



# Central Reference Laboratory & Biobank for Biomarker-Guided Phase 1 Trials

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30 JULY 2026

HORIZON-MISS-2027-02-CANCER-03

# HORIZON-MISS-2027-02-CANCER-03: Our Strategic Objective

CSD LAB and CSD BIO are positioning ourselves as a **strategic partner and technological contributor** under the EU Mission Cancer topic HORIZON-MISS-2027-02-CANCER-03 — Phase 1 clinical trials for biomarker-guided medicines in rare cancers. Our core objective is to provide a robust, centralized multi-omics infrastructure that accelerates biomarker identification, patient stratification, and minimal residual disease (MRD) monitoring for first-in-human trials of targeted therapies.

## Our Proposed Role

Central Reference Laboratory & Biobank — delivering high-throughput molecular testing, liquid biopsy monitoring, and ethically governed biospecimen management across all consortium sites.

## What We Bring to the Consortium

- Centralized, high-throughput biomarker testing across all trial sites
- Secure, GCP-compliant biobanking with deep clinical annotation
- Real-time MRD monitoring via liquid biopsy (ctDNA)
- Access to underrepresented Eastern European patient cohorts
- Integrated LIMS for end-to-end sample traceability

# Unmatched Operational Scale Across Eastern Europe

CSD LAB and CSD BIO represent the **largest pathomorphological laboratory complex and full-service biobank in Eastern Europe**. Our operational footprint, throughput, and infrastructure are purpose-built to support the demands of multi-center Phase 1 clinical trials requiring rapid, reliable, and compliant biomarker testing at scale.

2.7M

Tests Annually

High-volume diagnostic throughput demonstrating operational reliability and capacity for trial-scale testing.

185+

Collection Points

Active network across Ukraine, Moldova, and Georgia enabling rapid, protocol-driven prospective sample collection.

50K+

Annotated Biospecimens

Pathology-confirmed, deeply annotated human biospecimens in our biobank repository, ready for retrospective and prospective research.

900+

Professionals

Clinical and scientific team certified in Biorepository Science (ASCP BOC) and Good Clinical Practice (GCP).

Our focus areas span **rare and common solid tumors** as well as **hematologic malignancies**, giving consortia direct access to clinically relevant, well-characterized patient cohorts that are historically underrepresented in Western European and North American trial populations. All operations are TÜV-certified, GCP-compliant, and governed by a strict independent Ethics Committee.

# Advanced Multi-Omics Platform for Precision Trial Support

For Phase 1 biomarker-guided trials, analytical precision and turnaround time are critical. CSD LAB operates a fully integrated, in-house multi-omics platform capable of generating the high-resolution molecular data required to support patient stratification, target validation, and dynamic resistance monitoring throughout the trial lifecycle.

## Actionable Alteration Profiling

Comprehensive profiling for rare and clinically actionable targets including **MET exon 14 skipping, RET, NTRK, ROS1, HER2, EGFR, and ALK** — enabling precise patient selection for targeted therapy arms in first-in-human trials.

## Targeted NGS & DNA Sequencing

Full mutation profiling, tumor mutational burden (TMB) assessment, and copy-number alteration analysis using validated targeted next-generation sequencing panels optimized for low-input and FFPE samples.

## Liquid Biopsy (ctDNA)

Real-time monitoring of **Minimal Residual Disease (MRD)** and clonal evolution through circulating tumor DNA analysis, enabling non-invasive longitudinal assessment of treatment response and emerging resistance mechanisms.

## Transcriptomics & RNA Profiling

RNA-based fusion detection and gene expression profiling to identify transcriptional drivers, validate target engagement, and characterize tumor microenvironment signatures relevant to immunotherapy trials.

# A Proven Global Operational Hub, Not a Startup



## Global Trust & Collaborative Reach

CSD LAB and CSD BIO are established, long-term partners to **over 30 global pharmaceutical, biotech, and academic institutions** across the United States, European Union, and Japan. These are not one-off collaborations — they are sustained partnerships built on consistent quality, regulatory compliance, and operational reliability.

Our active clinical network includes **over 100 partner sites** capable of prospective, protocol-driven sample collection with standardized SOPs, ensuring sample integrity and chain-of-custody from point of collection to central biobank.

## Expert Team & Certifications

- **TÜV-certified** quality management systems
- **GCP-compliant** operations across all trial-related activities
- **LabKey LIMS** (US) integration for end-to-end sample traceability
- Team leads certified in **Biorepository Science (ASCP BOC)**
- Independent **Ethics Committee** oversight for all biobanking activities

# Who We Are Looking For — and What We Offer

CSD LAB and CSD BIO are actively seeking to join consortia preparing for **Phase 1 biomarker-guided trials in rare cancers** under the HORIZON-MISS-2027-02-CANCER-03 framework. We are not a passive service provider — we are a strategic technological contributor committed to the scientific and operational success of every consortium we join.

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| <h3>Ideal Consortium Leads</h3> <p>Comprehensive Cancer Centers, leading academic institutions, and pharmaceutical or biotech companies developing biomarker-guided targeted therapies or immunotherapies for rare cancers.</p> | <h3>Our Core Contribution</h3> <p>Central Reference Laboratory services including NGS, liquid biopsy, MRD monitoring, multi-omics data generation, and ethically governed biobanking — fully integrated into your trial protocol.</p> | <h3>Our Ask</h3> <p>Include CSD LAB/BIO as your designated central reference laboratory and biobanking partner from the outset, enabling seamless protocol integration and rapid site activation.</p> |
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 We welcome direct contact during matchmaking sessions. Reach us at [bio@csdbio.com.ua](mailto:bio@csdbio.com.ua) or visit [www.csdbio.com.ua](http://www.csdbio.com.ua) to explore how CSD LAB & CSD BIO can accelerate your Phase 1 trial consortium.