

**PRELIMINARY EVALUATION
QUESTIONNAIRE OF A SERVICE
PROVIDER/CONTRACT RESEARCH
ORGANISATION**

I. Description of the Service Provider/Contract Research Organisation

Company:

Address:

tel:

@:

Website:

Chief Executive Officer:

Company Business name:

Company set-up date:

Company Legal status:

Belonging to a Holding: ☐ no ☐ Yes (detail):

Subsidiary companies: ☐ no ☐ Yes (detail):

Connections with other companies: ☐ no ☐ Yes (detail):

List of principal customers:

1. Services

	2023	2024	2025
Number of customers			
Number of ongoing clinical trials			
Number of ongoing non-interventional studies			

Tick the performed services:

☐ **Interventional Study (Phases I to IV)**

- ☐ Phase I center
- ☐ Design of the study
- ☐ Medical writing (Protocol, Clinical Study Report, Investigator's Brochure, etc.)
- ☐ Case report form design
- ☐ Regulatory submissions
- ☐ Project Management
- ☐ Monitoring
- ☐ Data Management
- ☐ Statistical analysis
- ☐ IWRS/IVRS
- ☐ e-CRF
- ☐ Trial safety management (☐ including reporting to Competent Authorities)

☐ **Non Interventional study (registry, observational, PASS, etc.)**

- ☐ Design of the study
- ☐ Medical writing (Protocol, Clinical Study Report)
- ☐ Case report form design
- ☐ Regulatory submissions
- ☐ Monitoring
- ☐ Data Management
- ☐ e-CRF
- ☐ Statistical analysis
- ☐ Safety management (☐ including reporting to Competent Authorities)

☐ **Investigational Medicinal Products management (manufacturing, labeling, shipment, etc.)**

☐ **Biological Central laboratory**

☐ **Image Central Reading**

☐ **Other(s):**

Is the company specialized in some therapeutic areas:

☐ No

☐ Yes (please detail):

2. Staff

Thanks for filling out the table below or attaching an organizational chart of the company:

Numbers of employees	Qualification or Role or Function

3. Quality Assurance

Does the company have a Quality Assurance Department:

☐ No

☐ Yes (please specify resources in section 2)

Name and contact details of the Head of QA:

Does the company have :

- a Quality Manual: ☐ No ☐ Yes
- SOPs ☐ No ☐ Yes

Is your organization ISO certified: ☐ No ☐ Yes

If so, by whom?

How many audits were performed by your QA department:

	2023	2024	2025
Internal system audits			
Clinical trial audits (TMF, investigational sites, data management, etc.)			
Vendors audits			

How many audits/inspections were hosted by your company:

	2023	2024	2025
Qualification audits			
Routine audits			
Inspections			

4. Computerized systems

What are the main computerized systems (hardwares, softwares, , etc.) used to manage your activities, particularly for data management, statistical activities, IVRS/IWRS, e-CRF and pharmacovigilance?

Please specify name and version

5. Additional Information

Indicate below all additional information which seems useful:

6. Provide the following documents if possible

- ☐ Company overview presentation
- ☐ Organizational chart(s)
- ☐ Quality Manual
- ☐ List of applicable SOPs

Date :

Function:

Name: