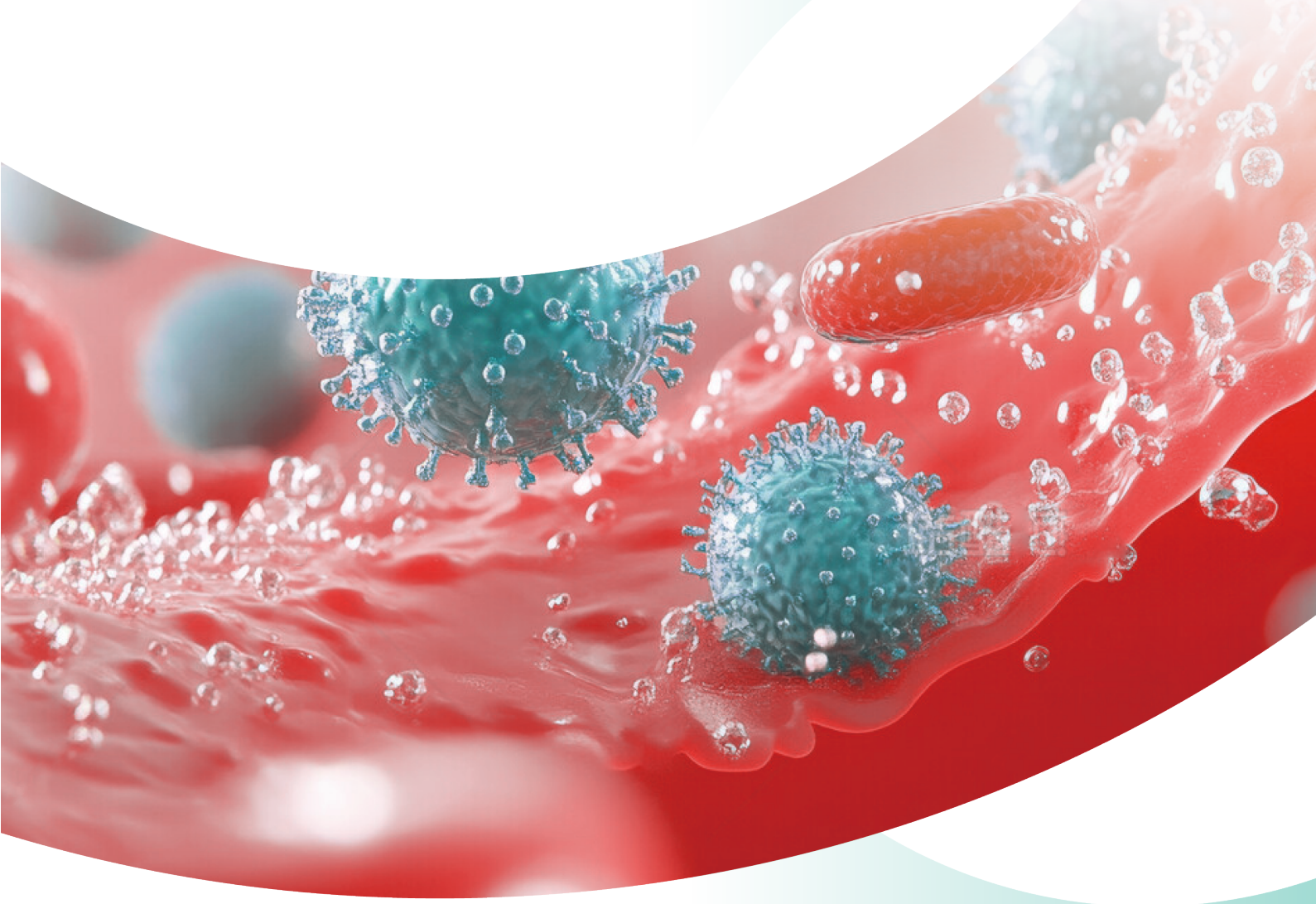
KingMYlab
A Core Member of KingMed
Since 2008

