

# KCLEAGENICS MEDICAL INC.

## CAPABILITY STATEMENT

Integrating Science, Care, and Innovation for Better Health

GCP Certified · FDA Compliant · ClinicalTrials.gov Registered

### WHO WE ARE

KCLEAGENICS MEDICAL INC. is a Chicago-based Contract Research Organisation (CRO) specialising in Phase I–III oncology, haematology, and metabolic medicine clinical trials. We partner with industry sponsors, academic institutions, and specialist clinical centres to deliver rigorous, FDA-compliant research — from first-in-human studies through late-phase registration trials. Our operations are built on GCP E6(R2) and FDA 21 CFR Part 11/50/56 compliance, with a dedicated biospecimen infrastructure and in-house biostatistics and regulatory teams.

### CORE CAPABILITIES

#### Trial Management

- Phase I–III design & protocol development
- Site activation & monitoring (SDV/RMM)
- Investigator & site staff training
- Trial Master File (TMF) management
- Safety reporting & SUSAR submission
- Data lock, CSR & publication support

#### Regulatory Strategy

- FDA 21 CFR Part 11, 50, 56 compliance
- IND/IDE liaison & pre-submission meetings
- IRB/Ethics submission management
- Protocol deviation & CAPA management
- Audit preparation & FDA inspection support
- International study support (REC, ICH GCP)

#### Data & Biostatistics

- Pre-specified SAP development
- EDC setup & data management
- Biostatistical analysis & reporting
- Adaptive design statistical modelling
- CDISC SDTM/ADaM dataset preparation
- Regulatory submission packages

### BIOSPECIMEN & TISSUE COLLECTION SERVICES

## Oncology Tissue Collection & Specimen Management

We provide end-to-end biospecimen and tissue collection services coordinated across multi-specialist oncology settings. Our site infrastructure includes dedicated solar-backed power for uninterrupted cold-chain specimen storage, independent of grid reliability.

#### Specimen types supported:

Breast · Colorectal · Gastric · Ovarian · Uterine · Cervical · Urological  
Formats: Fresh-frozen · FFPE · Liquid biopsy · Serum/plasma · Tumour-derived organoids

#### Cold-Chain Infrastructure

Dedicated solar-backed storage systems; uninterrupted -80°C, -20°C, and 4°C capacity. Independent of grid supply.

#### Multi-Specialist Coordination

Collection across surgical oncology, haematology, pathology, and radiology units — single-source coordination.

#### Logistics & Chain of Custody

Tracked specimen transport from collection site to sponsor or central laboratory. Full chain-of-custody documentation.

#### Data Integration

Biospecimen data linked to trial EDC — specimen tracking, aliquot logs, and quality metrics in real time.

## REGULATORY CREDENTIALS

### United States

#### FDA 21 CFR Compliance

Parts 11, 50 & 56 — electronic records, informed consent, and IRB requirements. IND-enabled study designs.

### International

#### ICH GCP E6(R2)

All trials conducted to ICH GCP E6(R2) — audit-ready documentation acceptable to global regulatory agencies.

### Transparency

#### ClinicalTrials.gov Registration

All interventional studies prospectively registered per FDAAA 801 requirements.

<b>Location</b>	1415 W 22nd Street, Tower Floor Oak Brook, IL 60523
<b>Specimen Storage</b>	-80°C, -20°C, 4°C capacity Solar-backed power (grid-independent)
<b>Clinical Network</b>	Specialist oncology, haematology, pathology, and surgical centres
<b>Sponsor Directories</b>	SCRS Site Finder - ACRP Directory ResearchMatch - ClinicalTrials.gov
<b>Contact (Research)</b>	research@kclgmedical.com 312-225-3916 - Mon-Fri 9am-5pm CT

## HOW TO ENGAGE

### 01

#### Initial Enquiry

Submit protocol concept or feasibility question. 2-day response guaranteed.

### 02

#### Feasibility Report

Site capability, patient population & specialist availability — within 10 days.

### 03

#### Contract & Setup

CTA, budget, IRB/ethics submission & site initiation run in parallel.

### 04

#### Study Delivery

Enrolment through data lock, CSR & publication. Full GCP-compliant delivery.

**KCLEAGENICS MEDICAL INC. 1415 W 22nd  
Street, Tower Floor · Oak Brook, IL 60523**

keog@kclgmedical.com · research@kclgmedical.com  
312-225-3916 · www.kclgmedical.com

GCP Certified · FDA 21 CFR  
Compliant ICH GCP E6(R2) ·  
ClinicalTrials.gov Registered