulations or standards?** | **YES** |
| GCPs |  |
| GLPs |  |
| IVDR |  |
| ISO 20916 |  |
| ISO 13485 |  |
| ISO 15189 |  |
| ISO 17025 |  |
| ISO 14155 |  |
| ISO 9001 |  |
| ISO 14971 |  |
| CLSI guidance, FDA requirements |  |

|  |  |
| --- | --- |
| **Where do the CRO’s experts come from?** | **YES** |
| IVD Notified Bodies |  |
| Competent Authorities |  |
| IVD Manufacturers |  |
| IVD Auditors |  |
| Other ……. |  |

1. **Have you ever performed any CTs in oncology?** YES  NO
2. **if yes, please fill below table:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Therapeutic area of CT** | **No. of projects** | **Number of sites per study** | **Type of studies** | **Indications** | **Your role in these projects** |
| **Oncology** |  |  |  |  | Full service  Operational activities  Monitoring  DM  Safety  Medical writing only  Supervision  Coordination  Other….. |

1. **Have you ever performed any CTs in oncology for IVD medical devices? If yes, please fill below table:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Therapeutic area of CT / type of CT** | **No. of projects** | **Number of sites per study** | **Intended purpose** | **Indications** | **Your role in these projects** |
| **Oncology / IVD medical device** |  |  |  |  | Full service  Operational activities  Monitoring  DM  Safety  Medical writing only  Supervision  Coordination  Other….. |

1. **Have you ever:**
2. performed a study with over 500 patients in oncology? YES  NO
3. In any therapeutic area? YES  NO
4. **Have you ever performed clinical site selection and feasibility process?** YES  NO

**If yes**, please answer the following questions:

1. Was oncology included? YES  NO
2. What kind of studies? ……………………………………………………………………………….
3. What is the usual feasibility time from your experience? …………………………………
4. **Do you have previous experience working with any clinical oncological sites in Poland?**

YES  NO

**If yes**, please list them below:

|  |  |
| --- | --- |
| **No** | **Oncological sites in Poland** |
| **1** |  |
| **2** |  |
| **3** |  |
| **4** |  |

1. **Do you have your own central lab to analyze urine specimens?\*\*\*** YES  NO

**If no**, please answer the following question:

1. What is your experience regarding organizing specimens analysis? Do you cover such activities?

……………………………………………………………………………………………

|  |
| --- |
| \*\*\* We will be analyzing biomarkers in human **urine**. The study is designed as major study intended for device certification by notified body and registration **in EU**. We can provide equipment needed for analyses (i.e. TECAN Infinite F Nano+ Microplate reader). |

1. **Would you be able to cover supervision of central laboratory and / or local laboratories?**

YES  NO

**If yes**, would you :

* propose vendor yourself? YES
* would you prefer Sponsor to select? YES

1. **Have you ever organized / supervised shipment of samples frozen on dry ice?**

YES  NO

If yes, what was your role? ……………………………………………………………………………………………………………………….

**13. Do you have your own branches in Poland?** YES  NO

**If yes,** where

………………………………………………………..