# Hematological Malignancies

## —Central Laboratory Solutions for Clinical Trials



Your Best Central Lab Partner for Clinical Trials in China

# About KingMylab

KingMylab is a leading provider of central laboratory services for clinical trials in China. Founded in 2008 as the Clinical Trial Department of Guangzhou KingMed Diagnostics—China's largest clinical diagnostics corporation—then became independent in 2020. We deliver scientific, compliant and one-stop comprehensive central laboratory and data solutions for clinical trials to our pharmaceutical and biotech partners locally and globally. Our services cover the entire drug development pipeline across a broad range of therapeutic areas—including but not limited to oncology, immunology, metabolism, neurology, infectious diseases, vaccines and cell&gene therapy, as well as the full clinical trial lifecycle and international multi-regional trials.

KingMylab's quality system complies with NMPA, FDA, EMA and GLP/GCP requirements, relevant three laboratories in Guangzhou, Shanghai and Hong Kong China have obtained CAP, CLIA and ISO 15189 accreditations. We are committed to building an integrated central laboratory service chain for clinical trials and expanding into diversified clinical trial CRO services.


**4200+**
Central Lab Tests

**800+**
Global Clients

**80+**
Technical Platforms

**4500+**
Clinical Trials

**90+**
Novel Drugs Supported

**160+**
NMPA/FDA/EMA Inspections

# Hematological Malignancies One-Stop Central Laboratory Testing Platform for Clinical Trials

Hematological neoplasms are a group of neoplastic disorders originating from the hematopoietic system or lymphoid tissues, which can involve the bone marrow, blood, and various organs and tissues throughout the body.

In recent years, hematological neoplasms (such as leukemia, lymphoma, and multiple myeloma) have witnessed significant advances in targeted therapy and immunotherapy. These developments have enabled more patients to benefit from novel therapeutic approaches, such as small-molecule targeted agents, antibody-based drugs (monoclonal or bispecific antibodies), and chimeric antigen receptor T (CAR-T) cell therapies, thereby improving patient prognosis and quality of life.

Compared with solid tumors, hematological neoplasms exhibit greater complexity in classification and present more challenges in endpoint assessment. In particular, the diagnosis and treatment of lymphoid and hematopoietic tumors place high demands on laboratory testing. Different subtypes of the same disease can significantly affect the pace of clinical trials. Therefore, the diagnosis and therapeutic monitoring of hematological neoplasms rely heavily on laboratory testing technologies, and the capability to measure laboratory parameters as well as the project management capacity of central laboratories plays a critical role in the progress of clinical trials.

KingMylab has a multidisciplinary team, multiple technology platforms, and a mature management system. Driven by client needs and co-creating with clients, the company has established a one-stop translational service platform for oncology clinical trials. In the field of hematological neoplasm research, it has served over 500 projects and operates the MICM integrated platform, providing end-to-end clinical diagnosis and treatment services for lymphoid and hematopoietic neoplasms. With extensive expertise in project execution, KingMylab has successfully supported the development of several Class 1 innovative anti-cancer drugs in China and US. We continue to empower innovative breakthroughs in oncology clinical trials through professional services and innovative technological solutions

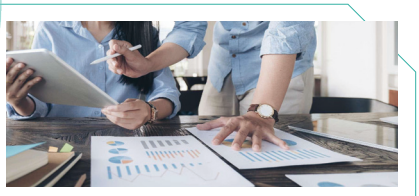
## Central laboratory

- Comprehensive and leading technology platform providing integrated multiomics solutions
- 4,000+ mature testing projects
- Robust project development capabilities

One-Stop Clinical Trial Platform for "Laboratory Testing + Data Services"

## Bioanalysis

- Well-equipped bioanalytical platform
- Provides PK and immunogenicity services for large molecules, cell therapies, and more



## Data services

- Biomarker discovery and exploration
- High-value data mining, analysis, and statistical support

