

Contracting Entity: BiconY Therapeutics GmbH Lagerhofstraße 4 04103 Leipzig	Contract: Central Laboratory Services for clinical trial
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Central Laboratory Services for Clinical Trial

Service Description (Terms of Reference)

for the

EU-wide open procedure (§ 15 VgV)

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1. General Information for Bidders

The Federal Agency for Disruptive Innovation - SPRIND GmbH ("SPRIND") - aims to create new disruptive innovations from Germany. That means products, services and systems that make all our lives noticeably and sustainably better. To achieve this, SPRIND brings together new thinkers from science and business, people with outstanding ideas, special expertise, and passion. Hence, SPRIND provides an entrepreneurial environment that turns ideas into reality.

The objective of BiconY Therapeutics GmbH, a SPRIND subsidiary, is the development of a bispecific antibody combination for the treatment of solid tumours. The combination consists of proprietary, bispecific CD3 anti-bodies (bsAbCD3) and bispecific CD28 co-stimulators (BiCos), which, when used together, significantly improve the specificity, sustainability, and efficiency of a T cell recruitment and thus the immune response against tumour cells. The aim of the research and development activities is to provide proof of concept for the effect of bispecific antibody therapy in the form of two phase I/IIa clinical trials.

For the conduct of the planned phase I/IIa clinical trials, comprehensive central laboratory services are required for the collection logistics, processing, analysis, management and long-term storage of the biological specimens obtained from the trial participants. This includes in particular the multiplex analysis of cytokines in serum (Multiplex 5: TNF- α , IFN- γ , IL-1 β , IL-6, IL-10) and the isolation of peripheral blood mononuclear cells (PBMC). Therefore, BiconY is looking for a service provider to act as central laboratory for these clinical trials.

2. Description of the Project and of the services to be provided

The central laboratory services are required for the following clinical study:

Table 1: Study parameters

Study protocol	Clinical trial protocol
Type of service	Central laboratory services for a clinical study (phase I/IIa)
Quality standard	GCP / GCLP laboratory accredited (e.g. ISO 15189 or equivalent)
Indication (background)	Bispecific antibody therapy for the treatment of solid tumours
Countries / sites	Germany / 5 sites
Number of subjects (planned)	90

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Project initiation	Mid of November 2026
First Subject In	December 2026
Project end	April 2028
Project length	18 months (services approx. 19 months incl. set-up and close-out)
Cytokine panel (serum)	TNF- α , IFN- γ , IL-1 β , IL-6, IL-10, IL-2
Sample preparation	Isolation of peripheral blood mononuclear cells (PBMC), Storage of serum (for external analysis (ADA, PK)), A and B sample
Specimen types	Serum blood and whole (heparin) blood
Storage conditions	-80 °C and/or liquid nitrogen (LN), temperature-monitored (24/7 alarm system)
Reporting / data	Study database (LIMS), cumulative data transfers, archiving

Table 2: Overview of the required central laboratory services

Pos.	Service group	Description of the required services	Indicative scope
A	Set-up and project management	Generation of the Statement of Work; set-up and validation of the study database (LIMS); project management over the project duration; creation and printing of the laboratory manual; trial-site set-up; study closure.	Set-up per lab; PM approx. 19 months; 5 sites
B	Provision of trial sites (lab kits)	Provision and storage of lab kits containing material for specimen collection and processing, coded labels for specimen tubes and study-specific requisition forms.	approx. 90 kits; 5 sites
C	Logistics – specimen shipment	Organised dry-ice courier shipment of frozen specimens from the trial sites to the central laboratory (inbound) and from the central laboratory to third parties (outbound), including handling, tracking, communication and documentation.	inbound approx. 30 shipments; outbound approx. 4 shipments
D	Routine laboratory analyses	Isolation of peripheral blood mononuclear cells (PBMC) from whole blood.	approx. 360 specimens
E	Special laboratory analyses (batchwise)	Cytokine multiplex analysis in serum (TNF- α , IFN- γ , IL-1 β , IL-6, IL-10).	approx. 2,250 tests
F	Specimen management	Specimen accession/receipt with quality control; cataloguing; storage administration; specimen check-out; specimen disposal; preparation of shipment lists.	approx. 4,500 specimens

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G	Reporting, data management, transfer and archiving	Set-up, validation and maintenance of the data-transfer specification and study database; cumulative data transfers; management of error logs; archiving of study data.	over project duration; ≥ 2 cumulative data transfers
H	Long-term storage of specimens	Temperature-monitored long-term storage of specimens at –80 °C and in liquid nitrogen (cell suspension) for defined durations, including a 24/7 alarm system.	serum and cell specimens; storage approx. 90–720 days per type

- The specimens are collected at the trial sites and shipped frozen to the central laboratory for processing, analysis, management and storage. Study protocol, laboratory specifications and requisition requirements will be shared by BiconY Therapeutics.
- The central laboratory sets up and validates a study-specific database (LIMS) and provides the laboratory manual and lab kits prior to First Subject In.

Kit material and collection/requisition specifications are coordinated between BiconY and the central laboratory.

Scope of Services

- Provision of the comprehensive central laboratory services described above for the duration of the clinical study.
- Regular update meetings with the BiconY project team and CRO (if necessary).
- Fast turn-around times when interacting with the trial sites and courier / logistics services.
- Temperature-controlled processing and long-term storage of specimens with continuous monitoring (–80 °C / liquid nitrogen).
- Reporting and data management: cumulative data transfers during the study and a final data package (specimen inventory and analytical results) provided in an agreed electronic format. All specimens and associated data are handled in compliance with GCP/GCLP and applicable data-protection requirements (GDPR).

The central laboratory must be fully set up and validated (LIMS database, laboratory manual and lab kits) and ready to receive specimens by First Subject In. The set-up completion / readiness date offered by the bidder in the form “Offer” is legally binding.