Experienced International Scientific & Management Team

18 Years of Established Compliance and Quality Management System

Comprehensive and Leading Integrated MultiOmics Platform

Fast and High-Quality Delivery Across the Entire Lifecycle

# Comprehensive Capabilities in Central Laboratory Testing Services for Hematological Malignancies

## Full-Cycle Testing: Screening ·Treatment ·Follow-up

### Screening period

(Inclusion/exclusion criteria and baseline values)

#### Disease diagnosis and prognostic stratification (MICM classification)

**M:** Bone marrow cytology, bone marrow biopsy + immunohistochemistry

**I:** Flow cytometric immunophenotyping for leukemia/lymphoma

**C:** Chromosomal karyotyping, FISH analysis

**M:** Fusion genes, gene mutations, etc.

#### Other inclusion/exclusion-related indicator testing

Therapeutic targets: BCMA, CD33, CD20, etc.

Viral nucleic acid quantification: EBV DNA, CMV DNA, etc.

Other tests: Complete blood count, liver function, kidney function,
coagulation function, etc.

#### Pretreatment baseline value testing

**Efficacy assessment indicators:** Complete blood count, blood/urine M-protein, etc.

**Serological prognostic indicators:** LDH, P2-MG, etc.

**Exploratory research:** PD indicators, MOA, etc

### Treatment and Follow up

(Efficacy assessment/safety/disease monitoring)

#### Conventional efficacy assessments (compared with baseline)

Bone marrow cytology examination

Bone marrow pathology/flow cytometry

Cytogenetics/molecular biology

Other indicators: Complete blood count, serology, urine tests, etc.

#### MRD efficacy assessment (depth of response)

Multiparameter flow cytometry (MFC)/next-generation flow (NGF): Sensitivity $10^{-4}$–$10^{-6}$ Molecular assays (PCR/NGS): Fusion genes, gene point mutations, immunoglobulin (Ig) or TCR clonal rearrangements, etc., sensitivity $10^{-4}$–$10^{-6}$

#### Safety endpoints

**Immunotherapy-related:** Th1/Th2 cytokine testing, lymphocyte subset analysis, etc.

**Organ function monitoring:** Liver function, kidney function, electrolytes, myocardial injury markers, coagulation function, etc.

#### Exploratory research indicators

Immune cell phenotyping

Molecular subtyping of lymphoid and hematopoietic malignancies

Target and pathway-related markers

### Post-treatment disease monitoring during follow-up period

(Disease monitoring/safety)

Bone marrow cytology examination

MRD testing

Lymphocyte subset analysis

Complete blood count

Liver function, kidney function, etc.

## Common Indications Covered in Clinical Trials of Hematopoietic and Lymphoid Tumors

### Myeloid Malignancies

- Acute myeloid leukemia (AML)
- Myelodysplastic syndromes (MDS)
- Chronic myeloid leukemia (CML)
- Chronic myelomonocytic leukemia (CMML)
- Polycythemia vera (PV)
- Essential thrombocythemia (ET)
- Primary myelofibrosis (PMF)

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### Lymphoid Malignancies

- Acute B-cell lymphoblastic leukemia (B-ALL)
- Multiple myeloma (MM)
- Chronic lymphocytic leukemia/Small lymphocytic lymphoma (CLL/SLL)
- Mantle cell lymphoma (MCL)
- Follicular lymphoma (FL)
- Diffuse large B-cell lymphoma (DLBCL)
- Peripheral T-cell lymphoma (PTCL)

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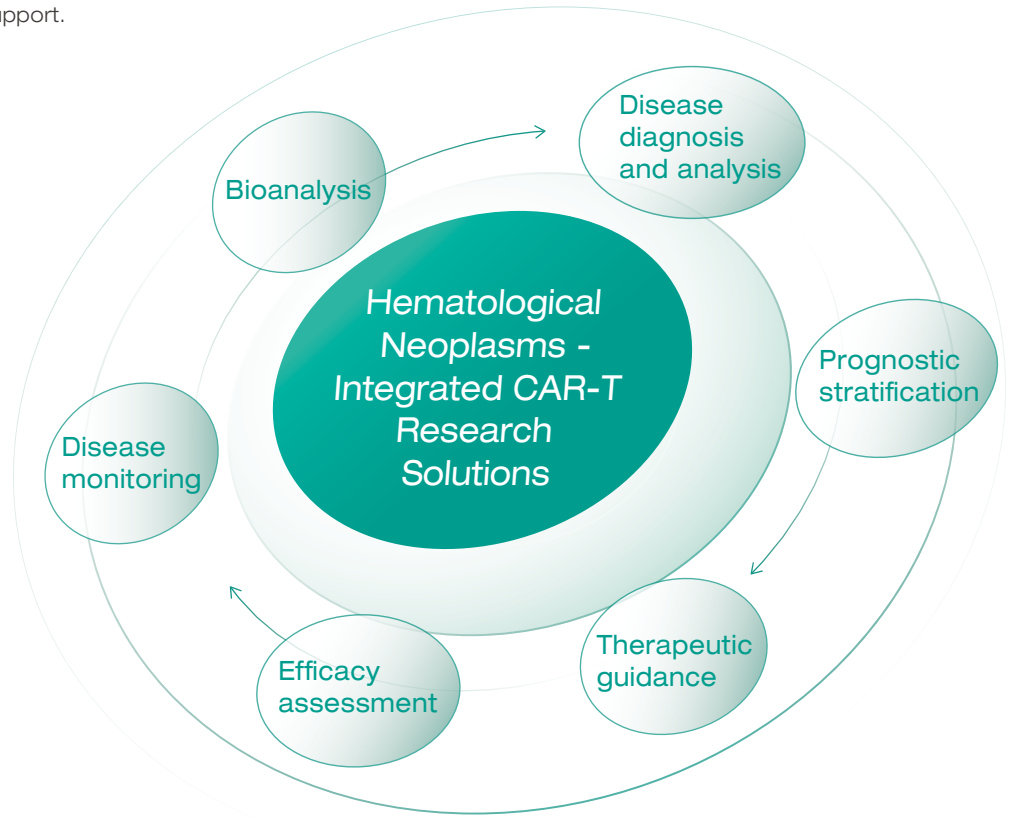
# Central Laboratory Solutions for Hematological Hematological Malignancies —CAR-T Cell Multi-Technology Platforms Enabling Drug Development

CAR-T cell therapy represents one of the most revolutionary breakthroughs in the treatment of hematological neoplasms in recent years. By harnessing autologous immune cells to target and eliminate tumor cells, this innovative therapeutic approach has enabled some patients with previously refractory or difficult-to-treat diseases to achieve durable remission and even the potential for cure. CAR-T cell therapy is primarily indicated for hematological neoplasms such as B-ALL, MM, and B-NHL. Our central laboratory offers an integrated solution for CAR-T cell therapy, including comprehensive bioanalytical support.




## PK

CAR cell count (flow cytometry)
CAR gene copy number (qPCR/ddPCR)

## Safety

Immunogenicity (ELISA/Flow)
Replication-competent lentivirus/retrovirus (qPCR/ddPCR)
Cytokines and inflammation-related markers (ELISA/MSD/Luminex)

## PD

Target antigen-positive cells in peripheral blood or bone marrow (flow cytometry)
Tumor target antigen expression (IHC)
Soluble target antigen levels in peripheral blood (ELISA)

## Effectiveness

Blood smear
Bone marrow smear
Histopathological examination (IHC)
MRD (flow cytometry)
Blood and urine tests

## Biomarker exploration

Immune cell function-related markers (HC/mIHC/RNAseq)
Immune-related factors (ELISA/MSD/Luminex)
CAR-T and immune cell phenotyping (flow cytometry)
Target and pathway-related markers

# Pipelines Across Diverse Therapeutic Modalities for Hematological malignancies

## Integration of cutting-edge diagnostic technologies and multiomics platforms to meet the needs of hematological neoplasm clinical trials

12 major platforms, including pathology, flow cytometry, cytogenetics, molecular biology, routine hematology, biochemical and immunology platforms, clinical immunology platform, molecular infectious disease, mass spectrometry and others, covering a total of 82 clinical testing techniques

Efficiently empowering diverse drug development pipelines in hematological neoplasms to meet a wide range of clinical trial needs, including disease diagnosis, prognostic stratification, efficacy assessment (including MRD), safety marker evaluation, pharmacodynamic measurements, exploratory research (e.g., immune microenvironment), and development of novel biomarker assay methodologies

### Integration of Multi-Omics Platforms to Empower Clinical Research

High-throughput sequencing

qPCR/ddPCR

Cytogenetics

Flow cytometry

Immunology

Routine hematology

Central pathology

Immunohistochemistry

Multiplex immunohistochemistry

# Global High-Quality Standards Central Laboratory

Operates a quality management system fully compliant with clinical trial regulations (GCP/GCLP) required by NMPA, FDA, and EMA, based on international quality system standards including CAP, CUA, and ISO 15189

## 18 consecutive years

Participating in and accredited by CAP
(College of American Pathologists)

★★★★★




# Equipped with a First-Class MICM+ Testing Platform, Conducting over 500 Projects

## Platform highlights

- Authoritative expert team
- Dual international quality assurance
- Development of personalized testing solutions
- Data-driven empowerment

**Hematopathology** testing volume
Over **60,000 cases/year**

**Flow cytometry platform**
Over **20,000 cases/year**

**Cytogenetics platform**
(FISH/Karyotyping)
Over **150,000 cases/year**

**Molecular biology platform**
(qPCR/NGS)
Over **60,000 cases/year**

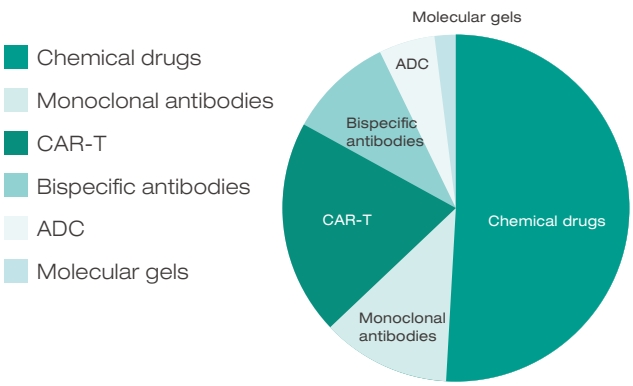
| | Morphology platform (M) | Immunology platforms (I) | Cytogenetics platform (C) | Molecular biology (M) |
|---|---|---|---|---|
| Technical Platform | Bone marrow cytology/bone marrow pathology/ lymphoid tissue pathology | Multiparameter flow cytometry(MFC)/ Next-generation flow (NGF) | Chromosome karyotyping/ FISH/CMA | qPCR/ddPCR/NGS |
| Testing content | **Bone marrow smears+ blood smears:** Cellular morphology<br>**Bone marrow biopsy + immunohistochemistry:** Definitive disease diagnosis, subtyping, and target expression<br>**Lymphoid tissue pathology:** Pathological diagnosis and differential diagnosis of lymphomas | **Immunophenotyping:** Acute and chronic leukemia/NHL/MDS<br>**MRD testing:** MFC or NGF-based, including AML/ALL, MM, CLL, MCL, etc<br>**Therapeutic targets:** CD33, CD371, CD123, CD20, CD19, CD38, BCMA, etc. | **Chromosome karyotyping:** Bone marrow cells, peripheral blood cells<br>**Fluorescence in situ hybridization(FISH):** Gene/Chromosome, fusion genes, amplifications, deletions, etc.<br>**Molecular karyotyping (CMA):** SNP-array for detecting chromosomal CNVs | **Real-time quantitative PCR(RQ-PCR)** Fusion genes, gene mutation, etc.<br>**Next-generation sequencing (NGS)** Hematological neoplasm gene panels, IgHV mutations, etc.<br>**Fragment analysis (PCR + capillary electrophoresis):** Ig/TCR gene clonal rearrangements<br>**Omics exploratory research** |

# Extensive Experience in Hematological Malignancies Projects, Providing Full Lifecycle Project Management to Support New Drug Development

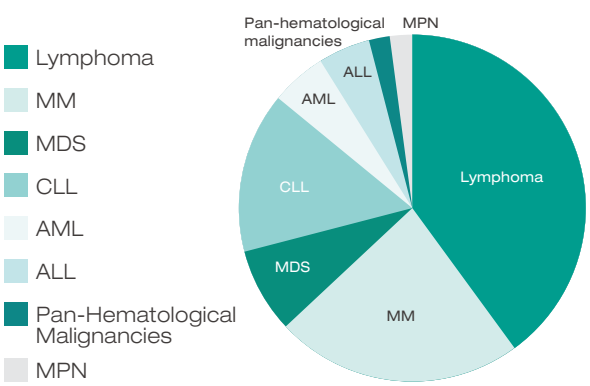
- As of April 2025, the central laboratory has undertaken over 500 hematological malignancies clinical trial projects, of which pivotal Phase III registration trials account for approximately 15%.
- 100% NMPA and FDA inspection compliance: As of April 2025, hematological malignancies clinical trial projects have successfully passed nearly 60 inspections and audits by NMPA and FDA, supporting the NMPA approval of nearly 20 drugs.
- Specialized Excellence in Multiple Myeloma: ~50 MM clinical trial projects supported, ~40% are pivotal Phase III registration trials , 8 NMPA-approved drugs.

## a. Analytical experience across clinical projects

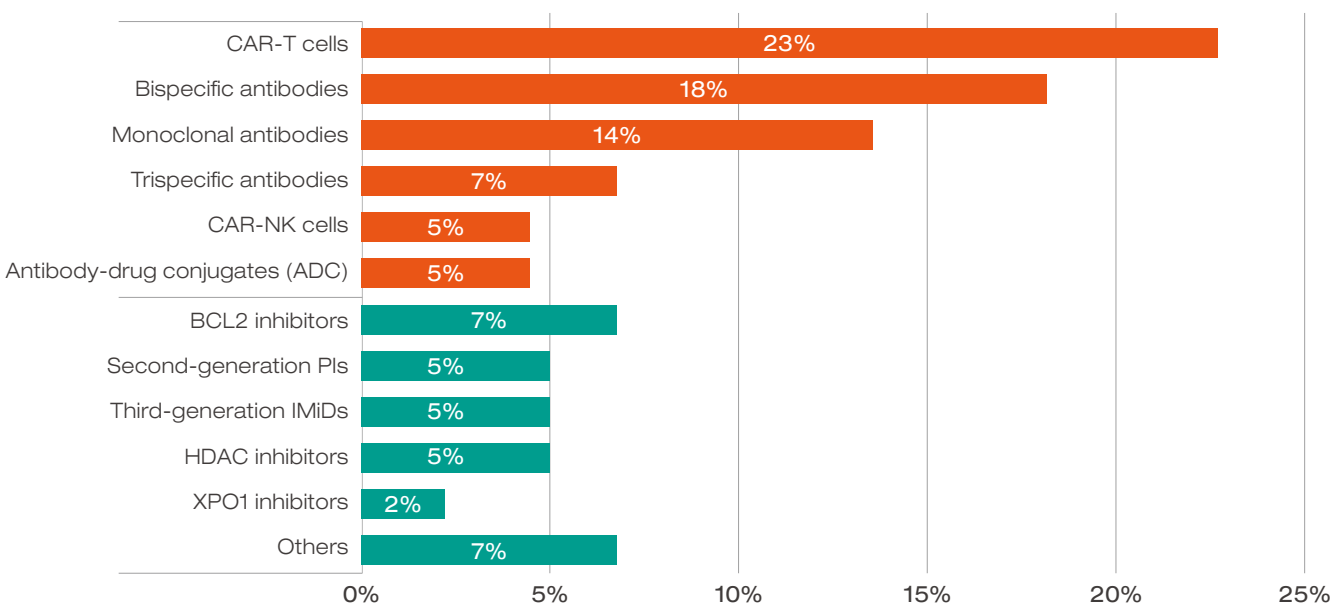

## b. Supported drug types




## c. Distribution of indications



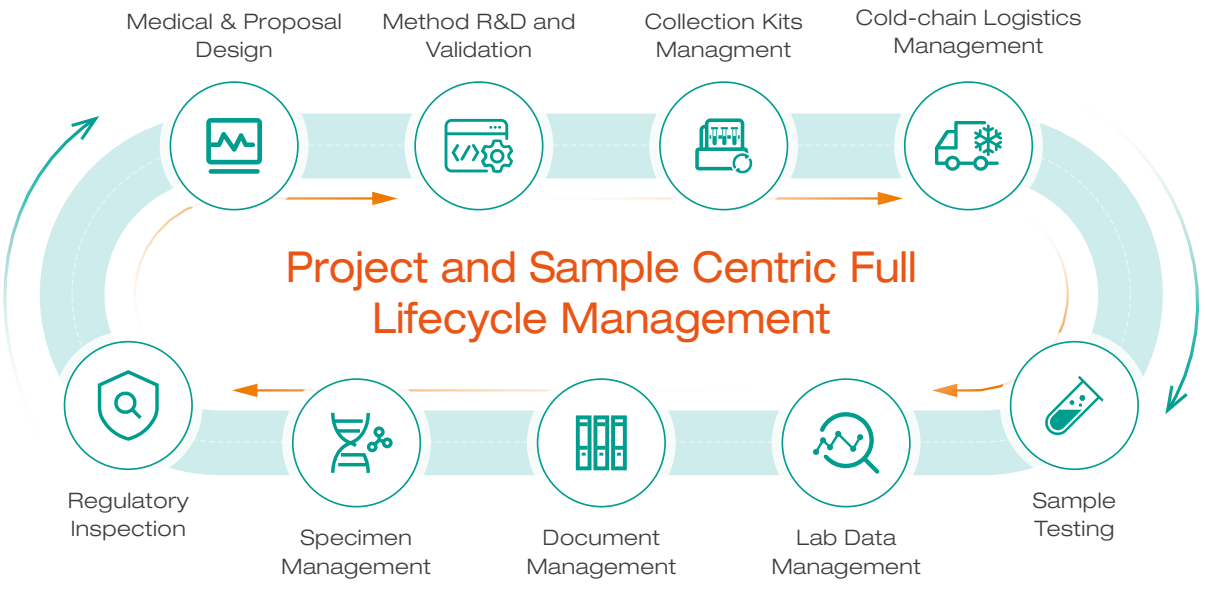

## d. Proportion of drug types in undertaken multiple myeloma (MM)



# Full lifecycle project management

Ensure the authenticity, integrity, consistency and traceability of project samples and data

Comprehensively reduce research costs and risks+Effectively shorten research time = Improve Efficiency




## Digitally Support

### Lab-CTMS

Project management system

### KMCS

Central lab informatics system

### Watson LIMS

BioA informatics system

### Remote pathological system

Professional IRC service

## KPI management of central lab projects

| | | | | |
|---|---|---|---|---|
| RFP confirmation | Sample tracking | Assay development | Document traceability | Project design |
| Kit supply | CTMS system configuration | Deviation/ Variation control | Quality control of first batch testing | Report/Data delivery |

KingMYlab

Scientific, Compliant & Comprehensive
Central Laboratory and Data Services for Clinical Trials

Accelerating drug development, advancing human health

www.kingmylab.com

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